

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007901477	1	12.03.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Not Recovered/Not Resolved -), Myocardial infarction (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ALENDRONATE SODIUM, ALENDRONIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [EZETIMIBE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - Idiopathic pulmonary fibrosis - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007901529	2	12.03.2021	65-85 Years	Elderly	Female	Decreased appetite (n/a - Not Recovered/Not Resolved -), Dehydration (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Mobility decreased (n/a - Not Recovered/Not Resolved -), Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [10min - 1{DF} - Intramuscular])	AERIUS [DES Loratadine] (C - n/a - n/a - [n/a - 5mg - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - 100mg - n/a]), [AMLODIPINE BESILATE, PERINDOPRIL ARGININE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [DESMOPRESSIN, DESMOPRESSIN ACETATE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCORTISONE] (C - n/a - n/a - [n/a - 10mg - n/a]), [LEVOTHYROXINE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007901674	3	12.03.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), Diet refusal (6d - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007901760	4	12.03.2021	18-64 Years	Adult	Male	Death (0d - Fatal - Results in Death), Syncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007901801	5	12.03.2021	18-64 Years	Adult	Male	Body temperature increased (1d - Unknown -), Cardiac tamponade (n/a - Fatal - Results in Death), Malaise (n/a - Unknown -), Myocardial infarction (n/a - Fatal - Results in Death), Myocardial rupture (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007902197	6	12.03.2021	65-85 Years	Elderly	Male	Diet refusal (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007902227	7	12.03.2021	65-85 Years	Elderly	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007902506	8	12.03.2021	65-85 Years	Elderly	Male	Asthenia (n/a - Not Recovered/Not Resolved -), Bradykinesia (n/a - Unknown -), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Recovered/Resolved -), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Recovered/Resolved -), Haematemesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Head banging (n/a - Recovered/Resolved -), Hypotension (30min - Recovered/Resolved -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	ASCALAN 40MG [NOT AVAILABLE] (C - n/a - Dose not changed - [n/a - 60mg - n/a]), TRUXAL 15MG [NOT AVAILABLE] (C - n/a - Dose not changed - [n/a - 30mg - n/a]), [ENALAPRIL MALEATE, HYDROCHLOROTHIAZIDE] (C - n/a - Dose not changed - [n/a - 1{DF} - n/a]), [FLUPENTIXOL HYDROCHLORIDE, MELITRACEN, FLUPENTIXOL HYDROCHLORIDE, MELITRACEN HYDROCHLORIDE, FLUPENTIXOL, MELITRACEN] (C - n/a - Dose not changed - [n/a - 1{DF} - n/a]), [FUROSEMIDE, SPIRONOLACTONE] (C - n/a - Dose not changed - [n/a - 1{DF} - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - 500mg - n/a]), [SOTALOL HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - 120mg - n/a])

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EU-EC-10007902877	9	12.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007903025	10	12.03.2021	65-85 Years	Not Specified	Female	Asthenia (22d - Fatal - Results in Death, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ENALAPRIL MALEATE, HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [TIAPRIDE, TIAPRIDE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007903251	11	12.03.2021	More than 85 Years	Elderly	Female	Cardiac failure congestive (0d - Fatal - Results in Death), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ischaemic cerebral infarction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - Not applicable - [1d - .3mL - Intramuscular])	[BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Hypertension - Unknown - [7y - 2.5mg - Oral]), [DIAZEPAM] (C - Insomnia - Unknown - [5y - 2mg - Oral]), [OXAZEPAM] (C - Anxiety - Unknown - [6y - 15mg - Oral])
EU-EC-10007903281	12	12.03.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007903591	13	12.03.2021	More than 85 Years	Elderly	Female	Abdominal pain (n/a - Unknown - Other Medically Important Condition), Hepatic infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pancreatic infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Splenic infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Truncus coeliacus thrombosis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ALLOPURINOL] (C - n/a - n/a - [n/a - 100mg - n/a]), [BISOPROLOL FUMARATE, BISOPROLOL FUMARATE, ACETYSALICYLIC ACID, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [DISTIGMINE BROMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - Oral]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM, LEVOTHYROXINE SODIUM, HYDRATE] (C - n/a - n/a - [n/a - 50ug - n/a]), [MESALAZINE] (C - n/a - n/a - [n/a - 400mg - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - 25mg - n/a]), [WARFARIN, WARFARIN SODIUM] (C - n/a - n/a -)
EU-EC-10007903788	14	12.03.2021	18-64 Years	Not Specified	Female	Incorrect route of product administration (n/a - Unknown -), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Subcutaneous])	[AMOXICILLIN TRIHYDRATE, CLAVULANIC ACID, AMOXICILLIN, CLAVULANIC ACID] (C - Arteriosclerosis, Folliculitis - n/a - [8d - 1875mg - Oral]), [CANDESARTAN CILEXETIL] (C - Hypertension - n/a - [n/a - 8mg - Oral]), [CLONAZEPAM] (C - Seizure - n/a - [n/a - .5mg - n/a - More in ICSR]), [CLOZAPINE] (C - Schizophrenia - n/a - [n/a - 100mg - Oral]), [FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE HYDRATE] (C - Bronchitis chronic - n/a - [n/a - 24ug - Respiratory (inhalation)]), [MEDROXYPROGESTERONE ACETATE] (C - Contraception - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE] (C - Gastrooesophageal reflux disease - n/a - [n/a - 20mg - Oral]), [ZUCLOPENTHIXOL, ZUCLOPENTHIXOL ACETATE, ZUCLOPENTHIXOL DECANOATE, ZUCLOPENTHIXOL HYDROCHLORIDE] (C - Schizophrenia - n/a - [n/a - 25mg - Oral - More in ICSR])

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EU-EC-10007903790	15	12.03.2021	65-85 Years	Not Specified	Female	COVID-19 pneumonia (n/a - Fatal - Results in Death), Diarrhoea (11d - Recovered/Resolved -), Drug ineffective (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular])	MYCOPHENOLATE MOFETIL [MYCOPHENOLATE MOFETIL] (C - Autoimmune eye disorder - n/a - [n/a - n/a - n/a]), [AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BECLOMETASONE DIPROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007904549	16	12.03.2021	More than 85 Years	Not Specified	Male	Cardiac arrest (0d - Fatal - Results in Death), Dyspnoea (0d - Fatal - Results in Death), Pyrexia (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FINASTERIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007904573	17	12.03.2021	65-85 Years	Not Specified	Male	Dyspnoea (3d - Fatal - Results in Death), Pyrexia (3d - Fatal - Results in Death), Sudden death (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - n/a - n/a]), [CANRENONE, POTASSIUM CANRENOATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [NEBIVOLOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - 20mg - n/a]), [TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TIMOLOL, TIMOLOL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE, TORASEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007904829	18	12.03.2021	More than 85 Years	Not Specified	Male	Malaise (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[CARBAMAZEPINE] (C - n/a - n/a - [n/a - 200mg - Oral]), [CLONAZEPAM] (C - n/a - n/a - [n/a - 2.5mg - Oral]), [LISINAPRIL DIHYDRATE, HYDROCHLOROTHIAZIDE] (C - Hypertension - n/a - [n/a - 20mg - Oral]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - Oral]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Psychomotor hyperactivity - n/a - [n/a - 25mg - Oral]), [TIMOLOL MALEATE] (C - Glaucoma - n/a - [n/a - .25mg - Subconjunctival]), [TIOTROPIUM, TIOTROPIUM BROMIDE, TIOTROPIUM BROMIDE MONOHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - 2.5mg - Respiratory (inhalation)])
EU-EC-10007905372	19	12.03.2021	65-85 Years	Elderly	Male	Arthralgia (n/a - Fatal - Results in Death), COVID-19 (n/a - Unknown -), Chills (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Myalgia (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	MACITENTAN TABLET 10MG / OPSUMIT TABLET FILMOMHULD 10MG [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), REVATIO 20 MG FILM-COATED TABLETS [SILDENAFIL, SILDENAFIL CITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BETAMETHASONE DIPROPIONATE, SALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [CALCIUM CARBONATE, CHOLECALCIFEROL CONCENTRATE (POWDER FORM)] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBASALATE CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [DENOSUMAB] (C - n/a - n/a - [n/a - n/a - n/a]), [DESOXIMETASONE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASONE PROPIONATE, SALMETEROL, FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [ROSUVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007905377	20	12.03.2021	65-85 Years	Elderly	Female	Dyspnoea (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NON SPECIFIED BLOEDVERDUNNER [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007905380	21	12.03.2021	Not Specified	Elderly	Male	Chills (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 40mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 50mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 80mg - n/a]), RIVASTIGMINE 9.5 MG/24 H - TRANSDERMAL PATCH (C - n/a - n/a - [n/a - 1{DF} - n/a]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [DENOSUMAB] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 100mg - n/a])
EU-EC-10007905383	22	12.03.2021	More than 85 Years	Elderly	Male	Delirium (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 2800{IU} - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 3.75mg - n/a]), [CITALOPRAM] (C - n/a - n/a - [n/a - 10mg - n/a])
EU-EC-10007905585	23	12.03.2021	More than 85 Years	Not Specified	Female	Fatigue (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[NORTRIPTYLINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 25mg - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a])
EU-EC-10007905619	24	12.03.2021	More than 85 Years	Elderly	Female	Cerebrovascular accident (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [ATENOLOL, ATENOLOL BP] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007905634	25	12.03.2021	Not Specified	Elderly	Male	Sudden cardiac death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 12.5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 200mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 20mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 500mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 60mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 75mg - n/a]), NOVORAPID FLEXPEN 100 U/ML SOLUTION FOR INJECTION IN PRE-FILLED PEN [INSULIN ASPART] (C - n/a - n/a - [n/a - 1{DF} - n/a]), PANTOPRAZOLE 20 MG - GASTRO-RESISTANT TABLET (C - n/a - n/a - [n/a - 20mg - n/a]), TRESIBA 200 UNITS/ML [INSULIN DEGLUDEC] (C - n/a - n/a - [n/a - 12{DF} - n/a]), [DISODIUM PHOSPHATE, SODIUM DIHYDROGEN PHOSPHATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - 1{DF} - n/a])

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EU-EC-10007906099	26	12.03.2021	65-85 Years	Adult	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	AVAMYS [FLUTICASON FUROATE] (C - n/a - n/a - [n/a - n/a - n/a]), BETMIGA [MIRABEGRON] (C - n/a - n/a - [n/a - n/a - n/a]), COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (C - COVID-19 immunisation - n/a - [n/a - n/a - n/a]), PRIVIGEN [HUMAN NORMAL IMMUNOGLOBULIN] (C - n/a - n/a - [n/a - n/a - n/a]), [CLONAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [CLOZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOMEPROMAZINE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [MAGNESIUM OXIDE, MAGNESIUM OXIDE, LIGHT] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007906550	27	12.03.2021	18-64 Years	Not Specified	Female	Cold sweat (0d - Recovered/Resolved -), Fear of death (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Hypotension (0d - Recovered/Resolved -), Nausea (0d - Recovered/Resolved -), Tremor (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	[LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007906719	28	12.03.2021	More than 85 Years	Not Specified	Male	Dyspnoea (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 120mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1{DF} - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 75mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 80mg - n/a]), [AMOXICILLIN, CLARITHROMYCIN, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007906731	29	12.03.2021	65-85 Years	Not Specified	Male	Diabetes mellitus inadequate control (n/a - Fatal - Results in Death, Life Threatening), Fatigue (n/a - Fatal - Results in Death, Life Threatening), Pneumonia (n/a - Fatal - Results in Death, Life Threatening), Pyrexia (n/a - Fatal - Results in Death, Life Threatening), Somnolence (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - .25ug - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - .5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 10mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 16mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 2.5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 200mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 20mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 40mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 500mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 5600{IU} - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 80mg - n/a]), [INSULIN GLARGINE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007906734	30	12.03.2021	More than 85 Years	Elderly	Male	Arthralgia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chills (n/a - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Inflammatory marker increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported

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EU-EC-10007906766	31	12.03.2021	More than 85 Years	Not Specified	Female	Cardiac failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Mobility decreased (n/a - Unknown - Other Medically Important Condition), Speech disorder (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007906769	32	12.03.2021	Not Specified	Not Specified	Male	Renal vasculitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007888269	33	11.03.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007888371	34	11.03.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007888459	35	11.03.2021	65-85 Years	Not Specified	Male	Aneurysm ruptured (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007888494	36	11.03.2021	More than 85 Years	Not Specified	Male	Chronic obstructive pulmonary disease (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007888556	37	11.03.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death), Cholecystitis (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007888638	38	11.03.2021	65-85 Years	Not Specified	Male	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007888722	39	11.03.2021	More than 85 Years	Not Specified	Female	Dyspnoea (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007889044	40	11.03.2021	More than 85 Years	Not Specified	Male	Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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EU-EC-10007889059	41	11.03.2021	18-64 Years	Not Specified	Female	Brain stem haemorrhage (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Brain stem syndrome (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Chest X-ray abnormal (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ACICLOVIR, ACICLOVIR SODIUM] (C - n/a - n/a - [n/a - 400mg - Oral]), [ANHYDROUS AZITHROMYCIN, AZITHROMYCIN, AZITHROMYCIN DIHYDRATE] (C - n/a - n/a - [n/a - 250mg - Oral]), [ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - n/a - n/a - [n/a - n/a - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - n/a - n/a - [n/a - 80mg - Oral]), [BUPROPION HYDROCHLORIDE] (C - n/a - n/a - [n/a - 150mg - Oral]), [COLECALCIFEROL, CALCIUM CITRATE] (C - n/a - n/a - [n/a - 2{DF} - Oral]), [EVEROLIMUS] (C - n/a - n/a - [n/a - 4mg - Oral]), [FLUTICASON PROPIONATE, SALMETEROL XINAFOATE] (C - n/a - n/a - [n/a - 2{DF} - Respiratory (inhalation)]), [GABAPENTIN] (C - n/a - n/a - [n/a - 300mg - Oral]), [LORATADINE] (C - n/a - n/a - [n/a - 10mg - Oral]), [METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 100mg - Oral]), [MINOXIDIL] (C - Alopecia - n/a - [n/a - n/a - Topical]), [OMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 40mg Oral]), [ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIHYDRATE] (C - Nausea - n/a - [n/a - 4mg - Oral]), [PREDNISONE] (C - n/a - n/a - [n/a - 5mg - Oral]), [SALBUTAMOL SULFATE] (C - Dyspnoea, Wheezing - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Dyspnoea, Wheezing - n/a - [n/a - 2{DF} - Respiratory (inhalation)]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Dyspnoea, Wheezing - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 200mg - Oral]),
EU-EC-10007889086	42	11.03.2021	Not Specified	Not Specified	Female	Haematoma (n/a - Not Recovered/Not Resolved - Disabling), Haematoma (n/a - Unknown - Disabling), Lymphadenopathy (n/a - Recovered/Resolved - Disabling), Nerve injury (n/a - Not Recovered/Not Resolved - Disabling), Pain in extremity (n/a - Fatal - Results in Death, Disabling), Vaccination site movement impairment (n/a - Unknown - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [THYROXINE] (C - Hypothyroidism - n/a - [n/a - n/a - n/a])
EU-EC-10007889250	43	11.03.2021	65-85 Years	Not Specified	Female	Arteriosclerosis (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown -), Nausea (n/a - Unknown -), Retching (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [DILTIAZEM, DILTIAZEM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [HEPARIN, HEPARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMINE, PYRIDOXINE HYDROCHLORIDE, VITAMIN B] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007889369	44	11.03.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	CELECOXIB [CELECOXIB] (C - Depression - n/a - [n/a - 10mg - Oral]), DEXAMETHASONE [DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (C - COVID-19 treatment - n/a - [5d - 4mg - Oral]), [ASCORBIC ACID] (C - COVID-19 treatment, Supplementation therapy - n/a - [n/a - 1000ug - Oral]), [CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Depression - n/a [n/a - 10mg - Oral]), [DIGOXIN] (C - Cardiac failure - n/a - [n/a - 250ug - Oral]), [DONEPEZIL HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 10mg - Oral]), [LORAZEPAM] (C - Anxiety, Restlessness - n/a - [1240min - .5mg - n/a]), [MEMANTINE HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 20mg - Oral]), [MORPHINE SULFATE] (C - Dyspnoea, Pain - n/a - [1235min - .25mL - Oral]), [PARACETAMOL] (C - Arthralgia - n/a - [n/a - 500mg - n/a]), [PARACETAMOL] (C - Arthritis - n/a - [n/a - 650mg - Oral])
EU-EC-10007889440	45	11.03.2021	More than 85 Years	Elderly	Female	C-reactive protein increased (n/a - Fatal - Results in Death), Cerebral infarction (n/a - Fatal - Results in Death), Cough (n/a - Fatal - Results in Death), Depressed level of consciousness (n/a - Fatal - Results in Death), Fall (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Hemiparesis (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[ESTRADIOL, ESTRADIOL HEMIHYDRATE] (C - n/a - n/a - [n/a - n/a - Vaginal]), [FUROSEMIDE] (C - Cardiac failure - n/a - [n/a - n/a - Oral]), [ISOSORBIDE MONONITRATE] (C - Coronary artery disease - n/a - [n/a - n/a - Oral]), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Atrial fibrillation - n/a - [n/a - n/a - Oral]), [MIRTAZAPINE] (C - Sleep disorder - n/a - [n/a - n/a - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Gastrooesophageal reflux prophylaxis - n/a - [n/a - n/a - Oral]), [VALSARTAN] (C - Cardiac failure - n/a - [n/a - n/a - Oral]), [WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BP] (C - Atrial fibrillation - n/a - [n/a - n/a - Oral])
EU-EC-10007889472	46	11.03.2021	More than 85 Years	Not Specified	Female	Atrial fibrillation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	[DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - COVID-19 immunisation - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 100ug - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007889588	47	11.03.2021	More than 85 Years	Elderly	Male	Multiple organ dysfunction syndrome (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Septic shock (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007889672	48	11.03.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Mental status changes (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	KEPPRA [LEVETIRACETAM] (C - Seizure - n/a - [n/a - 10mL - Oral]), LANTUS [INSULIN GLARGINE] (C - Diabetes mellitus - n/a - [n/a - 10[iU] - Subcutaneous]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Hyperlipidaemia - n/a - [n/a - 40mg - Oral]), [CASSIA] (C - Constipation - n/a - [n/a - 17.2mg - Oral]), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [n/a - 5000[iU] - Oral]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - n/a - [n/a - 40mg - Oral]), [METFORMIN HYDROCHLORIDE] (C - Diabetes mellitus - n/a - [n/a - 1000mg - Oral]), [METOPROLOL SUCCINATE] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [PARACETAMOL] (C - Body temperature increased, Pain - n/a - [n/a - 325mg - Oral])
EU-EC-10007889689	49	11.03.2021	More than 85 Years	Not Specified	Female	Cardiac failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Flatulence (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, BENAZEPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BENAZEPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [CARVEDILOL] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [UBIDECARENONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007890396	50	11.03.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - n/a])	ABASAGLAR 100 UNITS/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN [INSULIN GLARGINE] (C - n/a - n/a - [n/a - n/a - n/a]), ELIQUIS 2.5 MG FILM-COATED TABLETS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [INSULIN LISPRO] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007891075	51	11.03.2021	65-85 Years	Not Specified	Male	Hyporeflexia (n/a - Not Recovered/Not Resolved -), Unresponsive to stimuli (n/a - Fatal - Results in Death), Urinary tract infection (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - n/a]), [BENSERAZIDE HYDROCHLORIDE, LEVODOPA] (C - n/a - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [FLUDROCORTISONE] (C - n/a - n/a - [n/a - 100mg - n/a]), [LEVODOPA, CARBIDOPA MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - 40mg - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [TRIMETHOPRIM] (C - n/a - n/a - [n/a - 100mg - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007891078	52	11.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Hypophagia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - Cardiac disorder - n/a - [n/a - 81mg - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Hyperlipidaemia - n/a - [n/a - 20mg - Oral]), [DONEPEZIL HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 5mg - Oral]), [ESCITALOPRAM OXALATE] (C - Depression - n/a - [n/a - 5mg - Oral]), [GABAPENTIN] (C - Pain - n/a - [n/a - 300mg - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - n/a - [n/a - 10mg - Oral]), [METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [NAPROXEN SODIUM] (C - Pain - n/a - [n/a - 220mg - Oral]), [OMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Gastroesophageal reflux disease - n/a - [n/a - 40mg - Oral]), [PARACETAMOL] (C - Body temperature increased, Pain - n/a - [n/a - 325mg - Oral]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Abnormal behaviour, Dementia - n/a - [n/a - 250mg - Oral]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Pain - n/a - [n/a - 100mg - n/a])
EU-EC-10007891400	53	11.03.2021	More than 85 Years	Elderly	Male	Coma (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Hyperpyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007891956	54	11.03.2021	65-85 Years	Elderly	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007891990	55	11.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007892455	56	11.03.2021	More than 85 Years	Not Specified	Female	Dyspnoea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007892466	57	11.03.2021	More than 85 Years	Elderly	Male	Respiratory failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	CETOMACROGOLSMEERSEL / BRAND NAME NOT SPECIFIED [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), SALBUTAMOL/IPRATROPIUM VERNEVELVST 1/0,1MG/ML / BRAND NAME NOT SPECIFIED [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BENZATHINE BENZYL PENICILLIN] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALMETEROL, SALMETEROL XINAFOATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TIOTROPIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007892484	58	11.03.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death), Cough (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOMER] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYALURONATE, SODIUM HYALURONATE, CARBOMER 981] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYALURONATE] (C - n/a - n/a - [n/a - n/a - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007892489	59	11.03.2021	65-85 Years	Not Specified	Female	Circulatory collapse (n/a - Fatal - Results in Death), Heart rate increased (n/a - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [IPRATROPIUM BROMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007892516	60	11.03.2021	More than 85 Years	Elderly	Female	Dyspnoea (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007892804	61	11.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dysphagia (n/a - Unknown -), Eating disorder (n/a - Unknown -), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [MORPHINE SULFATE] (C - Dyspnoea, Pain - n/a - [n/a - 5mg - n/a]), [PARACETAMOL] (C - Pain, Temperature regulation disorder - n/a - [n/a - 325mg - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Sleep disorder - n/a - [n/a - 50mg - Oral])
EU-EC-10007892861	62	11.03.2021	65-85 Years	Elderly	Female	Cerebrovascular accident (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007892898	63	11.03.2021	18-64 Years	Adult	Male	Acute myocardial infarction (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007893389	64	11.03.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[GOSERELIN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007893426	65	11.03.2021	65-85 Years	Not Specified	Male	Confusional state (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Delusion (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovering/Resolving -), Mobility decreased (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007894779	66	11.03.2021	More than 85 Years	Elderly	Male	Abdominal pain (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown -), Fatigue (n/a - Unknown -), Hypokinesia (n/a - Unknown -), Mesenteric vascular insufficiency (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown -), Renal failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007894888	67	11.03.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [CHLORZOXAZONE] (C - n/a - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [DIGOXIN] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007894889	68	11.03.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	[ACETYLCYSTEINE] (C - n/a - n/a - [n/a - 300mg - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - n/a]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 800[iU] - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [DONEPEZIL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a]), [MACROGOL 400, OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [MEMANTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 45mg - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 50mg - n/a]), [SERTRALINE] (C - n/a - n/a - [n/a - 50mg - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - 3.75mg - n/a])
EU-EC-10007894934	69	11.03.2021	65-85 Years	Not Specified	Female	Hypothermia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007894941	70	11.03.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007894943	71	11.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007894949	72	11.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007894972	73	11.03.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007894973	74	11.03.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007895000	75	11.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Eating disorder (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Fatal - Results in Death), Hypersomnia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007895086	76	11.03.2021	More than 85 Years	Not Specified	Female	Abdominal pain (n/a - Fatal - Results in Death), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007895179	77	11.03.2021	18-64 Years	Not Specified	Male	Acute myocardial infarction (n/a - Fatal - Results in Death), Asthenia (n/a - Unknown -), Fatigue (n/a - Unknown -), Vaccination site pain (1d - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007895230	78	11.03.2021	Not Specified	Elderly	Female	Atrial fibrillation (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 40mg - n/a]), [COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007895255	79	11.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 200mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 30mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 80mg - n/a]), [CALCIUM POLYSTYRENE SULFONATE] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007895666	80	11.03.2021	More than 85 Years	Not Specified	Female	Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	NOT AVAILABLE (C - n/a - Unknown - [n/a - n/a - n/a]), ZURAMPIC 200 MG [LESINURAD] (C - n/a - Unknown - [n/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [BUMETANIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [EDOXABAN] (C - n/a - Unknown - [n/a - n/a - n/a]), [METHYLPREDNISOLONE] (C - n/a - Unknown - [n/a - n/a - n/a]), [MICRONISED SPIRONOLACTONE, SPIRONOLACTONE] (C - n/a - Unknown - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007895667	81	11.03.2021	65-85 Years	Not Specified	Female	Acute respiratory failure (n/a - Fatal - Results in Death), Cough (n/a - Fatal - Results in Death), Drug resistance (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Respiratory disorder (n/a - Fatal - Results in Death), Vitamin D deficiency (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [CARVEDILOL] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [CLOPIDOGREL] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [COLECALCIFEROL] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [DOMPERIDONE] (C - Nausea - Unknown - [n/a - 1{DF} - n/a]), [ENOXAPARIN SODIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [INDAPAMIDE, AMLODIPINE BESILATE, PERINDOPRIL ARGININE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [PARACETAMOL] (C - Pain - Unknown - [n/a - 1{DF} - n/a]), [PERINDOPRIL ARGININE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - Unknown - [n/a - 25mL - n/a]), [SACCHAROMYCES BOULARDII, SACCHAROMYCES BOULARDII CNCM I-745 LYOPHILIZED] (C - Diarrhoea - Unknown - [n/a - 1{DF} - n/a])
EU-EC-10007895786	82	11.03.2021	65-85 Years	Not Specified	Male	Cough (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Lung infiltration (n/a - Unknown -), Pneumonia (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	PLAVIX [CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE] (C - Arteriosclerosis - n/a - [n/a - 75mg - Oral]), [ACETYLSALICYLIC ACID] (C - Cardiac disorder - n/a - [n/a - 81mg - Oral]), [AMLODIPINE BESILATE] (C - Hypertension - n/a - [n/a - 5mg - Oral]), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [n/a - 1000[iU] - Oral]), [DONEPEZIL HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 10mg - Oral]), [FOLIC ACID] (C - Supplementation therapy - n/a - [n/a - 1mg - Oral]), [FUROSEMIDE] (C - Oedema - n/a - [n/a - 20mg - Oral]), [GUAIFENESIN] (C - Nasopharyngitis - n/a - [n/a - 30mL - Oral]), [MEMANTINE HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 20mg - Oral]), [METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 25mg - Oral]), [OMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Gastrooesophageal reflux disease - n/a - [n/a - 40mg - Oral]), [PARACETAMOL] (C - Body temperature increased, Pain - n/a - [n/a - 650mg - Oral]), [POTASSIUM CHLORIDE] (C - Supplementation therapy - n/a - [n/a - 10ug - Oral]), [PRIMIDONE] (C - Epilepsy - n/a - [n/a - 50mg - Oral])

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EU-EC-10007896176	83	11.03.2021	18-64 Years	Not Specified	Male	Apparent death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	BUMETANIDE [BUMETANIDE] (C - n/a - n/a - [n/a - 8{DF} - n/a]), EDOXABAN [EDOXABAN] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [ALLOPURINOL] (C - Gout - n/a - [n/a - 3{DF} - n/a]), [BENDROFLUMETHIAZIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [BENZALKONIUM CHLORIDE, CHLORHEXIDINE DIHYDROCHLORIDE, ISOPROPYL MYRISTATE, LIQUID PARAFFIN, BENZALKONIUM CHLORIDE, ISOPROPYL MYRISTATE, LIQUID PARAFFIN, NEOMYCIN SULFATE, PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [COLCHICINE] (C - Gout - n/a - [235d - n/a - n/a]), [FLUCLOXACILLIN, FLUCLOXACILLIN SODIUM, FLUCLOXACILLIN SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - 4{DF} - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [MOMETASONE] (C - Dermatitis - n/a - [n/a - 1{DF} - Topical]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [ZINC] (C - n/a - n/a - [1d - n/a - n/a])
EU-EC-10007896498	84	11.03.2021	More than 85 Years	Not Specified	Male	Drug ineffective (n/a - Fatal - Results in Death, Life Threatening), Suspected COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	RIVAROXABAN [RIVAROXABAN] (C - Anticoagulant therapy - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - Blood cholesterol - n/a - [n/a - n/a - n/a])
EU-EC-10007897564	85	11.03.2021	More than 85 Years	Not Specified	Female	Ischaemic stroke (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[ALLOPURINOL] (C - Hyperuricaemia - n/a - [n/a - 300mg - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - Hypertension - n/a - [n/a - 10mg - Oral]), [FUROSEMIDE] (C - Hypertension - n/a - [n/a - 40mg - Oral]), [PARACETAMOL, TRAMADOL, TRAMADOL HYDROCHLORIDE, PARACETAMOL] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - 1000mg - n/a])
EU-EC-10007897901	86	11.03.2021	65-85 Years	Elderly	Male	Cardio-respiratory arrest (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007874237	87	10.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007874325	88	10.03.2021	65-85 Years	Not Specified	Female	Pemphigoid (20d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (S - Depression - Dose not changed - [n/a - 37.5mg - Oral])	Not reported
EU-EC-10007874776	89	10.03.2021	65-85 Years	Not Specified	Male	Hypoxia (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007874843	90	10.03.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - Drug withdrawn - [n/a - 10{drp} - Oral]), [LOXAPINE] (C - n/a - Drug withdrawn - [n/a - 15{drp} - Oral]), [OXAZEPAM] (C - n/a - Drug withdrawn - [n/a - 5{drp} - Oral]), [PARACETAMOL] (C - n/a - Dose not changed - [n/a - 1{DF} - Oral])
EU-EC-10007874918	91	10.03.2021	65-85 Years	Not Specified	Male	Cardio-respiratory arrest (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	Not reported

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EU-EC-10007875099	92	10.03.2021	65-85 Years	Not Specified	Male	COVID-19 pneumonia (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dehydration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition), Ventricular tachycardia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007875124	93	10.03.2021	65-85 Years	Not Specified	Female	Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007875172	94	10.03.2021	65-85 Years	Not Specified	Male	Bronchopneumopathy (n/a - Fatal - Results in Death, Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007875182	95	10.03.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007876482	96	10.03.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), General physical condition abnormal (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007876975	97	10.03.2021	65-85 Years	Not Specified	Male	Circulatory collapse (n/a - Fatal - Results in Death)		[CANDESARTAN CILEXETIL] (C - n/a - n/a - [n/a - 4mg - n/a]), [CARBOMER] (C - n/a - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [DICLOFENAC DIETHYLAMINE, DICLOFENAC SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [ECONAZOLE NITRATE, TRIAMCINOLONE ACETONIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ECONAZOLE NITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 1mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - n/a]), [HYDROXYZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LAMOTRIGINE] (C - n/a - n/a - [n/a - 100mg - n/a]), [LAMOTRIGINE] (C - n/a - n/a - [n/a - 50mg - n/a]), [MACROGOL 400, OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - 750mg - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - .5mg - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - 20mg - n/a]), [SODIUM PICOFOSFATE, SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TERBINAFINE, TERBINAFINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 75mg - n/a]), [VENLAFAXINE] (C - n/a - n/a - [n/a - 150mg - n/a]), [VENLAFAXINE] (C - n/a - n/a - [n/a - 75mg - n/a]), [ZOLPIDEM, ZOLPIDEM HEMITARTRATE, ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOLPIDEM, ZOLPIDEM TARTRATE, ZOLPIDEM TARTRATE PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007877358	98	10.03.2021	65-85 Years	Not Specified	Male	Myocardial infarction (n/a - Fatal - Results in Death)		[ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [INDAPAMIDE, PERINDOPRIL, INDAPAMIDE, PERINDOPRIL ARGININE, PERINDOPRIL TERT-BUTYLAMINE, INDAPAMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007877464	99	10.03.2021	18-64 Years	Not Specified	Female	Acute pulmonary oedema (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Anaphylactic reaction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Flushing (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)		TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])
EU-EC-10007877723	100	10.03.2021	18-64 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])
EU-EC-10007878009	101	10.03.2021	More than 85 Years	Not Specified	Male	Pyrexia (n/a - Fatal - Results in Death)		COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])

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EU-EC-10007878394	102	10.03.2021	More than 85 Years	Elderly	Male	Cerebrovascular accident (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 1{DF} - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), RIVASTIGMINE 3 MG (C - n/a - n/a - [n/a - 1{DF} - n/a]), [COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 30{drp} - n/a]), [DUTASTERIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [IBUPROFEN] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [URAPIDIL] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007878664	103	10.03.2021	65-85 Years	Not Specified	Male	Acute respiratory failure (3d - Fatal - Results in Death), Pyrexia (3d - Fatal - Results in Death), Vomiting (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported
EU-EC-10007878883	104	10.03.2021	65-85 Years	Not Specified	Female	Abdominal pain (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007878925	105	10.03.2021	More than 85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Fall (n/a - Unknown - Other Medically Important Condition), Skin discolouration (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007879965	106	10.03.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007880646	107	10.03.2021	18-64 Years	Not Specified	Male	Acute myocardial infarction (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007880673	108	10.03.2021	More than 85 Years	Elderly	Female	COVID-19 pneumonia (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007880675	109	10.03.2021	More than 85 Years	Elderly	Female	COVID-19 pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007880676	110	10.03.2021	65-85 Years	Elderly	Female	COVID-19 pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007880678	111	10.03.2021	More than 85 Years	Elderly	Female	COVID-19 pneumonia (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007880734	112	10.03.2021	More than 85 Years	Not Specified	Male	Hyporesponsive to stimuli (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Urosepsis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[TRIMETHOPRIM] (C - Urinary tract infection - n/a - [8d - 300mg - n/a])
EU-EC-10007881019	113	10.03.2021	65-85 Years	Elderly	Male	Agitation (n/a - Not Recovered/Not Resolved -), Asthenia (n/a - Not Recovered/Not Resolved -), Bacterial sepsis (n/a - Fatal - Results in Death), Body temperature increased (n/a - Recovered/Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Disorientation (n/a - Not Recovered/Not Resolved -), Fall (n/a - Not Recovered/Not Resolved -), Gait disturbance (n/a - Unknown -), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death), Pneumonia aspiration (n/a - Fatal - Results in Death), Somnolence (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	EUCREAS 50 MG/1000 MG [METFORMIN HYDROCHLORIDE, VILDAGLIPTIN] (C - n/a - n/a - [n/a - 1{DF} - n/a]), FORXIGA 10 MG [DAPAGLIFLOZIN] (C - n/a - n/a - [n/a - 1{DF} - n/a]), TOUJEO [INSULIN GLARGINE] (C - n/a - n/a - [n/a - 6{DF} - n/a]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - .5{DF} - n/a]), [AMLODIPINE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 15{drp} - n/a]), [HYDROCHLOROTHIAZIDE, RAMIPRIL] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [HYDROXOCOBALAMIN] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [MELPERONE, MELPERONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [NEBIVOLOL, NEBIVOLOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - .5{DF} - n/a]), [PANCREAS POWDER, PANCREATIN] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SODIUM CHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [TRIAZOLAM] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007881172	114	10.03.2021	More than 85 Years	Not Specified	Female	Cardiac failure (14d - Fatal - Results in Death, Life Threatening), Cardiovascular disorder (14d - Fatal - Results in Death, Life Threatening), Dyspnoea (14d - Fatal - Results in Death, Life Threatening), N-terminal prohormone brain natriuretic peptide increased (14d - Fatal - Results in Death, Life Threatening), Respiratory disorder (14d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	BETMIGA [MIRABEGRON] (C - n/a - Unknown - [n/a - n/a - n/a]), [BROTIZOLAM] (C - n/a - Unknown - [n/a - n/a - n/a]), [LETROZOLE] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007881452	115	10.03.2021	More than 85 Years	Elderly	Male	Body temperature decreased (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Respiratory disorder (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 12.5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1{DF} - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 2.5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 20mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 40mg - n/a])
EU-EC-10007881927	116	10.03.2021	65-85 Years	Not Specified	Female	Myocardial infarction (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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EU-EC-10007882188	117	10.03.2021	65-85 Years	Not Specified	Male	Abdominal discomfort (n/a - Unknown -), Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Constipation (n/a - Unknown -), Cough (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown -), Dysphonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved -), Hyperhidrosis (n/a - Not Recovered/Not Resolved -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Unknown -), Pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Unknown -), Sensation of foreign body (n/a - Unknown -), Vomiting (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007882924	118	10.03.2021	18-64 Years	Not Specified	Female	Subarachnoid haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[PARACETAMOL] (C - Pain, Pyrexia - n/a - [n/a - n/a - n/a])
EU-EC-10007883090	119	10.03.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Haemoglobin decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lymphoedema (n/a - Unknown -), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Peripheral swelling (n/a - Unknown -), Swelling (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007883357	120	10.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Malaise (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	HYDROXOCOBALAMIN [HYDROXOCOBALAMIN] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 20mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CARBIDOPA, LEVODOPA, LEVODOPA, CARBIDOPA MONOHYDRATE] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007883445	121	10.03.2021	65-85 Years	Not Specified	Female	Dyspnoea (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 35mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 40mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 5600[iU] - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 75mg - n/a])

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EU-EC-10007883556	122	10.03.2021	18-64 Years	Not Specified	Female	Abdominal distension (n/a - Recovering/Resolving -), Abdominal pain (n/a - Recovering/Resolving -), Asthenia (n/a - Recovering/Resolving -), Back pain (n/a - Unknown -), Bronchospasm (n/a - Recovering/Resolving -), Chest pain (n/a - Unknown -), Cough (n/a - Unknown -), Diarrhoea (n/a - Recovering/Resolving -), Diarrhoea haemorrhagic (n/a - Recovering/Resolving -), Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving -), Dyspepsia (n/a - Unknown -), Dyspnoea (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Feeling abnormal (n/a - Unknown -), Headache (n/a - Recovering/Resolving -), Hypoaesthesia (n/a - Recovering/Resolving -), Limb discomfort (n/a - Unknown -), Migraine (n/a - Unknown -), Nausea (n/a - Unknown -), Near death experience (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown -), Panic disorder (n/a - Recovering/Resolving -), Sneezing (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007883770	123	10.03.2021	More than 85 Years	Elderly	Female	Hypophagia (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [FENTANYL] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE MAGNESIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007883786	124	10.03.2021	65-85 Years	Not Specified	Male	Cardiac failure (n/a - Fatal - Results in Death), Condition aggravated (n/a - Fatal - Results in Death), Lung disorder (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007883796	125	10.03.2021	65-85 Years	Not Specified	Female	Cardiac failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007883799	126	10.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), RIVAROXABAN 10MG TABLET (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007883811	127	10.03.2021	65-85 Years	Elderly	Male	Chest pain (20min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Hyperhidrosis (20min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	APIXABAN 5MG TABLET (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007883819	128	10.03.2021	65-85 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), XARELTO 15 MG FILM-COATED TABLETS [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007883824	129	10.03.2021	More than 85 Years	Not Specified	Female	Cardiac failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	BUMETANIDE [BUMETANIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PHENPROCOUMON] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007884396	130	10.03.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	GANFORT 0.3 MG/ML + 5 MG/ML [TIMOLOL MALEATE, BIMATOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [HALOPERIDOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007884529	131	10.03.2021	65-85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	BUMETANIDE - TABLET (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007885277	132	10.03.2021	Not Specified	Elderly	Male	Condition aggravated (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Hyperhidrosis (n/a - Fatal - Results in Death), Pulmonary haemorrhage (n/a - Fatal - Results in Death), Syncope (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	MICARDIS 40 MG TABLETS [TELMISARTAN] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID, CALCIUM GLUBIONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBIONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007885393	133	10.03.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Heart rate decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007885427	134	10.03.2021	65-85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007885716	135	10.03.2021	18-64 Years	Adult	Male	Acute respiratory failure (1d - Fatal - Results in Death), Depressed level of consciousness (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Unknown])	Not reported
EU-EC-10007885790	136	10.03.2021	18-64 Years	Adult	Male	Asphyxia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	LANTUS [INSULIN GLARGINE] (C - n/a - n/a -), [DIAZEPAM] (C - n/a - n/a -), [HALOPERIDOL] (C - n/a - n/a -), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a -)
EU-EC-10007885800	137	10.03.2021	18-64 Years	Adult	Female	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007858174	138	09.03.2021	18-64 Years	Not Specified	Male	Ischaemic stroke (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007858263	139	09.03.2021	More than 85 Years	Not Specified	Female	Cerebrovascular accident (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	[FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007858733	140	09.03.2021	More than 85 Years	Not Specified	Female	Acute respiratory failure (1d - Fatal - Results in Death), Productive cough (1d - Fatal - Results in Death), Pyrexia (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007859517	141	09.03.2021	65-85 Years	Not Specified	Male	Dysphagia (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007859715	142	09.03.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007860270	143	09.03.2021	More than 85 Years	Not Specified	Male	Fatigue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	UMECLIDINIUM BROMIDE, FLUTICASONE FUROATE, VILANTEROL [UMECLIDINIUM BROMIDE, FLUTICASONE FUROATE, VILANTEROL] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [BENDROFLUMETHIAZIDE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [PERINDOPRIL, PERINDOPRIL TERT-BUTYLAMINE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007860488	144	09.03.2021	18-64 Years	Not Specified	Female	Chest pain (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007861224	145	09.03.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - [n/a - n/a - n/a]), PREGABALIN [PREGABALIN] (C - n/a - n/a - [n/a - n/a - n/a]), XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRIMEBUTINE] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007861540	146	09.03.2021	More than 85 Years	Not Specified	Male	Cardiac failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007861582	147	09.03.2021	65-85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	ABASAGLAR [INSULIN GLARGINE] (C - n/a - n/a - [n/a - n/a - Subcutaneous]), LYRICA 25 MG HARD CAPSULES [PREGABALIN] (C - n/a - n/a - [n/a - 25mg - Oral]), MIMPARA 30 MG FILM-COATED TABLETS [CINACALCET, CINACALCET HYDROCHLORIDE] (C - n/a - n/a - [n/a - 30mg - Oral]), NOVORAPID [INSULIN ASPART] (C - n/a - n/a - [n/a - 1{DF} - Subcutaneous]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 40mg - Oral]), RENVELA 2.4 G POWDER FOR ORAL SUSPENSION [SEVELAMER CARBONATE] (C - n/a - n/a - [n/a - 2.4g - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a - [n/a - 40mg - Oral]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [CALCIUM CARBONATE] (C - n/a - n/a - [n/a - 500mg - Oral]), [CANDESARTAN CILEXETIL] (C - n/a - n/a - [n/a - 2mg - Oral]), [D,L-LYSINE ACETYLSALICYLATE] (C - n/a - n/a - [n/a - 75mg - Oral]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 500mg - Oral]), [LACTULOSE, LACTULOSE, PARAFFIN WHITE SOFT, LIQUID PARAFFIN, LACTULOSE, VASELINE, LIQUID PARAFFIN] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL, BELLADONNA DRY EXTRACT, CAFFEINE, OPIUM, PARACETAMOL, CAFFEINE, OPIUM, PARACETAMOL, CAFFEINE, OPIUM EXTRACTS, PARACETAMOL, CAFFEINE, OPIUM, PREPARED] (C - n/a - n/a - [n/a - n/a - Oral]), [RISPERIDONE] (C - n/a - n/a - [n/a - 1mg - Oral]), [SODIUM POLYSTYRENE SULPHONATE] (C - n/a - n/a - [n/a - n/a - Oral]), [VALPROATE SEMISODIUM] (C - n/a - n/a - [n/a - 250mg - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - 7.5mg - Oral])

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EU-EC-10007861643	148	09.03.2021	More than 85 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007861668	149	09.03.2021	More than 85 Years	Not Specified	Male	COVID-19 (21d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007861676	150	09.03.2021	More than 85 Years	Not Specified	Male	COVID-19 (24d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007861775	151	09.03.2021	18-64 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007861802	152	09.03.2021	65-85 Years	Not Specified	Male	Lower respiratory tract congestion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lung abscess (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (5d - Recovered/Resolved - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[ALPRAZOLAM] (C - n/a - n/a - [n/a - .125mg - Oral]), [APOMORPHINE HYDROCHLORIDE HEMIHYDRATE] (C - n/a - n/a - [n/a - 1{DF} - Subcutaneous]), [CARBIDOPA, LEVODOPA, LEVODOPA, CARBIDOPA MONOHYDRATE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - Oral]), [D,L-LYSINE ACETYLSALICYLATE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [LEVODOPA, ANHYDROUS CARBIDOPA, LEVODOPA, CARBIDOPA MONOHYDRATE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - 1{DF} - Oral])
EU-EC-10007862001	153	09.03.2021	More than 85 Years	Not Specified	Female	Acute respiratory failure (n/a - Fatal - Results in Death), Cardiac failure (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007862217	154	09.03.2021	More than 85 Years	Not Specified	Female	Cardiac failure (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular])	Not reported
EU-EC-10007862220	155	09.03.2021	More than 85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular])	Not reported

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EU-EC-10007862225	156	09.03.2021	More than 85 Years	Not Specified	Male	Oxygen saturation decreased (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular])	Not reported
EU-EC-10007862227	157	09.03.2021	65-85 Years	Not Specified	Male	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular])	Not reported
EU-EC-10007862787	158	09.03.2021	65-85 Years	Not Specified	Male	Haemorrhage (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - Intramuscular])	Not reported
EU-EC-10007862952	159	09.03.2021	More than 85 Years	Not Specified	Male	Disease recurrence (n/a - Unknown - Life Threatening), Myocardial infarction (n/a - Unknown - Life Threatening), Sudden death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007863160	160	09.03.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007863266	161	09.03.2021	More than 85 Years	Not Specified	Female	Loss of consciousness (n/a - Fatal - Results in Death), Tachycardia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007863381	162	09.03.2021	More than 85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), LYRICA 25 MG HARD CAPSULES [PREGABALIN] (C - n/a - n/a - [n/a - n/a - n/a]), NOVORAPID FLEXPEN 100 U/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), TOUJEO SOLOSTAR 100 UNITS/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN [INSULIN GLARGINE] (C - n/a - n/a - [n/a - n/a - n/a]), [ESOMEPRAZOLE MAGNESIUM DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LERCANIDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LIPIDOSTEROLIC EXTRACT OF SERENOA REPENS, SERENOA REPENS (BARTRAM) SMALL.] (C - n/a - n/a - [n/a - n/a - n/a]), [NEBIVOLOL] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007863518	163	09.03.2021	More than 85 Years	Not Specified	Female	General physical health deterioration (n/a - Fatal - Results in Death), Hypotension (n/a - Recovering/Resolving - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	ELIQUIS [APIXABAN] (C - n/a - Dose not changed - [n/a - 1{DF} - Oral]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - Dose not changed - [n/a - 20mg - Oral]), [AMIODARONE HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - 1{DF} - Oral]), [BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 1.25mg - Oral]), [FUROSEMIDE] (C - Hypertension - Dose reduced - [n/a - .5{DF} - Oral]), [LEVOTHYROXINE SODIUM] (C - n/a - Dose not changed - [n/a - 112ug - Oral]), [POTASSIUM CHLORIDE] (C - n/a - Dose not changed - [n/a - 1{DF} - Oral]), [RAMIPRIL] (C - n/a - Dose not changed - [n/a - 1.25mg - Oral])
EU-EC-10007863891	164	09.03.2021	More than 85 Years	Not Specified	Female	Malaise (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mg - Intramuscular])	Not reported
EU-EC-10007863925	165	09.03.2021	65-85 Years	Not Specified	Female	Ischaemic stroke (12d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mg - Intramuscular])	Not reported
EU-EC-10007864492	166	09.03.2021	More than 85 Years	Not Specified	Female	Hyperthermia (n/a - Recovered/Resolved - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007864662	167	09.03.2021	More than 85 Years	Not Specified	Female	Cerebrovascular accident (4d - Fatal - Results in Death, Other Medically Important Condition), Hyperhidrosis (1d - Unknown - Results in Death, Other Medically Important Condition), Hypertension (1d - Unknown - Results in Death, Other Medically Important Condition), Tachycardia (3d - Unknown - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007864731	168	09.03.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Dyspepsia (n/a - Not Recovered/Not Resolved - Results in Death), Feeling hot (n/a - Not Recovered/Not Resolved - Results in Death), Vomiting (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	APIXABAN [APIXABAN] (C - n/a - n/a - [n/a - n/a - Oral]), LEVETIRACETAM [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - Oral]), LUMIGAN [BIMATOPROST] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [ALFUZOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [CARTEOLOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [LERCANIDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [MACROGOL 4000] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-10007865223	169	09.03.2021	18-64 Years	Not Specified	Male	Pain (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Unresponsive to stimuli (4d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007865345	170	09.03.2021	18-64 Years	Adult	Female	Arrhythmia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Ascites (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Atrial fibrillation (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Tachycardia induced cardiomyopathy (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007865613	171	09.03.2021	65-85 Years	Not Specified	Male	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007865871	172	09.03.2021	65-85 Years	Not Specified	Male	Bradycardia (n/a - Recovered/Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death), Cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Ejection fraction decreased (n/a - Unknown - Other Medically Important Condition), Hiatus hernia (n/a - Unknown -), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Metabolic acidosis (n/a - Not Recovered/Not Resolved -), Nodal rhythm (n/a - Recovered/Resolved -), Pneumonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Suspected COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Ventricular fibrillation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - 81mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 20mg - n/a]), [BENAZEPRIL] (C - n/a - n/a - [n/a - 5mg - n/a]), [CARVEDILOL] (C - n/a - n/a - [n/a - n/a - n/a]), [FAMOTIDINE] (C - n/a - n/a - [n/a - 10mg - n/a]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - .4mg - n/a])

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EU-EC-10007865875	173	09.03.2021	65-85 Years	Not Specified	Male	Dysphagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Eating disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Toxicity to various agents (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CARVEDILOL] (C - Blood pressure measurement - n/a - [n/a - n/a - n/a]), [WARFARIN, WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007865882	174	09.03.2021	18-64 Years	Not Specified	Male	Arteriosclerosis (n/a - Fatal - Results in Death), Blood glucose decreased (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Unknown - Other Medically Important Condition), Hypertensive heart disease (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Sudden cardiac death (n/a - Fatal - Results in Death), Syncope (n/a - Unknown - Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIHYDRATE] (C - Nausea, Vomiting - n/a - [n/a - 12mg - n/a - More in ICSR])
EU-EC-10007865883	175	09.03.2021	18-64 Years	Not Specified	Male	Cerebral haemorrhage (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage intracranial (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007866134	176	09.03.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007866227	177	09.03.2021	65-85 Years	Not Specified	Male	Chest pain (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007866367	178	09.03.2021	More than 85 Years	Not Specified	Male	Circulatory collapse (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DILTIAZEM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007866372	179	09.03.2021	More than 85 Years	Not Specified	Male	Allergy to vaccine (n/a - Fatal - Results in Death), Balance disorder (n/a - Unknown -), Dysarthria (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	METHOTREXATE [METHOTREXATE] (C - Eczema - n/a - [n/a - n/a - n/a])
EU-EC-10007866523	180	09.03.2021	More than 85 Years	Not Specified	Female	General physical health deterioration (n/a - Fatal - Results in Death), Hypernatraemia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 40mg - n/a])
EU-EC-10007867709	181	09.03.2021	65-85 Years	Elderly	Female	Body temperature increased (n/a - Not Recovered/Not Resolved -), Cardio-respiratory arrest (n/a - Fatal - Results in Death), Cough (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Unknown -), Fatigue (n/a - Not Recovered/Not Resolved -), General physical health deterioration (n/a - Not Recovered/Not Resolved -), Headache (n/a - Unknown -), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved -), Pneumonia (n/a - Not Recovered/Not Resolved -), Productive cough (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	PRADAXA 150 MG [DABIGATRAN ETEXILATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [ACETYLCYSTEINE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [BISACODYL] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROMORPHONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [LACTOBACILLUS ACIDOPHILUS DSM 4149; AQUAEQUS SUBSTRATE OF METABOLIC PRODUCTS, ENTEROCOCCUS FAECALIS, LACTOBACILLUS HELVETICUS DSM 4183 AQUEOUS SUBSTRATE OF METABOLIC PRODUCTS, LACTOBACILLUS ACIDOPHILUS DSM 4149; AQUAEQUS SUBSTRATE OF METABOLIC PRODUCTS, ENTEROCOCCUS FAECALIS DSM 4086, AQUEOUS SUBSTRATE OF THE METABOLITES, ESCHERICHIA COLI DSM 4087 GERM-FREE, AQUAEQUS SUBSTRATE OF THE METABOLIC PRODUCTS] (C - n/a - n/a - [n/a - 20{drp} - n/a]), [LACTULOSE, LACTULOSE CRYSTALLINE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [MACROGOL 3350, SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL 70%, LIQUID (CRYSTALLISING), SODIUM CITRATE, SORBITOL (E420), SODIUM LAURYL SULFOACETATE, SODIUM CITRATE, SORBITOL SOLUTION 70% (CRYSTALLISING) (PH. EUR.), SODIUM LAURYL SULFOACETATE, SODIUM LAURYL SULFOACETATE, TRISODIUM CITRATE, SORBITOL 70%, LIQUID (CRYSTALLISING), SORBITOL (E420), SODIUM LAURYL SULFOACETATE, SORBITOL (E420), SODIUM LAURYL SULFOACETATE, SODIUM CITRATE DIHYDRATE, SORBITOL, LIQUID (CRYSTALLISING), SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL, LIQUID (CRYSTALLISING), SODIUM CITRATE, SODIUM LAURYL SULFOACETATE 70%] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [MAGNESIUM CARBONATE, LIGHT, MAGNESIUM OXIDE, LIGHT, MAGNESIUM CARBONATE, MAGNESIUM OXIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - 30{drp} - n/a]),
EU-EC-10007868243	182	09.03.2021	More than 85 Years	Not Specified	Female	Death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a -), [CARVEDILOL] (C - n/a - n/a -), [SPIRONOLACTONE] (C - n/a - n/a -)

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EU-EC-10007868298	183	09.03.2021	Not Specified	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death), Drug ineffective (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007869528	184	09.03.2021	65-85 Years	Not Specified	Not Specified	Asthenia (n/a - Fatal - Results in Death), Blood pressure decreased (n/a - Fatal - Results in Death), Diarrhoea (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Lividity (n/a - Fatal - Results in Death), Seizure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007870332	185	09.03.2021	More than 85 Years	Elderly	Female	Myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported
EU-EC-10007870518	186	09.03.2021	More than 85 Years	Elderly	Female	Kaposi's sarcoma AIDS related (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported
EU-EC-10007870893	187	09.03.2021	Not Specified	Foetus	Not Specified	Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Premature baby (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - Transplacental])
EU-EC-10007846353	188	08.03.2021	Not Specified	Not Specified	Female	Near death experience (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007846442	189	08.03.2021	Not Specified	Not Specified	Male	Asymptomatic COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition), Systemic inflammatory response syndrome (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007846516	190	08.03.2021	18-64 Years	Not Specified	Female	Neoplasm progression (n/a - Fatal - Results in Death), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ENOXAPARIN SODIUM] (C - Thrombosis prophylaxis - n/a - [n/a - n/a - Subcutaneous]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Dyspepsia - n/a - [n/a - n/a - Oral])
EU-EC-10007846664	191	08.03.2021	18-64 Years	Not Specified	Male	Angina pectoris (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death), Respiratory arrest (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007846667	192	08.03.2021	65-85 Years	Not Specified	Male	Feeling abnormal (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007846766	193	08.03.2021	More than 85 Years	Elderly	Male	Acute respiratory failure (n/a - Fatal - Results in Death), Cardiac failure (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	LIXIANA [EDOXABAN, EDOXABAN TOSYLATE] (C - n/a - n/a - [n/a - 30mg - n/a]), [AMIODARONE, AMIODARONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 200mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 62ug - n/a]), [MACROGOL, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007847365	194	08.03.2021	65-85 Years	Not Specified	Male	Asthenia (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Dyspnoea exertional (n/a - Unknown -), Haemolytic anaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown -), Hypoventilation (n/a - Unknown - Other Medically Important Condition), Jaundice (n/a - Unknown -), Lymphocytosis (n/a - Unknown -), Tremor (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007847612	195	08.03.2021	More than 85 Years	Not Specified	Female	Anaphylactic reaction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death), Pulmonary congestion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Tachycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[AMLODIPINE, AMLODIPINE BESILATE] (C - Hypertension - n/a - [413d - 5mg - Oral]), [ASCORBIC ACID] (C - Nutritional supplementation - n/a - [278d - 1000mg - Oral]), [ESTROGENS ESTERIFIED] (C - Hormone replacement therapy - n/a - [413d - .3mg - Oral]), [LEVODOPA, CARBIDOPA MONOHYDRATE] (C - Hormone replacement therapy - n/a - [n/a - .3mg - Oral]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [413d - 50mg - Oral])
EU-EC-10007847808	196	08.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007848072	197	08.03.2021	More than 85 Years	Elderly	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007848073	198	08.03.2021	65-85 Years	Elderly	Male	Acute abdomen (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Septic shock (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007848626	199	08.03.2021	65-85 Years	Not Specified	Female	Chronic obstructive pulmonary disease (n/a - Fatal - Results in Death), Cough (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Respiratory acidosis (n/a - Fatal - Results in Death), Respiratory failure (n/a - Fatal - Results in Death), Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007848907	200	08.03.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007848934	201	08.03.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007849163	202	08.03.2021	65-85 Years	Not Specified	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007849421	203	08.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - n/a - n/a - [n/a - n/a - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-10007849887	204	08.03.2021	More than 85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved -), Oedema peripheral (n/a - Not Recovered/Not Resolved -), Pyrexia (3d - Recovered/Resolved -), Vomiting (2d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	EXFORGE [VALSARTAN, AMLODIPINE, VALSARTAN, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), ZYPREXA 10 MG COATED TABLET [OLANZAPINE] (C - n/a - n/a - [n/a - 10mg - n/a]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [QUETIAPINE] (C - n/a - n/a - [n/a - 100mg - n/a])
EU-EC-10007850083	205	08.03.2021	65-85 Years	Elderly	Female	Cerebral haemorrhage (n/a - Fatal - Results in Death), Cerebrovascular accident (n/a - Fatal - Results in Death), Cranial nerve decompression (n/a - Fatal - Results in Death), Hemiparesis (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850085	206	08.03.2021	65-85 Years	Elderly	Male	Acute myocardial infarction (n/a - Fatal - Results in Death), Hepatic failure (n/a - Fatal - Results in Death), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850179	207	08.03.2021	18-64 Years	Adult	Male	Anaphylactic reaction (0d - Fatal - Results in Death), Respiratory distress (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850187	208	08.03.2021	More than 85 Years	Elderly	Female	Asymptomatic COVID-19 (n/a - Unknown -), Respiratory distress (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007850188	209	08.03.2021	65-85 Years	Elderly	Male	Cardiac arrest (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850191	210	08.03.2021	18-64 Years	Adult	Male	Respiratory failure (18d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported
EU-EC-10007850192	211	08.03.2021	More than 85 Years	Elderly	Female	Dyspnoea (n/a - Unknown -), Nasopharyngitis (n/a - Unknown -), Pneumonia (8d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported
EU-EC-10007850196	212	08.03.2021	Not Specified	Elderly	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007850200	213	08.03.2021	More than 85 Years	Elderly	Male	Arrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Disturbance in attention (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850202	214	08.03.2021	More than 85 Years	Elderly	Female	Atrial fibrillation (1d - Fatal - Results in Death), Haemoglobin decreased (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850211	215	08.03.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850212	216	08.03.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850217	217	08.03.2021	More than 85 Years	Elderly	Female	COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850219	218	08.03.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Respiratory distress (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported
EU-EC-10007850221	219	08.03.2021	65-85 Years	Elderly	Female	Bedridden (n/a - Unknown -), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported

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EU-EC-10007850222	220	08.03.2021	More than 85 Years	Elderly	Female	Chest pain (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Gait inability (n/a - Not Recovered/Not Resolved -), Quadriparesis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported
EU-EC-10007850224	221	08.03.2021	Not Specified	Elderly	Female	Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dysphonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Feeling cold (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007850226	222	08.03.2021	More than 85 Years	Elderly	Female	Asthenia (n/a - Unknown -), Chills (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Lethargy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850227	223	08.03.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Dehydration (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Gastrointestinal pain (n/a - Unknown -), Nausea (n/a - Unknown -), Oliguria (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported
EU-EC-10007850228	224	08.03.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported
EU-EC-10007850229	225	08.03.2021	More than 85 Years	Elderly	Male	Altered state of consciousness (n/a - Unknown -), Cerebral infarction (11d - Fatal - Results in Death), Hemiparesis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported
EU-EC-10007850231	226	08.03.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported
EU-EC-10007850235	227	08.03.2021	More than 85 Years	Elderly	Female	Apathy (n/a - Unknown -), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007850243	228	08.03.2021	65-85 Years	Elderly	Male	COVID-19 (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007850244	229	08.03.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850245	230	08.03.2021	More than 85 Years	Elderly	Female	C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Chronic kidney disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported
EU-EC-10007850248	231	08.03.2021	More than 85 Years	Elderly	Female	Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death), Pleural effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850254	232	08.03.2021	65-85 Years	Elderly	Female	Acute respiratory failure (3d - Fatal - Results in Death), COVID-19 (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported
EU-EC-10007850255	233	08.03.2021	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850256	234	08.03.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported
EU-EC-10007850257	235	08.03.2021	18-64 Years	Adult	Female	Acute myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported
EU-EC-10007850259	236	08.03.2021	Not Specified	Elderly	Not Specified	COVID-19 (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007850261	237	08.03.2021	65-85 Years	Elderly	Female	COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dementia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850264	238	08.03.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007850328	239	08.03.2021	More than 85 Years	Elderly	Male	Cerebral haemorrhage (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported
EU-EC-10007850420	240	08.03.2021	More than 85 Years	Not Specified	Male	Pneumonia (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850528	241	08.03.2021	More than 85 Years	Elderly	Female	Cardiac failure (n/a - Fatal - Results in Death), Electrolyte depletion (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850719	242	08.03.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850721	243	08.03.2021	Not Specified	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007850737	244	08.03.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Influenza like illness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported
EU-EC-10007850739	245	08.03.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007851039	246	08.03.2021	More than 85 Years	Elderly	Female	Death (1d - Fatal - Results in Death, Life Threatening), General physical health deterioration (8d - Fatal - Results in Death, Life Threatening), Haemorrhage subcutaneous (8d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - n/a])	[BISOPROLOL FUMARATE, BISOPROLOL FUMARATE, ACETYLSALICYLIC ACID, BISOPROLOL HEMIFUMARATE] (C - n/a - Not applicable - [n/a - 5mg - Oral]), [FUROSEMIDE] (C - n/a - Not applicable - [n/a - 40mg - Oral]), [LORAZEPAM] (C - n/a - Not applicable - [n/a - n/a - Oral]), [RAMIPRIL] (C - n/a - Not applicable - [n/a - 5mg - Oral])
EU-EC-10007851864	247	08.03.2021	18-64 Years	Not Specified	Female	Encephalitis (n/a - Fatal - Results in Death), Respiratory failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007852815	248	08.03.2021	65-85 Years	Not Specified	Female	Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	OZEMPIC 0.25 MG [SEMAGLUTIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [ANHYDROUS LEVOTHYROXINE SODIUM] (C - n/a - Unknown - [n/a - .5{DF} - n/a]), [ANHYDROUS LEVOTHYROXINE SODIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [CALCITRIOL] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [FERROUS SULFATE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [HYDROCHLOROTHIAZIDE, BISOPROLOL HEMIFUMARATE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [PRAVASTATIN SODIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [PRAZEPAM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [SERTRALINE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [THIAMINE HYDROCHLORIDE, CYANOCOBALAMIN, PYRIDOXINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [TRAZODONE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - .5{DF} - n/a])
EU-EC-10007852816	249	08.03.2021	More than 85 Years	Not Specified	Male	Cardiovascular disorder (1d - Fatal - Results in Death), Malaise (1d - Fatal - Results in Death), Oxygen saturation decreased (1d - Fatal - Results in Death), Respiratory disorder (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - Unknown - [n/a - 2{DF} - n/a]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - Unknown - [n/a - 2{DF} - n/a]), [LORAZEPAM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [MIRTAZAPINE] (C - n/a - Unknown - [n/a - .5{DF} - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - Unknown - [n/a - 1{DF} - n/a])
EU-EC-10007852817	250	08.03.2021	More than 85 Years	Not Specified	Female	Cardiovascular disorder (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	NOT AVAILABLE (C - n/a - Unknown - [n/a - n/a - n/a]), XARELTO 15 MG [RIVAROXABAN] (C - n/a - Unknown - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [VALSARTAN, HYDROCHLOROTHIAZIDE] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007853082	251	08.03.2021	More than 85 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007853096	252	08.03.2021	65-85 Years	Elderly	Male	Ischaemic cerebral infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [IPRATROPIUM BROMIDE, SALBUTAMOL, SALBUTAMOL, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LOPERAMIDE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007853098	253	08.03.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), NOVORAPID 100 E/ML, OPLOSSING VOOR INJECTIE IN FLACON. [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007853115	254	08.03.2021	Not Specified	Elderly	Male	Body temperature increased (n/a - Unknown -), Cardiac disorder (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Fatigue (n/a - Unknown -), Malaise (n/a - Unknown -), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - .06mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - .5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 25mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 40mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 5600[iU]/kg - n/a]), [TIMOLOL MALEATE, LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007853137	255	08.03.2021	65-85 Years	Elderly	Male	Arthralgia (n/a - Fatal - Results in Death), Decreased appetite (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported

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EU-EC-10007853156	256	08.03.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	IRBESARTAN 150 MG - TABLET (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PIPAMPERONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007853159	257	08.03.2021	65-85 Years	Elderly	Female	Body temperature increased (n/a - Recovering/Resolving -), Chills (1d - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Hepatitis C (n/a - Fatal - Results in Death), Jaundice (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 10mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 500mg - n/a])
EU-EC-10007853168	258	08.03.2021	65-85 Years	Not Specified	Female	Dyspnoea (0d - Recovering/Resolving -), Dyspnoea (n/a - Fatal - Results in Death), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), PANTOPRAZOLE 20 MG - GASTRO-RESISTANT TABLET (C - n/a - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007853282	259	08.03.2021	More than 85 Years	Elderly	Female	Ischaemic cerebral infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	GANFORT 0.3 MG/ML + 5 MG/ML [TIMOLOL MALEATE, BIMATOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), XARELTO 20 MG FILM-COATED TABLETS [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [CARMELLOSE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [DIGOXIN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007853323	260	08.03.2021	65-85 Years	Not Specified	Male	Cardiopulmonary failure (n/a - Fatal - Results in Death), Conjunctival oedema (n/a - Fatal - Results in Death), Lip swelling (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Mouth swelling (n/a - Fatal - Results in Death), Peripheral swelling (n/a - Fatal - Results in Death), Swelling face (n/a - Fatal - Results in Death), Swollen tongue (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [AMOXICILLIN, CLAVULANIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [HALOPERIDOL] (C - n/a - n/a - [n/a - n/a - n/a]), [METOCLOPRAMIDE, METOCLOPRAMIDE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007853867	261	08.03.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown -), Muscular weakness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	BUMETANIDE [BUMETANIDE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007853884	262	08.03.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown -), Injection site pain (n/a - Unknown -), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ENTRESTO 97 MG/103 MG FILM-COATED TABLETS [VALSARTAN, SACUBITRIL] (C - n/a - n/a - [n/a - n/a - n/a]), JANUVIA 50 MG FILM-COATED TABLETS [SITAGLIPTIN] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007854254	263	08.03.2021	More than 85 Years	Not Specified	Female	Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Decreased appetite (n/a - Unknown -), Peripheral swelling (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007854735	264	08.03.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ALFUZOSIN] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007854736	265	08.03.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Oral discharge (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007854802	266	08.03.2021	More than 85 Years	Not Specified	Female	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diet refusal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait inability (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mutism (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sedation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BISACODYL, DOCUSATE SODIUM, SODIUM PICOSULFATE MONOHYDRATE] (C - Constipation - n/a - [n/a - 10mg - Rectal]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [DOCUSATE SODIUM, SENNOSIDE A+B] (C - Constipation - n/a - [n/a - 500mg - Oral]), [ERYTHROMYCIN] (C - n/a - n/a - [n/a - .5g - Ophthalmic]), [ESTRADIOL] (C - n/a - n/a - [n/a - .5g - Vaginal]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (C - n/a - n/a - [n/a - .25mL - Oral]), [HYDROCORTISONE ACETATE, PERU BALSAM, ZINC OXIDE, BENZYL BENZOATE, BISMUTH OXIDE, BISMUTH SUBGALLATE, HYDROCORTISONE ACETATE, ZINC SULPHATE] (C - Proctalgia - n/a - [n/a - n/a - Rectal]), [MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 8{DF} - Oral]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - .5mg - Oral - More in ICSR]), [SENN ALEXANDRINA LEAF, CASSIA] (C - n/a - n/a - [n/a - 8.6mg - Oral]), [SODIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-1000785453	267	08.03.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Vascular dementia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[LISINOPRIL, LISINOPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - n/a - n/a - [n/a - .5mg - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 15mg - n/a])
EU-EC-1000785456	268	08.03.2021	More than 85 Years	Not Specified	Male	Respiratory distress (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007855458	269	08.03.2021	Not Specified	Not Specified	Female	Pulmonary oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007857025	270	08.03.2021	More than 85 Years	Elderly	Female	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Choking (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [2d - n/a - Intramuscular])	Not reported
EU-EC-10007857293	271	08.03.2021	Not Specified	Elderly	Male	Blue toe syndrome (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling cold (n/a - Unknown -), Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (n/a - Unknown -), Pneumothorax (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (5d - Recovered/Resolved -), Skin discolouration (n/a - Unknown -), Tremor (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007810999	272	06.03.2021	18-64 Years	Not Specified	Male	Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007796252	273	05.03.2021	More than 85 Years	Not Specified	Male	Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007797262	274	05.03.2021	18-64 Years	Not Specified	Female	Brain death (n/a - Fatal - Results in Death), Haemorrhagic stroke (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Intracranial aneurysm (n/a - Fatal - Results in Death), Subarachnoid haemorrhage (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007797263	275	05.03.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007797264	276	05.03.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007797276	277	05.03.2021	65-85 Years	Not Specified	Male	Abdominal discomfort (n/a - Recovering/Resolving -), Cardiac arrest (n/a - Fatal - Results in Death), Condition aggravated (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved -), Pericardial effusion (n/a - Fatal - Results in Death), Pyrexia (n/a - Recovering/Resolving -), Suspected COVID-19 (n/a - Fatal - Results in Death), Vomiting (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	TRESIBA [INSULIN DEGLUDEC] (C - n/a - n/a - [n/a - n/a - n/a]), VICTOZA [LIRAGLUTIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [AMITRIPTYLINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 20mg - n/a]), [DUTASTERIDE] (C - n/a - n/a - [n/a - .5mg - n/a]), [GABAPENTIN] (C - n/a - n/a - [n/a - 300mg - n/a]), [LINACLOTIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - n/a - [n/a - 10mg - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - 5mg - n/a])
EU-EC-10007797881	278	05.03.2021	65-85 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Malaise (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007798210	279	05.03.2021	More than 85 Years	Elderly	Female	Acute kidney injury (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Disturbance in attention (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Epilepsy (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical condition abnormal (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypercalcaemia (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular])	[BISACODYL] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [CALCIUM, CALCIUM CARBONATE, CALCIUM LACTATE GLUCONATE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [CANDESARTAN] (C - n/a - n/a - [n/a - 16mg - Oral]), [CHOLECALCIFEROL CONCENTRATE (POWDER FORM), COLECALCIFEROL, COLECALCIFEROL CONCENTRATE (OILY FORM)] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [MACROGOL 4000] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [METAMIZOLE, METAMIZOLE MAGNESIUM, METAMIZOLE SODIUM] (C - n/a - n/a - [n/a - 500mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 40mg - Oral]), [PREDNISOLONE] (C - n/a - n/a - [n/a - 5mg - Oral]), [SIMETICONE] (C - n/a - n/a - [n/a - 4{DF} - Oral]), [TAPENTADOL, TAPENTADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 50mg - Oral]), [TORASEMIDE] (C - n/a - n/a - [n/a - 20mg - Oral])
EU-EC-10007798312	280	05.03.2021	65-85 Years	Not Specified	Male	Dehydration (3d - Fatal - Results in Death, Life Threatening), Disturbance in attention (3d - Fatal - Results in Death, Life Threatening), Dyspnoea (3d - Fatal - Results in Death, Life Threatening), Pneumonia bacterial (3d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007798319	281	05.03.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007798396	282	05.03.2021	More than 85 Years	Elderly	Female	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007798450	283	05.03.2021	More than 85 Years	Not Specified	Female	Dehydration (4d - Fatal - Results in Death, Life Threatening), Disturbance in attention (4d - Fatal - Results in Death, Life Threatening), Dyspnoea (4d - Fatal - Results in Death, Life Threatening), Pneumonia bacterial (4d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007798774	284	05.03.2021	18-64 Years	Not Specified	Male	Pain (n/a - Unknown -), Sudden death (n/a - Fatal - Results in Death), Vaccination site pain (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	INCRUSE [UMECLIDINIUM BROMIDE] (C - Chronic obstructive pulmonary disease - n/a [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN, WARFARIN SODIUM] (C - Atrial fibrillation - n/a - [n/a - n/a - n/a])
EU-EC-10007798788	285	05.03.2021	Not Specified	Neonate (Preterm and Term newborns)	Not Specified	Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Neonatal pneumothorax (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Neonatal respiratory distress (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Premature baby (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Transplacental])	[FOLIC ACID] (C - Vitamin supplementation - n/a - [n/a - 400ug - Transplacental])
EU-EC-10007799865	286	05.03.2021	More than 85 Years	Elderly	Female	Chills (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypotension (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [NOT AVAILABLE] (S - Cardiac failure - Drug withdrawn - [n/a - .5mg - n/a])	APIXABAN 5MG TABLET (C - n/a - n/a - [n/a - 5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007799883	287	05.03.2021	More than 85 Years	Not Specified	Female	Nausea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007799885	288	05.03.2021	More than 85 Years	Elderly	Female	Malaise (n/a - Unknown -), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported

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EU-EC-10007799916	289	05.03.2021	More than 85 Years	Not Specified	Female	Diarrhoea (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Hand deformity (n/a - Fatal - Results in Death), Influenza like illness (n/a - Fatal - Results in Death), Livedo reticularis (n/a - Fatal - Results in Death), Peripheral coldness (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOMER] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007799929	290	05.03.2021	More than 85 Years	Not Specified	Female	Fall (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [FORMOTEROL FUMARATE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007799930	291	05.03.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Influenza like illness (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [BARNIDIPINE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007799947	292	05.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007800087	293	05.03.2021	More than 85 Years	Not Specified	Female	Chills (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Pain (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007801089	294	05.03.2021	65-85 Years	Not Specified	Female	Decreased appetite (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007801138	295	05.03.2021	More than 85 Years	Not Specified	Female	Cerebrovascular accident (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 10mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 5mg - n/a])
EU-EC-10007802046	296	05.03.2021	More than 85 Years	Not Specified	Female	Dizziness (n/a - Unknown -), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007802116	297	05.03.2021	More than 85 Years	Elderly	Female	Dyspnoea (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	EDOXYBAN 30MG TABLET (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007802146	298	05.03.2021	Not Specified	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [TOLTERODINE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007802167	299	05.03.2021	More than 85 Years	Not Specified	Female	Malaise (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Transient ischaemic attack (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007802890	300	05.03.2021	Not Specified	Elderly	Female	Dehydration (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NON SPECIFIED ANTIDEPRESSIVUM [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007802911	301	05.03.2021	More than 85 Years	Not Specified	Male	Cardiogenic shock (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASON PROPRIONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007802948	302	05.03.2021	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM VALPROATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007802958	303	05.03.2021	65-85 Years	Not Specified	Male	Arrhythmia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PERICIAZINE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007802971	304	05.03.2021	65-85 Years	Not Specified	Female	Cough (n/a - Fatal - Results in Death, Life Threatening), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMINE HYDROCHLORIDE, DEXPANTHENOL, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007802977	305	05.03.2021	More than 85 Years	Not Specified	Female	Ischaemic cerebral infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), NOVORAPID 100 E/ML, OPLOSSING VOOR INJECTIE IN FLACON. [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007803008	306	05.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [IPRATROPIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007803157	307	05.03.2021	More than 85 Years	Elderly	Male	Cardiac failure (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Nasopharyngitis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - Oral]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - Oral]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)])
EU-EC-10007803222	308	05.03.2021	65-85 Years	Not Specified	Female	Coma (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved -), Oesophageal varices haemorrhage (n/a - Fatal - Results in Death), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007803232	309	05.03.2021	18-64 Years	Not Specified	Male	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Constipation (n/a - Unknown -), Pyrexia (n/a - Fatal - Results in Death, Other Medically Important Condition), Rhabdomyolysis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	BUDESONIDE [BUDESONIDE] (C - n/a - n/a - [n/a - n/a - n/a]), MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BACLOFEN] (C - Cerebral palsy - n/a - [n/a - n/a - n/a]), [COLISTIMETHATE SODIUM, COLISTIN SULFATE] (C - Cerebral palsy - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - Pain - n/a - [n/a - n/a - n/a]), [LAMOTRIGINE] (C - Epilepsy - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007803265	310	05.03.2021	More than 85 Years	Elderly	Female	General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[AMLODIPINE, AMLODIPINE MALEATE, TEMAZEPAM] (C - n/a - n/a - [n/a - n/a - Oral]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - Oral]), [MACROGOL 4000] (C - n/a - n/a - [n/a - n/a - Oral]), [NALOXONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE, NALOXONE, OXYCODONE, OXYCODONE HYDROCHLORIDE, NALOXONE, OXYCODONE HYDROCHLORIDE, NALOXONE HYDROCHLORIDE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-10007803277	311	05.03.2021	More than 85 Years	Elderly	Female	General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - Oral]), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral])

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EU-EC-10007803283	312	05.03.2021	More than 85 Years	Elderly	Male	Cardiac failure (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	DARBEPOETIN ALFA [DARBEPOETIN ALFA] (C - n/a - n/a - [n/a - n/a - n/a]), ESOMEPRAZOLE [ESOMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CEFUROXIME] (C - n/a - n/a - [n/a - n/a - n/a]), [FINASTERIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE MONONITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [MEMANTINE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYCODONE, OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TINZAPARIN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007804653	313	05.03.2021	Not Specified	Not Specified	Male	Abnormal behaviour (n/a - Unknown -), Amnesia (n/a - Unknown -), Decreased appetite (n/a - Unknown -), Disturbance in attention (n/a - Unknown -), Feeling cold (n/a - Unknown -), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Indifference (n/a - Unknown -), Myocardial infarction (n/a - Fatal - Results in Death), Pain (n/a - Unknown -), Respiratory disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007804663	314	05.03.2021	More than 85 Years	Not Specified	Female	Cerebrovascular accident (n/a - Fatal - Results in Death, Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved - Other Medically Important Condition), Sudden death (n/a - Fatal - Results in Death, Other Medically Important Condition), Vaccination site pain (n/a - Recovered/Resolved - Other Medically Important Condition), Vascular dementia (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CARBAMAZEPINE, CARBAMAZEPINE (PH. EUR.)) (C - n/a - n/a - [n/a - 100mg - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - 30mg - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - 50mg - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 15mg - n/a]), [SODIUM HYDROGEN CARBONATE PHEUR, CALCIUM CARBONATE PH. EUR., SODIUM ALGINATE PH. EUR., SODIUM HYDROGEN CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE] (C - n/a - n/a - [n/a - 10mL - n/a]), [SODIUM HYDROGEN CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE] (C - n/a - n/a - [n/a - 10mL - n/a])

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EU-EC-10007804665	315	05.03.2021	65-85 Years	Not Specified	Male	Cerebral haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Contusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Epistaxis (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Retching (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[GABAPENTIN] (C - Back pain - n/a - [n/a - n/a - n/a])
EU-EC-10007805208	316	05.03.2021	More than 85 Years	Elderly	Male	Body temperature increased (n/a - Not Recovered/Not Resolved - Life Threatening), COVID-19 pneumonia (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Not Recovered/Not Resolved - Life Threatening), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007805365	317	05.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007805818	318	05.03.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Incorrect route of product administration (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous])	Not reported
EU-EC-10007805860	319	05.03.2021	More than 85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death), Fall (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported

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EU-EC-10007806375	320	05.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - n/a])	[ATORVASTATIN, RIVASTIGMINE] (C - n/a - n/a - [n/a - n/a - n/a]), [BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE DIHYDRATE, BECLOMETASONE DIPROPIONATE ANHYDROUS] (C - n/a - n/a - [n/a - n/a - n/a]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOMER, CARBOMER 980] (C - n/a - n/a - [n/a - n/a - n/a]), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ESTRIOL] (C - n/a - n/a - [n/a - n/a - n/a]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007806388	321	05.03.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007808535	322	05.03.2021	More than 85 Years	Not Specified	Male	Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dehydration (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Dizziness (n/a - Unknown -), Immunodeficiency (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Unknown -), Pyrexia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007808587	323	05.03.2021	65-85 Years	Not Specified	Female	Cerebrovascular accident (n/a - Fatal - Results in Death, Other Medically Important Condition), Condition aggravated (n/a - Fatal - Results in Death), Vascular dementia (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ALENDRONATE SODIUM, ALENDRONIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - Poor quality sleep - n/a - [n/a - n/a - n/a])
EU-EC-10007809139	324	05.03.2021	More than 85 Years	Not Specified	Female	Depressed mood (n/a - Not Recovered/Not Resolved -), General physical health deterioration (n/a - Not Recovered/Not Resolved -), Sepsis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[FENTANYL, FENTANYL CITRATE] (C - Pain - n/a - [n/a - 1{DF} - Transdermal]), [RISPERIDONE] (C - n/a - n/a - [n/a - 2mg - Oral])

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EU-EC-10007809379	325	05.03.2021	18-64 Years	Not Specified	Female	Aphonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysphonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypersensitivity (n/a - Unknown - Caused/Prolonged Hospitalisation), Lack of spontaneous speech (n/a - Unknown - Caused/Prolonged Hospitalisation), Near death experience (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin discolouration (n/a - Unknown - Caused/Prolonged Hospitalisation), Throat irritation (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	REPAGLINIDE [REPAGLINIDE] (C - n/a - n/a - [n/a - n/a - n/a]), SEVELAMER [SEVELAMER, SEVELAMER CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), TACROLIMUS [TACROLIMUS, TACROLIMUS MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CARVEDILOL] (C - n/a - n/a - [n/a - n/a - n/a]), [CLONIDINE] (C - n/a - n/a - [n/a - n/a - n/a]), [NIFEDIPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007809729	326	05.03.2021	More than 85 Years	Elderly	Female	COVID-19 (n/a - Fatal - Results in Death), Severe acute respiratory syndrome (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007809819	327	05.03.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[ACETYLSALICYLIC ACID, ASPIRIN BP] (C - n/a - n/a - [n/a - 75mg - n/a]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - 500mg - n/a]), [FERROUS FUMARATE BP] (C - n/a - n/a - [n/a - 305mg - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 5mg - n/a]), [HYDROXOCOBALAMIN CHLORIDE] (C - n/a - n/a - [n/a - 1000ug - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 50ug - n/a])
EU-EC-10007783993	328	04.03.2021	65-85 Years	Elderly	Male	Cardiopulmonary failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonia aspiration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007784620	329	04.03.2021	More than 85 Years	Not Specified	Male	Arthralgia (1d - Fatal - Results in Death), Coma (1d - Fatal - Results in Death), Dyspnoea (1d - Fatal - Results in Death), Loss of consciousness (1d - Fatal - Results in Death), Malaise (1d - Fatal - Results in Death), Pulmonary oedema (1d - Fatal - Results in Death), Pyrexia (1d - Fatal - Results in Death), Rales (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	OLANZAPINE [OLANZAPINE] (C - Agitated depression - n/a - [n/a - 2.5mg - Oral]), [AMIODARONE, AMIODARONE HYDROCHLORIDE] (C - Tachycardia - n/a - [n/a - 200mg Oral]), [BISOPROLOL FUMARATE] (C - Atrial flutter - n/a - [n/a - 5mg - Oral]), [ENALAPRIL MALEATE] (C - Hypertension - n/a - [n/a - 10mg - Oral]), [LORAZEPAM] (C - Anxiety disorder - n/a - [n/a - 3mg - Oral]), [TRAZODONE HYDROCHLORIDE] (C - Depression - n/a - [n/a - 20{drp} - Oral]), [WARFARIN SODIUM] (C - Aortic valve replacement - n/a - [n/a - .5{DF} - Oral])
EU-EC-10007784981	330	04.03.2021	More than 85 Years	Not Specified	Female	Acute myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007785730	331	04.03.2021	65-85 Years	Not Specified	Female	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Aortic arteriosclerosis (n/a - Fatal - Results in Death), Arteriosclerosis coronary artery (n/a - Fatal - Results in Death), Chest discomfort (n/a - Not Recovered/Not Resolved -), Constipation (n/a - Not Recovered/Not Resolved -), Cough (n/a - Fatal - Results in Death), Decreased appetite (n/a - Not Recovered/Not Resolved -), Emphysema (n/a - Fatal - Results in Death), Myocardial ischaemia (n/a - Fatal - Results in Death, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved -), Overflow diarrhoea (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	PREGABALIN [PREGABALIN] (C - n/a - n/a - [n/a - n/a - n/a]), RIVAROXABAN [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [ALENDRONATE SODIUM, ALENDRONIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMITRIPTYLINE, AMITRIPTYLINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [GEMFIBROZIL] (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [LETROZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [THYROXINE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [VERAPAMIL, VERAPAMIL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007785800	332	04.03.2021	More than 85 Years	Not Specified	Female	Intestinal infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Sepsis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007786121	333	04.03.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition), Dysstasia (n/a - Not Recovered/Not Resolved -), Feeling abnormal (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Skin discolouration (n/a - Not Recovered/Not Resolved -), Tremor (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported
EU-EC-10007787520	334	04.03.2021	More than 85 Years	Not Specified	Female	Asthenia (n/a - Fatal - Results in Death), Cerebrovascular accident (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	TRIMBOW [BECLOMETASONE DIPROPIONATE, GLYCOPYRROLIUM BROMIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOCISTEINE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOCUSATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 500mg - n/a])
EU-EC-10007788105	335	04.03.2021	More than 85 Years	Not Specified	Male	Vaccination complication (7d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007789597	336	04.03.2021	65-85 Years	Not Specified	Male	Sudden cardiac death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[LANSOPRAZOLE] (C - Gastrooesophageal reflux disease - n/a - [n/a - 30mg - n/a])

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EU-EC-10007789634	337	04.03.2021	More than 85 Years	Not Specified	Male	Back pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007790701	338	04.03.2021	Not Specified	Not Specified	Female	Congestive cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Ventricular fibrillation (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ATENOLOL, ATENOLOL BP] (C - Palpitations - n/a - [n/a - n/a - n/a])
EU-EC-10007791535	339	04.03.2021	65-85 Years	Not Specified	Male	Chest pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Heart rate decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ANASTROZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [DILTIAZEM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007793183	340	04.03.2021	More than 85 Years	Not Specified	Male	Pneumonitis (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Respiratory rate decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007794294	341	04.03.2021	18-64 Years	Not Specified	Female	Abdominal pain (n/a - Recovered/Resolved -), Asthenia (n/a - Recovered/Resolved -), Bezold-Jarisch reflex (n/a - Recovered/Resolved -), Bradyphrenia (n/a - Recovered/Resolved -), Cold sweat (n/a - Recovered/Resolved -), Defaecation urgency (n/a - Recovered/Resolved -), Dizziness (2d - Recovered/Resolved -), Ear pain (n/a - Recovered/Resolved -), Fear of death (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Heart rate decreased (n/a - Recovered/Resolved -), Hypotension (n/a - Recovered/Resolved - Life Threatening), Nausea (n/a - Recovered/Resolved -), Sleep disorder (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Tremor (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ACETYSALICYLIC ACID] (C - Headache - n/a - [1d - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a])
EU-EC-10007794501	342	04.03.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a - More in ICSR])	Not reported

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EU-EC-10007794559	343	04.03.2021	More than 85 Years	Elderly	Male	Dyspnoea (n/a - Fatal - Results in Death), Pain (n/a - Unknown - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Restlessness (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	FENTANYL [FENTANYL, FENTANYL CITRATE] (C - Pain - n/a - [n/a - n/a - n/a]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Prophylaxis against gastrointestinal ulcer - n/a - [n/a - n/a - n/a]), PRADAXA [DABIGATRAN ETEXILATE, DABIGATRAN ETEXILATE MESILATE] (C - Thrombosis prophylaxis - n/a - [n/a - n/a - n/a]), [ATENOLOL, ATENOLOL BP] (C - Heart rate irregular - n/a - [n/a - n/a - n/a]), [BISACODYL] (C - Constipation - n/a - [n/a - n/a - n/a]), [CLINDAMYCIN, CLINDAMYCIN HYDROCHLORIDE, CLINDAMYCIN PHOSPHATE] (C - Pneumonia - n/a - [n/a - n/a - n/a]), [FLUTICASON PROPRIONATE, SALMETEROL, FLUTICASON PROPRIONATE, SALMETEROL XINAFOATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - Diuretic therapy - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE, GLYCERYL TRINITRATE SOLUTION] (C - Angina pectoris - n/a - [n/a - n/a - n/a]), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - Pain - n/a - [n/a - n/a - n/a]), [NYSTATIN] (C - Oral fungal infection - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - Sedative therapy - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - Adrenocortical steroid therapy - n/a - [n/a - n/a - n/a]), [TIOTROPIUM] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - Insomnia - n/a - [n/a - n/a - n/a])
EU-EC-10007794566	344	04.03.2021	65-85 Years	Elderly	Male	Abdominal pain upper (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Back pain (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Ileus paralytic (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Septic shock (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007794847	345	04.03.2021	More than 85 Years	Elderly	Male	Sudden death (1d - Fatal - Results in Death), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [1d - 1{DF} - Unknown])	Not reported
EU-EC-10007794932	346	04.03.2021	More than 85 Years	Elderly	Male	Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007769997	347	03.03.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007770511	348	03.03.2021	More than 85 Years	Not Specified	Female	Coma (n/a - Fatal - Results in Death), Diarrhoea (2d - Recovered/Resolved - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007770670	349	03.03.2021	65-85 Years	Not Specified	Male	Abdominal distension (n/a - Unknown -), Cardiomegaly (n/a - Unknown -), Condition aggravated (n/a - Unknown -), Contusion (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Fatigue (n/a - Unknown -), Ocular hyperaemia (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Productive cough (n/a - Unknown -), Sepsis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYSALICYLIC ACID] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXAZOSIN, DOXAZOSIN MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [FINASTERIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [IPRATROPIUM BROMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [NICORANDIL] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL, CODEINE PHOSPHATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - Benign prostatic hyperplasia - n/a [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007772223	350	03.03.2021	65-85 Years	Not Specified	Female	Acute respiratory distress syndrome (n/a - Fatal - Results in Death), Cardio-respiratory arrest (n/a - Fatal - Results in Death), Coma (n/a - Fatal - Results in Death), Lung disorder (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[ALPRAZOLAM] (C - n/a - n/a - [n/a - n/a - n/a]), [CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CYAMEMAZINE, CYAMEMAZINE TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIDODRINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007772266	351	03.03.2021	65-85 Years	Not Specified	Male	Chest pain (n/a - Unknown - Results in Death), Decreased appetite (n/a - Unknown - Results in Death), Lung disorder (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported
EU-EC-10007772312	352	03.03.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death), Hypoxia (20min - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007772328	353	03.03.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007772331	354	03.03.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007773133	355	03.03.2021	65-85 Years	Not Specified	Male	Dyspnoea (0d - Fatal - Results in Death), Pyrexia (0d - Fatal - Results in Death), Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007773970	356	03.03.2021	More than 85 Years	Not Specified	Male	Sepsis (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007774522	357	03.03.2021	18-64 Years	Adult	Male	Aspiration (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007775337	358	03.03.2021	Not Specified	Not Specified	Male	Cerebral haemorrhage (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007775340	359	03.03.2021	65-85 Years	Not Specified	Male	Headache (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007775464	360	03.03.2021	65-85 Years	Not Specified	Female	Myocardial infarction (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007775477	361	03.03.2021	65-85 Years	Not Specified	Male	Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007775623	362	03.03.2021	65-85 Years	Not Specified	Male	Haemorrhagic stroke (3d - Fatal - Results in Death), Nervous system disorder (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [CYANOCOBALAMIN, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [LORMETAZEPAM] (C - n/a - Unknown - [n/a - n/a - n/a]), [PROCYCLIDINE HYDROCHLORIDE, PROCYCLIDINE HYDROCHLORIDE BP] (C - n/a - Unknown - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007776047	363	03.03.2021	65-85 Years	Not Specified	Female	Chills (1d - Fatal - Results in Death), Pyrexia (1d - Fatal - Results in Death), Renal disorder (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007777707	364	03.03.2021	18-64 Years	Adult	Female	Respiratory failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Vaccination complication (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-1000777709	365	03.03.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-1000777739	366	03.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-1000777844	367	03.03.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Fatal - Results in Death), Diarrhoea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	[MEMANTINE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007778073	368	03.03.2021	65-85 Years	Elderly	Male	Vaccination complication (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007778163	369	03.03.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007778231	370	03.03.2021	18-64 Years	Not Specified	Male	Blood potassium decreased (n/a - Unknown -), Dysgeusia (n/a - Unknown -), Near death experience (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007778990	371	03.03.2021	65-85 Years	Elderly	Male	COVID-19 (9d - Fatal - Results in Death), Oxygen saturation decreased (9d - Fatal - Results in Death), Respiratory distress (9d - Fatal - Results in Death), Vaccination failure (9d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - n/a - n/a])	Not reported
EU-EC-10007779199	372	03.03.2021	More than 85 Years	Not Specified	Male	Jaundice (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007779202	373	03.03.2021	65-85 Years	Not Specified	Female	Cerebrovascular disorder (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN, PYRIDOXINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE PH. EUR., CYANOCOBALAMIN, PYRIDOXINE, THIAMINE, CYANOCOBALAMIN, THIAMINE, PYRIDOXINE HYDROCHLORIDE, THIAMINE DISULFIDE, CYANOCOBALAMIN, PYRIDOXINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE, CYANOCOBALAMIN, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 3mL - n/a]), [DONEPEZIL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007780529	374	03.03.2021	18-64 Years	Not Specified	Male	Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death), Non-Hodgkin's lymphoma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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EU-EC-10007781751	375	03.03.2021	More than 85 Years	Elderly	Male	Asthenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Gait inability (n/a - Unknown -), Pneumonia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [HYDROCHLOROTHIAZIDE, AMILORIDE HYDROCHLORIDE DIHYDRATE, HYDROCHLOROTHIAZIDE, ANHYDROUS AMILORIDE HYDROCHLORIDE] (C - n/a - n/a -), [RAMIPRIL] (C - n/a - n/a - [n/a - 1.25mg - n/a]), [WARFARIN, WARFARIN SODIUM] (C - Pulmonary embolism - n/a - [n/a - 5mg - Oral])
EU-EC-10007781770	376	03.03.2021	Not Specified	Foetus	Not Specified	Foetal heart rate abnormal (n/a - Fatal - Results in Death, Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Transplacental])	[ASCORBIC ACID, FOLIC ACID, NICOTINAMIDE, ASCORBIC ACID, RETINOL] (C - n/a - n/a - [n/a - n/a - Transplacental]), [FOLATE SODIUM] (C - n/a - n/a - [n/a - n/a - Transplacental]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 25mg - Transplacental]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - Transplacental])
EU-EC-10007782349	377	03.03.2021	More than 85 Years	Elderly	Female	Bacterial infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), Swelling (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Swelling face (n/a - Recovering/Resolving - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ZOLPIDEM, ZOLPIDEM TARTRATE] (C - Insomnia - n/a - [n/a - n/a - n/a])
EU-EC-10007782353	378	03.03.2021	18-64 Years	Adult	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [23d - 1{DF} - Intramuscular])	Not reported
EU-EC-10007783130	379	03.03.2021	More than 85 Years	Elderly	Female	Bronchial hyperreactivity (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a])	Not reported
EU-EC-10007783603	380	03.03.2021	65-85 Years	Not Specified	Female	Blood pressure increased (n/a - Unknown - Life Threatening, Other Medically Important Condition), Near death experience (n/a - Unknown - Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007760253	381	02.03.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007760798	382	02.03.2021	More than 85 Years	Not Specified	Male	Dyspnoea (0d - Fatal - Results in Death), Sopor (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007761030	383	02.03.2021	18-64 Years	Not Specified	Female	Cerebral venous sinus thrombosis (3d - Fatal - Results in Death), Coagulopathy (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007761334	384	02.03.2021	65-85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007761342	385	02.03.2021	65-85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007761353	386	02.03.2021	More than 85 Years	Not Specified	Female	Respiratory distress (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[MIANSERIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-10007761382	387	02.03.2021	18-64 Years	Not Specified	Male	Cardio-respiratory arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007761407	388	02.03.2021	65-85 Years	Not Specified	Male	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Hypotension (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007761417	389	02.03.2021	65-85 Years	Not Specified	Male	Myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007761419	390	02.03.2021	18-64 Years	Not Specified	Male	Chest pain (n/a - Recovered/Resolved - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypertension (n/a - Recovering/Resolving - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007761831	391	02.03.2021	More than 85 Years	Not Specified	Male	Cerebrovascular accident (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007762217	392	02.03.2021	65-85 Years	Not Specified	Female	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Condition aggravated (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Illness (n/a - Unknown -), Malaise (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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EU-EC-10007762734	393	02.03.2021	More than 85 Years	Not Specified	Male	Anal incontinence (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (3d - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (3d - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007763237	394	02.03.2021	18-64 Years	Adult	Female	Arterial thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Gastrointestinal necrosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hepatic failure (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007763350	395	02.03.2021	65-85 Years	Elderly	Female	Asthenia (n/a - Fatal - Results in Death), Bedridden (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Hypotonia (n/a - Fatal - Results in Death), Irregular breathing (n/a - Fatal - Results in Death), Rhonchi (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	TURATANITIN [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLCYSTEINE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID, ACETYLSALICYLIC ACID PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [AZATHIOPRINE] (C - n/a - n/a - [n/a - n/a - n/a]), [BISACODYL, DOCUSATE SODIUM, SODIUM PICOSULFATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MELPERONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYALURONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TIANEPTINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [TOLTERODINE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007763353	396	02.03.2021	65-85 Years	Not Specified	Female	COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007763358	397	02.03.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death), Diabetes mellitus (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID, ACETYLSALICYLIC ACID PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007763741	398	02.03.2021	More than 85 Years	Not Specified	Female	Cold sweat (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BUPRENORPHINE] (C - n/a - n/a - [n/a - 10ug - n/a]), [MEMANTINE] (C - n/a - n/a - [n/a - 20mg - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 100mg - n/a])
EU-EC-10007764042	399	02.03.2021	More than 85 Years	Not Specified	Male	Respiratory disorder (n/a - Fatal - Results in Death, Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007764043	400	02.03.2021	More than 85 Years	Not Specified	Male	Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition), Renal failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007764414	401	02.03.2021	65-85 Years	Not Specified	Female	Abdominal wall haematoma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Abdominal wall haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypotension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007764846	402	02.03.2021	18-64 Years	Not Specified	Male	Dysphagia (n/a - Not Recovered/Not Resolved -), Ear pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Fear of death (n/a - Not Recovered/Not Resolved -), Formication (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Skin sensitisation (n/a - Not Recovered/Not Resolved -), Vaccination site lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	Not reported

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EU-EC-10007765372	403	02.03.2021	More than 85 Years	Not Specified	Female	Cerebrovascular accident (9d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007765505	404	02.03.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007765594	405	02.03.2021	18-64 Years	Not Specified	Female	Disseminated intravascular coagulation (n/a - Fatal - Results in Death), Hepatic failure (n/a - Fatal - Results in Death), Intestinal gangrene (n/a - Fatal - Results in Death), Visceral venous thrombosis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007765649	406	02.03.2021	More than 85 Years	Not Specified	Female	Body temperature decreased (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007765739	407	02.03.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007766581	408	02.03.2021	65-85 Years	Not Specified	Female	Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Faeces discoloured (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypophagia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	RELVAR ELLIPTA [FLUTICASONE FUROATE, VILANTEROL] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - Gastritis - n/a - [n/a - n/a - n/a]), [LISINOPRIL, LISINOPRIL DIHYDRATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Blood cholesterol increased - n/a - [n/a - n/a - n/a]), [TIOTROPIUM, TIOTROPIUM BROMIDE, TIOTROPIUM BROMIDE MONOHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a])
EU-EC-10007766593	409	02.03.2021	18-64 Years	Not Specified	Male	Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), INSULIN ASPART [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), [ALENDRONATE SODIUM, ALENDRONIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOCUSATE] (C - n/a - n/a - [n/a - n/a - n/a]), [INFLUENZA VIRUS] (C - n/a - n/a - [1d - n/a - n/a]), [LAMOTRIGINE] (C - n/a - n/a - [n/a - n/a - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007767090	410	02.03.2021	65-85 Years	Not Specified	Female	Asthenia (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Near death experience (n/a - Recovering/Resolving - Other Medically Important Condition), Pain (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Unknown -), Vaccination site swelling (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007767324	411	02.03.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular])	[ALPRAZOLAM] (C - n/a - n/a - [n/a - .25mg - n/a]), [ENOXAPARIN SODIUM] (C - n/a - n/a - [n/a - 4000[iU] - n/a]), [PERINDOPRIL, PERINDOPRIL ARGININE] (C - n/a - n/a - [n/a - 5mg - n/a]), [TIAPRIDE, TIAPRIDE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 100mg - n/a]), [VINPOCETINE] (C - n/a - n/a -)
EU-EC-10007767400	412	02.03.2021	More than 85 Years	Elderly	Female	Condition aggravated (n/a - Unknown -), Eating disorder (n/a - Unknown -), Pulmonary embolism (n/a - Fatal - Results in Death), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - Unknown -), [COLECALCIFEROL] (C - n/a - Unknown -), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - Unknown -), [MEMANTINE] (C - n/a - Unknown -)
EU-EC-10007767645	413	02.03.2021	65-85 Years	Not Specified	Male	General physical health deterioration (14d - Fatal - Results in Death), Pneumonia (14d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[PREDNISOLONE] (C - n/a - n/a - [n/a - 5mg - Oral])
EU-EC-10007767907	414	02.03.2021	18-64 Years	Not Specified	Female	Cardiac failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Choking (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007768949	415	02.03.2021	65-85 Years	Not Specified	Male	Blood glucose increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	VIAGRA [SILDENAFIL, SILDENAFIL CITRATE] (C - Erectile dysfunction - n/a - [n/a - 100mg - Oral]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 2000[iU] - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Weight increased - n/a - [n/a - 40mg - Oral]), [GLYCERYL TRINITRATE] (C - Chest pain - n/a - [n/a - .4mg - Sublingual]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - 25mg - Oral]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 125ug - Oral]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 125ug - Oral]), [METOPROLOL SUCCINATE] (C - n/a - n/a - [n/a - 50mg - Oral]), [MICRONISED SPIRONOLACTONE, POTASSIUM CANRENOATE, SPIRONOLACTONE, SPIRONOLACTONE BP] (C - n/a - n/a - [n/a - 25mg - Oral]), [MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - n/a - [n/a - 10mg - Oral]), [PRASUGREL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - Oral - More in ICSR]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - n/a - n/a - [n/a - 40mg - Oral]), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - Wheezing - n/a - [n/a - 2.5mg - Respiratory (inhalation)]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Wheezing - n/a - [n/a - 2.5mg - Respiratory (inhalation)]), [TESTOSTERONE] (C - n/a - n/a - [n/a - 30g - Topical])

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EU-EC-10007769024	416	02.03.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007769539	417	02.03.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007769578	418	02.03.2021	65-85 Years	Not Specified	Female	Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mobility decreased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ANHYDROUS METHYLDOPA, METHYLDOPA] (C - Hypertension - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Blood cholesterol increased - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [INFLUENZA VIRUS] (C - Immunisation - n/a - [n/a - n/a - n/a]), [LERCANIDIPINE, LERCANIDIPINE HYDROCHLORIDE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [PROCHLORPERAZINE] (C - Dizziness - n/a - [n/a - n/a - n/a])
EU-EC-10007769626	419	02.03.2021	More than 85 Years	Not Specified	Male	Acute myocardial infarction (n/a - Fatal - Results in Death), Fall (n/a - Fatal - Results in Death), Head injury (n/a - Fatal - Results in Death), Peripheral vascular disorder (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007770459	420	02.03.2021	More than 85 Years	Not Specified	Male	Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Tachyarrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported

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EU-EC-10007770521	421	02.03.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	KEPPRA [LEVETIRACETAM] (C - Epilepsy - n/a - [n/a - 2.5mL - n/a]), TOUJEO SOLOSTAR [INSULIN GLARGINE] (C - Diabetes mellitus - n/a - [n/a - 14{iU} - n/a]), [CHLORZOXAZONE] (C - Muscle relaxant therapy - n/a - [n/a - 250mg - n/a]), [CLOPIDOGREL] (C - Thrombosis prophylaxis - n/a - [n/a - 75mg - n/a]), [FENTANYL, FENTANYL CITRATE] (C - Pain - n/a - [n/a - 12ug - n/a]), [GLYCOPYRROLONIUM BROMIDE, GLYCOPYRROLONIUM BROMIDE, NEOSTIGMINE METHYLSULFATE] (C - Airway secretion clearance therapy - n/a - [n/a - 1mL - n/a]), [LANSOPRAZOLE] (C - Prophylaxis against gastrointestinal ulcer - n/a - [n/a - 30mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Metabolic disorder - n/a - [n/a - 50ug - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 1{DF} - n/a]), [MIRTAZAPINE] (C - Depression - n/a - [n/a - 15mg - n/a]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - [n/a - 10mL - n/a])
EU-EC-10007771037	422	02.03.2021	65-85 Years	Elderly	Male	Cerebral haematoma (7d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported
EU-EC-10007771159	423	02.03.2021	65-85 Years	Not Specified	Male	Guillain-Barre syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypokinesia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBIDOPA, LEVODOPA, LEVODOPA, ANHYDROUS CARBIDOPA, LEVODOPA, CARBIDOPA MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SOTALOL, SOTALOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007771204	424	02.03.2021	65-85 Years	Not Specified	Female	Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Musculoskeletal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Neutropenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007771345	425	02.03.2021	More than 85 Years	Not Specified	Female	Bronchitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported

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EU-EC-10007746127	426	01.03.2021	65-85 Years	Not Specified	Male	Asthenia (3d - Fatal - Results in Death), Pyrexia (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 20mg - n/a]), [ENOXAPARIN SODIUM] (C - n/a - n/a - [n/a - 4000[iU] - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007746806	427	01.03.2021	65-85 Years	Not Specified	Female	Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	[ALENDRONATE SODIUM, ALENDRONATE SODIUM TRIHYDRATE, ALENDRONIC ACID] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [ALFUZOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [FERROUS FUMARATE] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [LIQUID PARAFFIN] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [PRAVASTATIN SODIUM] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [SOLIFENACIN, SOLIFENACIN SUCCINATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [TROPATEPINE, TROPATEPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007746818	428	01.03.2021	More than 85 Years	Not Specified	Male	Dyspnoea (3d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	TOVIAZ [FESOTERODINE, FESOTERODINE FUMARATE] (C - n/a - n/a - [n/a - n/a - Oral]), ZOMARIST [METFORMIN HYDROCHLORIDE, VILDAGLIPTIN] (C - n/a - n/a - [n/a - n/a - Oral]), [GLIMEPIRIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [MEMANTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [TAMSULOSIN HYDROCHLORIDE, SOLIFENACIN SUCCINATE] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-10007747826	429	01.03.2021	Not Specified	Not Specified	Male	Cardiac disorder (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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EU-EC-10007748731	430	01.03.2021	More than 85 Years	Not Specified	Male	Other Medically Important Condition), Angioedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma scale abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypothermia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Other Medically Important Condition), Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pruritus (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	METHOTREXATE [METHOTREXATE] (C - n/a - n/a - [n/a - 7.5mg - n/a]), [FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 120mg - n/a]), [HYDROXYZINE, HYDROXYZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 25mg - n/a])
EU-EC-10007748840	431	01.03.2021	More than 85 Years	Elderly	Male	Abdominal pain (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007748854	432	01.03.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007748939	433	01.03.2021	More than 85 Years	Elderly	Female	Bacterial test positive (n/a - Fatal - Results in Death), Blood glucose increased (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Muscle twitching (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Pyelonephritis (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), SARS-CoV-2 test negative (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	TRAJENTA [LINAGLIPTIN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [ANTIFOAM M COMPOUND, DIMETICONE, DIMETICONE, COLLOIDAL SILICON DIOXIDE, DIMETICONE, SILICA, COLLOIDAL ANHYDROUS, SILICA, COLLOIDAL ANHYDROUS, DIMETICONE 1000] (C - Flatulence - n/a - [n/a - n/a - Oral]), [BUPRENORPHINE] (C - Pain - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - Swelling - n/a - [n/a - n/a - n/a]), [MACROGOL 4000] (C - Constipation - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral]), [ZOPICLONE] (C - Insomnia - n/a - [n/a - n/a - Oral])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007749029	434	01.03.2021	65-85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007749281	435	01.03.2021	More than 85 Years	Not Specified	Male	Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007749289	436	01.03.2021	18-64 Years	Not Specified	Male	Arrhythmia (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Coma (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007749406	437	01.03.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	[TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007749477	438	01.03.2021	65-85 Years	Not Specified	Male	Diarrhoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007750968	439	01.03.2021	65-85 Years	Not Specified	Male	Oxygen saturation decreased (1d - Fatal - Results in Death), Pyrexia (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007751125	440	01.03.2021	65-85 Years	Not Specified	Male	Cardiac disorder (n/a - Fatal - Results in Death), Cerebrovascular accident (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), PRALUENT [ALIROCUMAB] (C - n/a - n/a - [n/a - n/a - n/a]), [DILTIAZEM, DILTIAZEM HYDROCHLORIDE] (C - n/a - n/a - [n/a - 120mg - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007751128	441	01.03.2021	65-85 Years	Not Specified	Female	Aphonia (n/a - Unknown - Other Medically Important Condition), Guillain-Barre syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007751131	442	01.03.2021	18-64 Years	Not Specified	Male	Caused/Prolonged Hospitalisation), Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - 5mg - n/a]), [ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [CARVEDILOL HYDROCHLORIDE] (C - Hypertension - n/a - [n/a - 3.125mg - n/a]), [COD-LIVER OIL] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE] (C - Hypertension - n/a - [n/a - 1.25mg - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - n/a - [n/a - 40mg - n/a])
EU-EC-10007751326	443	01.03.2021	More than 85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	SIFROL [PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE] (C - n/a - n/a - [n/a - .25mg - Oral]), XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - 20mg - Oral]), [AMIODARONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 200mg - Oral]), [CALCIUM CARBONATE, CHOLECALCIFEROL CONCENTRATE (POWDER FORM), COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - Oral]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - 5mg - Transdermal]), [METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - 500mg - Oral]), [METHOTREXATE, METHOTREXATE DISODIUM, METHOTREXATE SODIUM] (C - n/a - n/a - [n/a - 10mg - Subcutaneous]), [NALOXONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE, ANHYDROUS NALOXONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE, NALOXONE HYDROCHLORIDE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 40mg - Oral]), [TORASEMIDE, TORASEMIDE SODIUM] (C - n/a - n/a - [n/a - 10mg - Oral])

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EU-EC-10007751337	444	01.03.2021	More than 85 Years	Not Specified	Female	Haemorrhage intracranial (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	APIXABAN [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [ALFACALCIDOL] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [DIGOXIN] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [INFLUENZA VIRUS] (C - n/a - n/a - [n/a - n/a - n/a]), [INSULIN HUMAN ISOPHANE] (C - n/a - n/a - [n/a - n/a - n/a]), [LETROZOLE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007751454	445	01.03.2021	More than 85 Years	Not Specified	Male	Pleural effusion (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007751458	446	01.03.2021	Not Specified	Not Specified	Male	Acute myocardial infarction (n/a - Fatal - Results in Death), Vaccination site pain (n/a - Unknown -), Vaccination site swelling (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007751465	447	01.03.2021	65-85 Years	Not Specified	Male	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Fatal - Results in Death), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	[ALLOPURINOL] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINOPRIL ANHYDROUS] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINOPRIL, LISINOPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN, WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007751714	448	01.03.2021	65-85 Years	Not Specified	Male	Illness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACRIVASTINE, DIPHENHYDRAMINE HYDROCHLORIDE, DIPHENHYDRAMINE HYDROCHLORIDE, ZINC ACETATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007754176	449	01.03.2021	18-64 Years	Not Specified	Female	COVID-19 (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007754355	450	01.03.2021	More than 85 Years	Not Specified	Female	Coma (3d - Fatal - Results in Death), Hypotonia (3d - Fatal - Results in Death), Sudden death (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007754544	451	01.03.2021	65-85 Years	Not Specified	Male	Oxygen saturation abnormal (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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EU-EC-10007754939	452	01.03.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	OLANZAPINE [OLANZAPINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [BILASTINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - Unknown - [n/a - n/a - n/a]), [DESMOPRESSIN, DESMOPRESSIN ACETATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [INDAPAMIDE, INDAPAMIDE HEMIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [LORAZEPAM] (C - n/a - Unknown - [n/a - n/a - n/a]), [MELATONIN] (C - n/a - Unknown - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [PRAZEPAM] (C - n/a - Unknown - [n/a - n/a - n/a]), [QUETIAPINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007755394	453	01.03.2021	65-85 Years	Not Specified	Female	Pyrexia (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[CARBOMER, CARBOMER 980] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 30mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007755395	454	01.03.2021	65-85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 50ug - n/a]), [NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, RIBOFLAVIN SODIUM PHOSPHATE, THIAMINE HYDROCHLORIDE, NICOTINAMIDE, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TIOTROPIUM, OLODATEROL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007755983	455	01.03.2021	More than 85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ATORVASTATIN] (C - n/a - Unknown - [n/a - n/a - n/a]), [BUMETANIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [COLECALCIFEROL, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [LEVOCETIRIZINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [NADROPARIN, NADROPARIN CALCIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [PARACETAMOL, PARACETAMOL, CODEINE PHOSPHATE HEMIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007756340	456	01.03.2021	More than 85 Years	Not Specified	Male	Cardiac arrest (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - Coronary artery disease - n/a - [19y - 75mg - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C Myocardial infarction - n/a - [19y - 80mg - Oral]), [LERCANIDIPINE, LERCANIDIPINE HYDROCHLORIDE] (C - Hypertension - n/a - [n/a - 10mg - Oral]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Myocardial infarction - n/a - [19y - 100mg - Oral]), [TAMSULOSIN HYDROCHLORIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - .4mg - Oral])

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EU-EC-10007756435	457	01.03.2021	More than 85 Years	Not Specified	Male	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - Transient ischaemic attack - n/a - [n/a - 75mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Gastrooesophageal reflux disease - n/a - [n/a - 20mg - Oral]), [TAMSULOSIN HYDROCHLORIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - .4mg - Oral])
EU-EC-10007756795	458	01.03.2021	More than 85 Years	Not Specified	Male	Fatigue (n/a - Unknown - Other Medically Important Condition), Limb discomfort (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007756859	459	01.03.2021	More than 85 Years	Not Specified	Male	Death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular])	NOVORAPID [INSULIN ASPART] (C - n/a - n/a -), TRESIBA [INSULIN DEGLUDEC] (C - n/a - n/a - [n/a - 30[iU] - n/a]), [ASCORBIC ACID, DRIED FERROUS SULFATE, ASCORBIC ACID, FERROUS SULFATE, ASCORBIC ACID, FERROUS SULFATE HYDRATE, DRIED FERROUS SULFATE] (C - n/a - n/a - [n/a - 300mg - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [CALCIUM CITRATE, MAIZE STARCH, STEARIC ACID, TALC, CALCIUM CITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXAZOSIN, DOXAZOSIN MESILATE] (C - n/a - n/a - [n/a - 2mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - 1000mg - n/a]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - .4mg - n/a]), [TRIMETAZIDINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 35mg - n/a]), [VALSARTAN, HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007757946	460	01.03.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007758466	461	01.03.2021	Not Specified	Not Specified	Female	Abdominal pain upper (n/a - Unknown -), Ageusia (n/a - Unknown -), Eye pain (n/a - Unknown -), Headache (n/a - Unknown -), Illness (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Congenital Anomaly, Other Medically Important Condition), Muscle twitching (n/a - Unknown -), Neck pain (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Somnolence (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition), Vision blurred (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CODEINE PHOSPHATE] (C - n/a - n/a - [1d - n/a - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007758591	462	01.03.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Unknown -), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[PREDNISOLONE] (C - COVID-19 - n/a - [n/a - 40mg - n/a])
EU-EC-10007758712	463	01.03.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Dehydration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[FLUCONAZOLE] (C - Fungal infection - n/a - [8d - 100mg - Oral])
EU-EC-10007758721	464	01.03.2021	18-64 Years	Adult	Male	Acute respiratory distress syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Transplant failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	MYFENAX [MYCOPHENOLATE MOFETIL] (C - Prophylaxis against transplant rejection - n/a - [n/a - n/a - n/a]), [CICLOSPORIN] (C - Prophylaxis against transplant rejection - n/a - [n/a - n/a - n/a]), [FELODIPINE] (C - Cardiovascular event prophylaxis - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE] (C - Gastroesophageal reflux prophylaxis - n/a - [n/a - n/a - n/a]), [PRAVASTATIN SODIUM] (C - Hypercholesterolaemia - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - Steroid therapy - n/a - [n/a - n/a - n/a]), [PREGABALIN] (C - Pain prophylaxis - n/a - [n/a - n/a - n/a]), [SULFAMETHOXAZOLE] (C - Infection prophylaxis - n/a - [n/a - n/a - n/a])
EU-EC-10007759951	465	01.03.2021	65-85 Years	Not Specified	Female	COVID-19 pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoxia (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007744498	466	28.02.2021	65-85 Years	Elderly	Male	Ischaemic stroke (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	KEPPRA 500 MG FILM-COATED TABLETS [LEVETIRACETAM] (C - n/a - Dose not changed - [n/a - 500mg - Oral]), NOT AVAILABLE (C - n/a - Dose not changed - [n/a - 10mg - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - Dose not changed - [n/a - 20mg - Oral]), [CYANOCOBALAMIN, FOLIC ACID] (C - n/a - Dose not changed - [n/a - n/a - Oral]), [DRIED FERROUS SULFATE, FERROUS SULFATE, FERROUS SULFATE HYDRATE, FERROUS SULPHATE SESQUIHYDRATE] (C - n/a - Dose not changed - [n/a - n/a - n/a]), [LACTULOSE, LACTULOSE, LIQUID] (C - n/a - Dose not changed - [n/a - n/a - Oral]), [LANSOPRAZOLE] (C - n/a - Dose not changed - [n/a - 15mg - Oral]), [SPIRONOLACTONE] (C - n/a - Dose not changed - [n/a - 25mg - Oral]), [TAMSULOSIN HYDROCHLORIDE, DUTASTERIDE] (C - n/a - Dose not changed - [n/a - n/a - Oral]), [TRAZODONE HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - 50mg - Oral])
EU-EC-10007744624	467	28.02.2021	More than 85 Years	Elderly	Female	Multiple organ dysfunction syndrome (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007744631	468	28.02.2021	More than 85 Years	Elderly	Female	Hypotension (n/a - Fatal - Results in Death), Oxygen saturation decreased (2d - Fatal - Results in Death), Petit mal epilepsy (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported
EU-EC-10007739423	469	27.02.2021	65-85 Years	Not Specified	Female	Asthenia (n/a - Recovered/Resolved - Other Medically Important Condition), Fear of death (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007739436	470	27.02.2021	65-85 Years	Not Specified	Female	Dyspnoea (n/a - Fatal - Results in Death), Hypoxia (n/a - Fatal - Results in Death), Sepsis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007739437	471	27.02.2021	65-85 Years	Not Specified	Female	Asthenia (n/a - Not Recovered/Not Resolved - Results in Death), Cardiac arrest (n/a - Fatal - Results in Death), Dropped head syndrome (n/a - Not Recovered/Not Resolved - Results in Death), Faecaloma (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007739446	472	27.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007739459	473	27.02.2021	More than 85 Years	Not Specified	Female	Cerebral haemorrhage (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007739542	474	27.02.2021	More than 85 Years	Not Specified	Male	Abdominal pain (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007739661	475	27.02.2021	More than 85 Years	Not Specified	Male	Brain stem haemorrhage (n/a - Fatal - Results in Death), International normalised ratio increased (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), [D,L-LYSINE ACETYL SALICYLATE] (S - Atrial fibrillation - Not applicable - [n/a - 75mg - Oral]), [WARFARIN SODIUM] (S - Atrial fibrillation - Not applicable - [n/a - 1.25{DF} - Oral])	XELEVIA 100 MG FILM-COATED TABLETS [SITAGLIPTIN] (C - n/a - n/a - [n/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [NEBIVOLOL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007739812	476	27.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007740078	477	27.02.2021	More than 85 Years	Not Specified	Female	Atrial fibrillation (2d - Fatal - Results in Death), Dyspnoea (2d - Fatal - Results in Death), Oxygen saturation decreased (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007740086	478	27.02.2021	More than 85 Years	Not Specified	Female	Coma (n/a - Fatal - Results in Death), Hypoxia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CLOTIAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [FERROUS FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - n/a - n/a - [n/a - n/a - n/a]), [LERCANIDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [VALSARTAN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007740184	479	27.02.2021	18-64 Years	Not Specified	Male	Myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007740366	480	27.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007740378	481	27.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007740421	482	27.02.2021	More than 85 Years	Not Specified	Male	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007740481	483	27.02.2021	65-85 Years	Not Specified	Male	Myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007740613	484	27.02.2021	More than 85 Years	Not Specified	Male	Fall (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Cardiovascular event prophylaxis - Not applicable - [n/a - 1{DF} - Oral]), [BROMAZEPAM] (S - Mixed anxiety and depressive disorder - Not applicable - [n/a - 2{DF} - Oral]), [FLUOXETINE HYDROCHLORIDE] (S - Mixed anxiety and depressive disorder - Not applicable - [n/a - 10mg - Oral])	Not reported
EU-EC-10007740738	485	27.02.2021	More than 85 Years	Not Specified	Female	Hypertension (n/a - Not Recovered/Not Resolved - Results in Death), Respiratory distress (n/a - Fatal - Results in Death), Tachycardia (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007740753	486	27.02.2021	18-64 Years	Not Specified	Female	Asthenia (n/a - Not Recovered/Not Resolved - Results in Death), Choking (n/a - Fatal - Results in Death), Decreased appetite (n/a - Recovering/Resolving - Results in Death), Pyrexia (n/a - Recovering/Resolving - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007740926	487	27.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[CARBIMAZOLE] (C - n/a - n/a - [n/a - 5mg - Oral]), [NADOLOL] (C - n/a - n/a - [n/a - 40mg - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - 500mg - Oral])

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EU-EC-10007740927	488	27.02.2021	More than 85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741169	489	27.02.2021	More than 85 Years	Not Specified	Male	Atrial fibrillation (n/a - Recovering/Resolving - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Recovering/Resolving - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Recovering/Resolving - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741216	490	27.02.2021	More than 85 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741252	491	27.02.2021	More than 85 Years	Not Specified	Female	COVID-19 (6d - Fatal - Results in Death), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741258	492	27.02.2021	65-85 Years	Not Specified	Male	COVID-19 (4d - Fatal - Results in Death), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741259	493	27.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (4d - Fatal - Results in Death), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741263	494	27.02.2021	65-85 Years	Not Specified	Male	COVID-19 (6d - Fatal - Results in Death), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741264	495	27.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (7d - Fatal - Results in Death), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741269	496	27.02.2021	More than 85 Years	Not Specified	Female	COVID-19 (2d - Fatal - Results in Death), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007741270	497	27.02.2021	65-85 Years	Not Specified	Female	COVID-19 (5d - Fatal - Results in Death), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741309	498	27.02.2021	More than 85 Years	Not Specified	Female	Lung disorder (n/a - Unknown - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741311	499	27.02.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741378	500	27.02.2021	More than 85 Years	Not Specified	Female	Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[PAROXETINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007741395	501	27.02.2021	More than 85 Years	Not Specified	Female	Myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741528	502	27.02.2021	More than 85 Years	Not Specified	Male	Aplasia (n/a - Fatal - Results in Death), Shock (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007741594	503	27.02.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741600	504	27.02.2021	More than 85 Years	Not Specified	Female	Pneumonia aspiration (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741614	505	27.02.2021	More than 85 Years	Not Specified	Male	Atrioventricular block complete (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Sudden death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007741627	506	27.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Hypotension (n/a - Not Recovered/Not Resolved - Results in Death), Malaise (n/a - Recovered/Resolved - Results in Death), Tachycardia (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741695	507	27.02.2021	65-85 Years	Not Specified	Female	Haemorrhagic stroke (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hypertension (n/a - Recovered/Resolved - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular]), [D,L-LYSINE ACETYSALICYLATE] (S - Cerebrovascular accident prophylaxis - Drug withdrawn [n/a - 75mg - Oral])	KEPPRA 500 MG FILM-COATED TABLETS [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBAMAZEPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FERROUS SULPHATE SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - n/a - n/a - [n/a - n/a - n/a]), [PHENOBARBITAL] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007741701	508	27.02.2021	More than 85 Years	Not Specified	Female	Acute respiratory distress syndrome (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007741745	509	27.02.2021	65-85 Years	Not Specified	Male	Cerebral haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition), Hemiplegia (n/a - Not Recovered/Not Resolved - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007742344	510	27.02.2021	More than 85 Years	Not Specified	Male	Acute respiratory failure (n/a - Fatal - Results in Death), COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007742409	511	27.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Hypertension (1d - Recovered/Resolved - Results in Death), Hyperthermia (n/a - Not Recovered/Not Resolved - Results in Death), Lung disorder (n/a - Not Recovered/Not Resolved - Results in Death), Vaccination site inflammation (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007742670	512	27.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007742765	513	27.02.2021	More than 85 Years	Not Specified	Male	Status epilepticus (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Oral])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007742785	514	27.02.2021	More than 85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death), Chest pain (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007742816	515	27.02.2021	More than 85 Years	Not Specified	Female	Cardiac failure (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory distress (3d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Supraventricular tachyarrhythmia (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007749301	516	27.02.2021	More than 85 Years	Elderly	Female	Escherichia infection (2d - Fatal - Results in Death), Sepsis (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	NOT AVAILABLE (C - n/a - Dose not changed -), VIPDOMET [METFORMIN HYDROCHLORIDE, ALOGLIPTIN] (C - n/a - Dose not changed -), [ACETYSALICYLIC ACID] (C - n/a - Dose not changed - [n/a - 100mg - Oral]), [ENALAPRIL MALEATE] (C - n/a - Dose not changed - [n/a - 5mg - Oral]), [GALANTAMINE] (C - n/a - Dose not changed -), [PARACETAMOL] (C - n/a - Dose not changed -), [TRAZODONE HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - 100mg - Oral])
EU-EC-10007728535	517	26.02.2021	More than 85 Years	Not Specified	Male	Cardiac arrest (3d - Fatal - Results in Death), Cardiac failure (3d - Fatal - Results in Death), Hypotension (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007729771	518	26.02.2021	More than 85 Years	Not Specified	Female	Cerebrovascular accident (n/a - Fatal - Results in Death), Seizure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 100ug - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 12.5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1{DF} - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 75mg - n/a]), PANTOPRAZOLE 20 MG - GASTRO-RESISTANT TABLET (C - n/a - n/a - [n/a - 20mg - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 5600{iU} - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007729792	519	26.02.2021	More than 85 Years	Not Specified	Female	Decreased appetite (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NON SPECIFIED DRUG [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007729795	520	26.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	XARELTO 2.5 MG FILM-COATED TABLETS [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007729813	521	26.02.2021	More than 85 Years	Not Specified	Female	Malaise (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NON SPECIFIED ANTIBIOTICA [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007729826	522	26.02.2021	More than 85 Years	Not Specified	Female	Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Nausea (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007729833	523	26.02.2021	Not Specified	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), PANTOPRAZOLE 20 MG - GASTRO-RESISTANT TABLET (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007729843	524	26.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007729845	525	26.02.2021	More than 85 Years	Elderly	Male	Dysphagia (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Pneumonia aspiration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007729856	526	26.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007730003	527	26.02.2021	More than 85 Years	Not Specified	Female	Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoglycaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypophagia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypotension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypothermia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown -), Oedema peripheral (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Skin ulcer (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	BRINZOLAMIDE [BRINZOLAMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID, ASPIRIN BP] (C - n/a - n/a - [n/a - 3mg - n/a]), [DIPYRIDAMOLE] (C - n/a - n/a - [n/a - 3mg - n/a]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [TIMOLOL, TIMOLOL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007730862	528	26.02.2021	More than 85 Years	Elderly	Male	Circulatory collapse (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007731386	529	26.02.2021	More than 85 Years	Not Specified	Male	Asthenia (8d - Fatal - Results in Death), Cardiovascular disorder (8d - Fatal - Results in Death), General physical condition abnormal (8d - Fatal - Results in Death), Hyperpyrexia (0d - Fatal - Results in Death), Jaundice (0d - Fatal - Results in Death), Myocarditis septic (0d - Fatal - Results in Death), Nasopharyngitis (8d - Fatal - Results in Death), Pain in extremity (8d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007732636	530	26.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), General physical health deterioration (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007733102	531	26.02.2021	More than 85 Years	Not Specified	Male	Sudden cardiac death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007733945	532	26.02.2021	More than 85 Years	Not Specified	Female	Abdominal pain (19d - Fatal - Results in Death, Other Medically Important Condition), Fatigue (19d - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (19d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - Intramuscular])	[CARVEDILOL] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007734304	533	26.02.2021	More than 85 Years	Not Specified	Male	Pneumonia (n/a - Fatal - Results in Death), Sepsis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007734821	534	26.02.2021	18-64 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	OPSUMIT [MACITENTAN] (C - Pulmonary arterial hypertension - n/a - [n/a - 10mg - n/a]), UPTRAVI [SELEXIPAG] (C - Pulmonary arterial hypertension - n/a - [n/a - 1600ug - n/a])
EU-EC-10007737139	535	26.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYSALICYLIC ACID, ASPIRIN BP] (C - n/a - n/a - [n/a - 75mg - n/a]), [ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 20mg - n/a]), [BUMETANIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007718294	536	25.02.2021	18-64 Years	Not Specified	Male	Epilepsy (n/a - Unknown - Other Medically Important Condition), Obstructive airways disorder (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007718525	537	25.02.2021	Not Specified	Elderly	Male	Chills (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death), Myalgia (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007718594	538	25.02.2021	65-85 Years	Not Specified	Male	Malaise (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[CITALOPRAM, CITALOPRAM HYDROBROMIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007718595	539	25.02.2021	More than 85 Years	Not Specified	Male	Confusional state (n/a - Fatal - Results in Death), Depressed level of consciousness (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Seizure (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 1{DF} - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 40mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 500mg - n/a]), [AVENA SATIVA FERM 33C Ø, HUMULUS LUPULUS EX HERBA ET FRUCTIBUS FERM 34D Ø (HAB, VS. 34D), VALERIANA OFFICINALIS E RADICE FERM 33C Ø (HAB, VS. 33C), PASSIFLORA CAERULEA EX HERBA FERM 33C Ø (HAB, VS. 33C), PASSIFLORA] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 25ug - n/a])
EU-EC-10007718598	540	25.02.2021	More than 85 Years	Not Specified	Female	Blood pressure increased (n/a - Unknown -), Dizziness (n/a - Unknown -), Injection site pain (n/a - Unknown -), Ischaemic cerebral infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	GREPID 75 MG FILM-COATED TABLETS [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007718653	541	25.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007718860	542	25.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (1d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematemesis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	APIXABAN [APIXABAN] (C - Anticoagulant therapy - n/a - [n/a - 10mg - n/a]), EMPAGLIFLOZIN [EMPAGLIFLOZIN] (C - Type 2 diabetes mellitus - n/a - [n/a - 10mg - n/a]), RASAGILINE [RASAGILINE, RASAGILINE TARTRATE] (C - Parkinson's disease - n/a - [n/a - 1mg - n/a]), [BENSERAZIDE HYDROCHLORIDE, LEVODOPA] (C - Parkinson's disease - n/a - [n/a - 4{DF} - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a - More in ICSR]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 20mg - n/a]), [GLICLAZIDE] (C - Type 2 diabetes mellitus - n/a - [n/a - 160mg - n/a - More in ICSR]), [INDAPAMIDE, INDAPAMIDE HEMIHYDRATE] (C - Diuretic therapy - n/a - [n/a - 1.5mg - n/a]), [METFORMIN HYDROCHLORIDE] (C - Type 2 diabetes mellitus - n/a - [n/a - 1000mg - n/a]), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - n/a - n/a - [n/a - 40mg - n/a])
EU-EC-10007719978	543	25.02.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007720021	544	25.02.2021	More than 85 Years	Not Specified	Female	Back pain (n/a - Unknown -), Confusional state (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Hypertension (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - Pulmonary embolism - n/a - [n/a - 5mg - n/a]), [GLYCERYL TRINITRATE] (C - n/a - n/a -), [METOCLOPRAMIDE HYDROCHLORIDE] (C - n/a - n/a -), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [OXAZEPAM] (C - n/a - n/a -), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - Respiratory (inhalation)])
EU-EC-10007720090	545	25.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007720134	546	25.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007720437	547	25.02.2021	65-85 Years	Not Specified	Female	Acute kidney injury (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007720934	548	25.02.2021	65-85 Years	Not Specified	Female	Diplegia (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007720964	549	25.02.2021	More than 85 Years	Elderly	Male	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007721011	550	25.02.2021	65-85 Years	Not Specified	Male	Back pain (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Chest pain (n/a - Fatal - Results in Death), Costochondritis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007721191	551	25.02.2021	65-85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - Cardiac failure - n/a - [n/a - 2.5mg - Oral]), [ACETYLSALICYLIC ACID] (C - Myocardial ischaemia - n/a - [n/a - 75mg - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Cardiac failure - n/a - [n/a - 40mg - Oral]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - 500mg - n/a]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 100mg - Oral]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - 750mg - Oral]), [RAMIPRIL] (C - Cardiac failure - n/a - [n/a - 5mg - Oral])
EU-EC-10007721239	552	25.02.2021	More than 85 Years	Elderly	Female	COVID-19 (n/a - Unknown - Other Medically Important Condition), Cardio-respiratory arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007722038	553	25.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Hyperpyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007722134	554	25.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007722257	555	25.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007722492	556	25.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007722796	557	25.02.2021	More than 85 Years	Not Specified	Female	Altered state of consciousness (2d - Fatal - Results in Death), General physical health deterioration (2d - Fatal - Results in Death), Restlessness (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007722822	558	25.02.2021	65-85 Years	Not Specified	Male	Cardiac arrest (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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EU-EC-10007723042	559	25.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007723054	560	25.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE, GLYCERYL TRINITRATE SOLUTION] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007723172	561	25.02.2021	65-85 Years	Not Specified	Male	Death (0d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007723549	562	25.02.2021	65-85 Years	Not Specified	Female	Arthralgia (n/a - Unknown -), Cardiac failure (n/a - Fatal - Results in Death), Myalgia (n/a - Unknown -), Myocardial ischaemia (n/a - Fatal - Results in Death), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ASCORBIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [CLARITHROMYCIN, OMEPRAZOLE, OMEPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 20mg n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [MENAQUINONE, MENAQUINONE 6] (C - n/a - n/a - [n/a - n/a - n/a]), [PERINDOPRIL, PERINDOPRIL TERT-BUTYLAMINE] (C - Hypertension - n/a - [n/a - 4mg - n/a]), [ZINC] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007724924	563	25.02.2021	More than 85 Years	Not Specified	Female	Atrioventricular block (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Bradycardia (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cardiac arrest (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cardiovascular disorder (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), General physical health deterioration (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Loss of consciousness (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Respiration abnormal (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Rhythm idioventricular (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ARANESP [DARBEPOETIN ALFA] (C - n/a - Unknown - [n/a - n/a - n/a]), IRON [IRON] (C - n/a - Unknown - [n/a - 2{DF} - n/a]), [ATENOLOL] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [COLECALCIFEROL] (C - n/a - Unknown - [n/a - n/a - n/a]), [INDAPAMIDE, INDAPAMIDE HEMIHYDRATE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [LERCANIDIPINE, LERCANIDIPINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [SULFASALAZINE] (C - n/a - Unknown - [n/a - 2{DF} - n/a])
EU-EC-10007725729	564	25.02.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Not Recovered/Not Resolved -), COVID-19 pneumonia (n/a - Fatal - Results in Death), Confusional state (n/a - Unknown -), Hypertension (n/a - Fatal - Results in Death), Malaise (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - Prophylaxis - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Prophylaxis - n/a - [n/a - n/a - n/a]), [DILTIAZEM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - Hypertension - n/a - [n/a - n/a - n/a])

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EU-EC-10007725730	565	25.02.2021	65-85 Years	Not Specified	Male	Atrial fibrillation (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007725846	566	25.02.2021	More than 85 Years	Not Specified	Female	Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Influenza like illness (6d - Recovered/Resolved -), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007726397	567	25.02.2021	65-85 Years	Elderly	Female	General physical health deterioration (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular - More in ICSR])	[LACTULOSE] (C - n/a - Not applicable -), [PARACETAMOL] (C - n/a - Not applicable - [n/a - 500mg - Oral]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - n/a - Not applicable - [n/a - 50mg - n/a])
EU-EC-10007703160	568	24.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown -), Fatigue (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ALISKIREN 300MG TABLET (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007703165	569	24.02.2021	More than 85 Years	Not Specified	Female	Loss of consciousness (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CETOMACROGOL 1000] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [VASELINE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007706278	570	24.02.2021	More than 85 Years	Not Specified	Female	Dyspnoea (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007706280	571	24.02.2021	18-64 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007706282	572	24.02.2021	65-85 Years	Not Specified	Female	C-reactive protein increased (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Red blood cell sedimentation rate increased (n/a - Fatal - Results in Death), Respiratory rate increased (n/a - Fatal - Results in Death), Wheezing (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported

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EU-EC-10007706284	573	24.02.2021	65-85 Years	Elderly	Female	General physical health deterioration (15d - Fatal - Results in Death), Pyrexia (15d - Fatal - Results in Death), Upper respiratory tract infection (15d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007706343	574	24.02.2021	65-85 Years	Elderly	Female	Asthenia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007706344	575	24.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007706729	576	24.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007706796	577	24.02.2021	More than 85 Years	Not Specified	Female	Cerebrovascular accident (n/a - Fatal - Results in Death), Pain (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Somnolence (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007706851	578	24.02.2021	More than 85 Years	Not Specified	Female	Cardiac failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007706926	579	24.02.2021	18-64 Years	Not Specified	Male	Abdominal pain (n/a - Unknown -), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown -), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007706971	580	24.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007707211	581	24.02.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007708490	582	24.02.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007708562	583	24.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007708715	584	24.02.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007708779	585	24.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007708780	586	24.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007709311	587	24.02.2021	More than 85 Years	Elderly	Female	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007709317	588	24.02.2021	More than 85 Years	Elderly	Female	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007709323	589	24.02.2021	More than 85 Years	Elderly	Male	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007709425	590	24.02.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007709426	591	24.02.2021	More than 85 Years	Elderly	Female	General physical condition abnormal (n/a - Fatal - Results in Death, Life Threatening), Pneumonia (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007709427	592	24.02.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007709493	593	24.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007709494	594	24.02.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007709800	595	24.02.2021	More than 85 Years	Elderly	Female	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007710096	596	24.02.2021	More than 85 Years	Elderly	Female	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007710551	597	24.02.2021	More than 85 Years	Elderly	Female	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007710733	598	24.02.2021	More than 85 Years	Not Specified	Female	C-reactive protein increased (7d - Fatal - Results in Death), Secretion discharge (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007711469	599	24.02.2021	More than 85 Years	Not Specified	Male	Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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EU-EC-10007711478	600	24.02.2021	More than 85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	[CARBOMER] (C - n/a - n/a - [n/a - n/a - Intraocular]), [CLOMETHIAZOLE, CLOMETHIAZOLE EDISILATE] (C - n/a - n/a - [n/a - 5mL - n/a]), [FLUCLOXACILLIN] (C - n/a - n/a - [n/a - 10mL - n/a]), [GLYCEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [MACROGOL, MACROGOL 4000] (C - n/a - n/a - [n/a - 10g - n/a]), [MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Subcutaneous]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007711838	601	24.02.2021	More than 85 Years	Not Specified	Female	Aortic aneurysm rupture (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular])	BIMATOPROST [BIMATOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [BUPRENORPHINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a]), [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - 75mg - n/a]), [FELODIPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCORTISONE ACETATE, LIDOCAINE, LIDOCAINE, HYDROCORTISONE ACETATE PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [MACROGOL 4000] (C - n/a - n/a - [n/a - 1[DF] - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a])
EU-EC-10007711855	602	24.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	TRIMBOW [BECLOMETASONE DIPROPIONATE, GLYCOPYRRONIUM BROMIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLCYSTEINE] (C - n/a - n/a - [n/a - 200mg - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007713205	603	24.02.2021	65-85 Years	Not Specified	Male	Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - 10mg - n/a]), [ATORVASTATIN CALCIUM] (C - Blood cholesterol increased - n/a - [n/a - 10mg - n/a]), [DONEPEZIL] (C - n/a - n/a - [n/a - 10mg - n/a - More in ICSR]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMINE] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007713444	604	24.02.2021	65-85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death, Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), SILDENAFIL [SILDENAFIL] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [UMECLIDINIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [VILANTEROL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007713454	605	24.02.2021	65-85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening), Chest pain (n/a - Not Recovered/Not Resolved - Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	BUMETANIDE [BUMETANIDE] (C - Polyuria - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - Blood cholesterol - n/a - [n/a - n/a - n/a]), [TIOTROPIUM, OLODATEROL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007713584	606	24.02.2021	More than 85 Years	Not Specified	Female	Acute respiratory distress syndrome (n/a - Fatal - Results in Death), SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Cardiovascular event prophylaxis - Drug withdrawn - [n/a - 1{DF} - Oral]), [AMLODIPINE, AMLODIPINE BESILATE] (S - Hypertension - Drug withdrawn - [n/a - 1{DF} - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (S - Dyslipidaemia - Drug withdrawn - [n/a - 1{DF} - Oral]), [COLECALCIFEROL] (S - Prophylaxis - Unknown - [n/a - n/a - Oral]), [RAMIPRIL] (S - Hypertension - Drug withdrawn - [n/a - 1{DF} - Oral])	Not reported
EU-EC-10007713710	607	24.02.2021	18-64 Years	Not Specified	Not Specified	Asthenia (n/a - Fatal - Results in Death), Chest pain (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Syncope (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007693238	608	23.02.2021	65-85 Years	Not Specified	Not Specified	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007693621	609	23.02.2021	More than 85 Years	Not Specified	Female	Decreased appetite (n/a - Unknown - Life Threatening, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), General physical health deterioration (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Lower respiratory tract infection (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007693624	610	23.02.2021	More than 85 Years	Not Specified	Female	Cerebral infarction (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Unknown -), Hemiplegia (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown -), Weight decreased (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007693631	611	23.02.2021	More than 85 Years	Not Specified	Male	Asthenia (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Gastrointestinal disorder (1d - Recovered/Resolved -), Malaise (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007693772	612	23.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	EBIXA [MEMANTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - n/a - Oral]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [ISOSORBIDE DINITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral])

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EU-EC-10007693773	613	23.02.2021	65-85 Years	Elderly	Male	Pneumonia (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - n/a - Oral]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - Oral]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - Oral]), [CLONAZEPAM] (C - n/a - n/a - [n/a - n/a - Oral]), [DIGOXIN] (C - n/a - n/a - [n/a - n/a - Oral]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [ORPHENADRINE CITRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [PANTOPRAZOLE] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral]), [SODIUM VALPROATE, VALPROIC ACID, SODIUM VALPROATE] (C - n/a - n/a - [n/a - n/a - Oral]), [TIZANIDINE, TIZANIDINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-10007693777	614	23.02.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007694075	615	23.02.2021	More than 85 Years	Not Specified	Not Specified	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007694081	616	23.02.2021	65-85 Years	Not Specified	Not Specified	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007694613	617	23.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007694638	618	23.02.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	PREGABALIN [PREGABALIN] (C - n/a - n/a - [n/a - 75mg - n/a]), [ACETYSALICYLIC ACID, ACETYSALICYLIC ACID PH. EUR.] (C - n/a - n/a - [n/a - 100mg - n/a]), [CEFALOXIN] (C - n/a - n/a - [n/a - 600mg - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 5mg - n/a]), [KHELLIN] (C - n/a - n/a - [n/a - n/a - n/a]), [METAMIZOLE, METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - 500mg - n/a])
EU-EC-10007694640	619	23.02.2021	65-85 Years	Not Specified	Female	Parkinson's disease (n/a - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007695539	620	23.02.2021	Not Specified	Elderly	Female	Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007696434	621	23.02.2021	More than 85 Years	Not Specified	Female	Cerebrovascular accident (1d - Fatal - Results in Death), Loss of consciousness (1d - Fatal - Results in Death), Tachycardia (1d - Fatal - Results in Death), Tachypnoea (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007696437	622	23.02.2021	More than 85 Years	Not Specified	Female	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - Osteoporosis - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE HYDROCHLORIDE] (C - Hypovitaminosis n/a - [n/a - n/a - Oral]), [METOPROLOL, METOPROLOL TARTRATE] (C - Cardiac disorder - n/a -), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a -), [PARACETAMOL] (C - Arthralgia - n/a -), [PREDNISOLONE] (C - Rheumatoid arthritis - n/a -)
EU-EC-10007696780	623	23.02.2021	65-85 Years	Not Specified	Male	General physical health deterioration (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007696925	624	23.02.2021	More than 85 Years	Not Specified	Male	Dyspnoea (1mo - Fatal - Results in Death), General physical health deterioration (13d - Fatal - Results in Death), Lethargy (13d - Fatal - Results in Death), Pneumonia (1mo - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[PHENOXYMETHYLPENICILLIN, PHENOXYMETHYLPENICILLIN POTASSIUM] (C - Pneumonia - n/a - [n/a - n/a - Oral])
EU-EC-10007697106	625	23.02.2021	More than 85 Years	Elderly	Female	Cardiac failure congestive (n/a - Fatal - Results in Death), Electrolyte imbalance (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007697182	626	23.02.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardiac failure (n/a - Fatal - Results in Death), Cardiopulmonary failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Cough (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	JANUVIA [SITAGLIPTIN, SITAGLIPTIN PHOSPHATE, SITAGLIPTIN PHOSPHATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), LIXIANA [EDOXABAN, EDOXABAN TOSYLATE] (C - n/a - n/a - [n/a - n/a - n/a]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE, BECLOMETASONE PROPIONATE, FORMOTEROL FUMARATE HYDRATE, FORMOTEROL FUMARATE DIHYDRATE PH.EUR., BECLOMETASONE DIPROPIONATE PH. EUR., FORMOTEROL FUMARATE DIHYDRATE PH.EUR., BECLOMETASONE DIPROPIONATE PH. EUR., FORMOTEROL FUMARATE DIHYDRATE, BECLOMETASONE DIPROPIONATE ANHYDROUS] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [METAMIZOLE, METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OLMESARTAN, OLMESARTAN MEDOXOMIL] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007697263	627	23.02.2021	More than 85 Years	Not Specified	Female	Pneumonia (7d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007697379	628	23.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007697435	629	23.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007697512	630	23.02.2021	More than 85 Years	Elderly	Male	Circulatory collapse (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007697790	631	23.02.2021	More than 85 Years	Not Specified	Female	C-reactive protein increased (n/a - Recovering/Resolving -), Chronic obstructive pulmonary disease (n/a - Fatal - Results in Death), Pyrexia (n/a - Recovering/Resolving -), Somnolence (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - Atrial fibrillation - n/a - [n/a - 2.5mg - n/a]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 20mg - n/a]), [BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE DIHYDRATE, BECLOMETASONE DIPROPIONATE ANHYDROUS] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [BISACODYL] (C - n/a - n/a - [n/a - 10mg - n/a]), [BUMETANIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - 1mL - n/a]), [NALOXONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE, NALOXONE, OXYCODONE, OXYCODONE HYDROCHLORIDE, NALOXONE, OXYCODONE HYDROCHLORIDE, NALOXONE HYDROCHLORIDE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - 5mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - 2.5mL - n/a]), [SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - 15{DF} - n/a]), [ZOPICLONE] (C - n/a - n/a -)
EU-EC-10007698215	632	23.02.2021	More than 85 Years	Elderly	Female	Acute respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardio-respiratory arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a -), [AMLODIPINE BESILATE, PERINDOPRIL ARGININE] (C - n/a - n/a -), [ETHYLENEDIAMINE, THEOPHYLLINE, THEOPHYLLINE] (C - n/a - n/a -), [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM, OMEPRAZOLE SODIUM] (C - n/a - n/a -), [THIAMAZOLE] (C - n/a - n/a -), [URAPIDIL, URAPIDIL HYDROCHLORIDE] (C - n/a - n/a -)
EU-EC-10007698501	633	23.02.2021	More than 85 Years	Not Specified	Female	Syncope (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	XARELTO [RIVAROXABAN] (C - Atrial fibrillation - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [MESALAZINE] (C - Crohn's disease - n/a - [n/a - 500mg - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007698831	634	23.02.2021	65-85 Years	Not Specified	Not Specified	COVID-19 (n/a - Fatal - Results in Death), Necrosis (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown -), Wound (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007699430	635	23.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FOLIC ACID] (C - n/a - Not applicable - [n/a - n/a - n/a]), [METHOTREXATE, METHOTREXATE DISODIUM, METHOTREXATE SODIUM] (C - Gouty arthritis - Not applicable - [n/a - n/a - n/a]), [PREDNISONE] (C - n/a - Not applicable - [n/a - n/a - n/a])
EU-EC-10007699705	636	23.02.2021	More than 85 Years	Not Specified	Female	Aphasia (n/a - Fatal - Results in Death), Blood pressure systolic increased (n/a - Unknown -), Cerebrovascular accident (n/a - Fatal - Results in Death), Coma scale abnormal (n/a - Unknown - Other Medically Important Condition), Contusion (n/a - Unknown -), Fall (n/a - Fatal - Results in Death), Hemiplegia (n/a - Fatal - Results in Death), Somnolence (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	LUMIGAN [BIMATOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - 20mg - Oral]), [BISOPROLOL FUMARATE, BISOPROLOL FUMARATE, ACETYLSALICYLIC ACID, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MAGNESIUM CITRATE, MAGNESIUM OXIDE] (C - n/a - n/a - [n/a - 300mg - n/a]), [MEMANTINE HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 20mg - Oral]), [PARACETAMOL, PARACETAMOL, CODEINE PHOSPHATE HEMIHYDRATE] (C - n/a - n/a - [n/a - 3g - n/a]), [QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - 3g - n/a]), [ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - 10mg - Oral])
EU-EC-10007700282	637	23.02.2021	18-64 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007700853	638	23.02.2021	18-64 Years	Not Specified	Male	Atelectasis (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007700922	639	23.02.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown - Results in Death), Fatigue (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[DONEPEZIL, DONEPEZIL HYDROCHLORIDE] (C - Dementia Alzheimer's type - n/a - [n/a - 10mg - Oral]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 25mg - Oral])
EU-EC-10007681463	640	22.02.2021	65-85 Years	Not Specified	Male	Atrial fibrillation (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	APIXABAN [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [METRONIDAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007681560	641	22.02.2021	More than 85 Years	Not Specified	Female	Dyspnoea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	[ENOXAPARIN SODIUM] (C - n/a - n/a - [4mo - 4000mg - Subcutaneous]), [FERROUS GLUCONATE, FERROUS ION] (C - n/a - n/a - [107d - 80mg - Oral]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [87d - 500mg - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Intravenous (not otherwise specified)]), [PROMAZINE HYDROCHLORIDE] (C - n/a - n/a - [4mo - n/a - Oral]), [TIMOLOL, TIMOLOL MALEATE] (C - n/a - n/a - [n/a - n/a - Ophthalmic])

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EU-EC-10007681970	642	22.02.2021	18-64 Years	Not Specified	Male	Dyspnoea (n/a - Unknown -), Heart rate increased (n/a - Unknown -), Myocarditis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007683100	643	22.02.2021	More than 85 Years	Elderly	Female	Cardiac death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - n/a])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - Unknown -), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - Unknown -)
EU-EC-10007683514	644	22.02.2021	More than 85 Years	Not Specified	Female	Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007683526	645	22.02.2021	Not Specified	Not Specified	Male	Death (n/a - Fatal - Results in Death), Sepsis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007684362	646	22.02.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Unknown -), Pneumonia (n/a - Fatal - Results in Death, Life Threatening), Respiratory failure (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007684469	647	22.02.2021	18-64 Years	Not Specified	Female	Sepsis (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007684475	648	22.02.2021	More than 85 Years	Not Specified	Female	Cerebral infarction (n/a - Fatal - Results in Death, Other Medically Important Condition), Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007684953	649	22.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007685320	650	22.02.2021	More than 85 Years	Not Specified	Female	Nasopharyngitis (6d - Fatal - Results in Death), Upper respiratory tract infection (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007685425	651	22.02.2021	More than 85 Years	Not Specified	Male	Malaise (2d - Fatal - Results in Death), Nausea (2d - Fatal - Results in Death), Vomiting (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular - More in ICSR])	[CODEINE PHOSPHATE SESQUIHYDRATE, PARACETAMOL, PARACETAMOL, CODEINE PHOSPHATE] (C - Pain - n/a - [n/a - 400mg - Oral]), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [n/a - 800[iU] - Oral]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - 500mg - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - Pain - n/a - [n/a - 500mg - Oral]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - Oral]), [SULFAMETHOXAZOLE, TRIMETHOPRIM] (C - Urinary tract infection - n/a - [n/a - 800mg - Oral]), [WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BP] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-10007685708	652	22.02.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007685843	653	22.02.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007686436	654	22.02.2021	More than 85 Years	Elderly	Male	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007686787	655	22.02.2021	More than 85 Years	Not Specified	Male	Loss of consciousness (58min - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	NOT AVAILABLE (C - n/a - n/a - [n/a - 7.5mg - Oral]), NOT AVAILABLE (C - n/a - n/a - [n/a - 850mg - Oral]), PREGABALIN 25 MG [PREGABALIN] (C - n/a - n/a - [n/a - 50mg - Oral]), SILODOSIN [SILODOSIN] (C - n/a - n/a - [n/a - 8mg - Oral]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - Oral]), [CALCIUM CARBONATE, CHOLECALCIFEROL CONCENTRATE (POWDER FORM), COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [FOLIC ACID] (C - n/a - n/a - [n/a - 5mg - Oral]), [LOSARTAN POTASSIUM, HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [MAGNESIUM L-ASPARTATE HYDROCHLORIDE TRIHYDRATE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - Oral])
EU-EC-10007686964	656	22.02.2021	More than 85 Years	Not Specified	Not Specified	Acute myocardial infarction (n/a - Fatal - Results in Death), Bradyarrhythmia (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Fatal - Results in Death), Cardiogenic shock (n/a - Fatal - Results in Death), Hypotonic-hyporesponsive episode (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported

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EU-EC-10007687662	657	22.02.2021	65-85 Years	Not Specified	Female	Aspiration (n/a - Fatal - Results in Death), Diarrhoea (n/a - Not Recovered/Not Resolved -), Hypotension (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007687666	658	22.02.2021	18-64 Years	Not Specified	Female	Angina pectoris (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Pulmonary embolism (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007687672	659	22.02.2021	More than 85 Years	Not Specified	Female	Acute kidney injury (n/a - Recovered/Resolved - Other Medically Important Condition), COVID-19 (n/a - Fatal - Results in Death), Confusional state (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - Results in Death), Encephalopathy (n/a - Fatal - Results in Death, Other Medically Important Condition), Hallucination (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myoclonus (n/a - Fatal - Results in Death), Seizure (n/a - Fatal - Results in Death, Other Medically Important Condition), Tremor (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	EDOXABAN [EDOXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [FAMOTIDINE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007687682	660	22.02.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death), COVID-19 pneumonia (n/a - Fatal - Results in Death), Drug ineffective (n/a - Fatal - Results in Death), Sepsis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007687684	661	22.02.2021	18-64 Years	Not Specified	Female	COVID-19 (n/a - Unknown - Life Threatening, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening), Drug ineffective (n/a - Unknown - Life Threatening, Other Medically Important Condition), Malaise (n/a - Recovered/Resolved - Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	OLANZAPINE [OLANZAPINE] (C - Behaviour disorder - n/a - [n/a - n/a - n/a]), PREGABALIN [PREGABALIN] (C - Behaviour disorder - n/a - [n/a - n/a - n/a]), [CARBAMAZEPINE, CARBAMAZEPINE (PH. EUR.)] (C - Behaviour disorder - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Depressed mood - n/a - [n/a - n/a - n/a])
EU-EC-10007687861	662	22.02.2021	Not Specified	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007687863	663	22.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ATORVASTATIN] (C - Hypercholesterolaemia - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM CARBONATE] (C - Osteopenia - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Dyspepsia - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - Hypertension - n/a - [n/a - n/a - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007688255	664	22.02.2021	65-85 Years	Not Specified	Male	Fatigue (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Hypophagia (n/a - Fatal - Results in Death), Myalgia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007688608	665	22.02.2021	18-64 Years	Not Specified	Male	COVID-19 (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Hangover (n/a - Unknown -), Headache (n/a - Unknown -), Inflammation (n/a - Fatal - Results in Death), Pain (n/a - Unknown -), Pericardial disease (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown -), Sepsis (n/a - Fatal - Results in Death), Systemic inflammatory response syndrome (n/a - Fatal - Results in Death), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported
EU-EC-10007689504	666	22.02.2021	More than 85 Years	Not Specified	Female	Coma (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Disturbance in attention (n/a - Fatal - Results in Death), Peripheral vascular disorder (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), ENTRESTO [VALSARTAN, SACUBITRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007690292	667	22.02.2021	65-85 Years	Not Specified	Male	Cerebral haemorrhage (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	APIXABAN 5MG TABLET (S - Atrial flutter - Unknown - [n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [DICLOFENAC DIETHYLAMINE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [NORTRIPTYLINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007690294	668	22.02.2021	More than 85 Years	Not Specified	Female	Intestinal ischaemia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	JANUVIA 100 MG FILM-COATED TABLETS [SITAGLIPTIN] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE MONONITRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007691196	669	22.02.2021	More than 85 Years	Not Specified	Male	Pneumonia aspiration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown -), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [NOT AVAILABLE] (S - Hallucination - Dose reduced - [n/a - 2{DF} - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007676007	670	20.02.2021	More than 85 Years	Not Specified	Female	Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	HUMALOG 100 U/ML, SOLUTION FOR INJECTION IN VIAL [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]), LANTUS [INSULIN GLARGINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLECAINIDE ACETATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [SENNA GLYCOSIDES STANDARDIZED 60%, SENNOSIDE A+B] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007676917	671	20.02.2021	65-85 Years	Not Specified	Male	Jaundice (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007677192	672	20.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007677199	673	20.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007677265	674	20.02.2021	65-85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007677322	675	20.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (18d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007677384	676	20.02.2021	65-85 Years	Not Specified	Male	Road traffic accident (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	[LERCANIDIPINE HYDROCHLORIDE] (C - Hypertension - Not applicable - [n/a - 1{DF} - Oral])
EU-EC-10007677558	677	20.02.2021	More than 85 Years	Not Specified	Not Specified	Coronavirus infection (n/a - Fatal - Results in Death), Dysphagia (n/a - Unknown -), SARS-CoV-2 test positive (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007677562	678	20.02.2021	More than 85 Years	Not Specified	Not Specified	Coronavirus infection (n/a - Fatal - Results in Death), Dysphagia (n/a - Unknown -), SARS-CoV-2 test positive (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007677567	679	20.02.2021	More than 85 Years	Not Specified	Not Specified	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007677568	680	20.02.2021	More than 85 Years	Not Specified	Not Specified	Coronavirus infection (n/a - Fatal - Results in Death), Dysphagia (n/a - Unknown -), SARS-CoV-2 test positive (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007677575	681	20.02.2021	More than 85 Years	Not Specified	Female	Asthenia (n/a - Fatal - Results in Death), Dehydration (n/a - Fatal - Results in Death), Tooth abscess (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007677580	682	20.02.2021	More than 85 Years	Not Specified	Female	Atrial fibrillation (n/a - Fatal - Results in Death), Tachycardia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007677789	683	20.02.2021	More than 85 Years	Not Specified	Female	Diarrhoea (n/a - Recovering/Resolving - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Pyrexia (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[CEFTRIAXONE] (C - n/a - n/a - [n/a - 1{DF} - Intravenous (not otherwise specified)]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - Oral])
EU-EC-10007677806	684	20.02.2021	65-85 Years	Not Specified	Male	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[CODEINE] (C - n/a - n/a - [n/a - n/a - Oral]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - Oral]), [GABAPENTIN] (C - n/a - n/a - [n/a - n/a - Oral]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - Oral]), [LOXAPINE] (C - n/a - n/a - [n/a - n/a - Oral]), [MACROGOL 3350, POTASSIUM CHLORIDE, SODIUM CARBONATE, SODIUM CHLORIDE, SODIUM SULFATE ANHYDROUS, MACROGOL 3350, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350, SODIUM SULPHATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, SODIUM SULFATE ANHYDROUS, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - Oral]), [MIANSERIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral]), [TETRABENAZINE] (C - n/a - n/a - [n/a - n/a - Oral]), [TROSPIUM, TROSPIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-10007677877	685	20.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007679410	686	20.02.2021	18-64 Years	Not Specified	Male	Aspiration (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Epilepsy (n/a - Fatal - Results in Death), Seizure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007662144	687	19.02.2021	More than 85 Years	Not Specified	Female	Myalgia (5d - Fatal - Results in Death), Regurgitation (5d - Fatal - Results in Death), Somnolence (5d - Fatal - Results in Death), Vomiting (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	ELIQUIS 2.5 MG FILM-COATED TABLETS [APIXABAN] (C - n/a - n/a - [n/a - 5mg - n/a]), [ALENDRONATE SODIUM] (C - n/a - n/a - [n/a - 70mg - n/a]), [BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, SPIRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 20mg - n/a]), [PARACETAMOL, CODEINE PHOSPHATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PAROXETINE, PAROXETINE HYDROCHLORIDE HEMIHYDRATE, PAROXETINE HYDROCHLORIDE, ANHYDROUS] (C - n/a - n/a - [n/a - 20mg - n/a]), [VALSARTAN] (C - n/a - n/a - [n/a - 40mg - n/a])
EU-EC-10007662946	688	19.02.2021	More than 85 Years	Not Specified	Female	Cerebral haemorrhage (5d - Fatal - Results in Death), Facial paralysis (5d - Fatal - Results in Death), Monoplegia (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007663700	689	19.02.2021	65-85 Years	Not Specified	Male	Anaemia (n/a - Not Recovered/Not Resolved - Results in Death), Asthenia (n/a - Not Recovered/Not Resolved - Results in Death), Atrial fibrillation (n/a - Unknown - Results in Death), Atrioventricular block (n/a - Not Recovered/Not Resolved - Results in Death), Bradycardia (n/a - Not Recovered/Not Resolved - Results in Death), Cardiac arrest (n/a - Recovered/Resolved With Sequelae - Results in Death), Diplopia (n/a - Not Recovered/Not Resolved - Results in Death), Dysarthria (n/a - Not Recovered/Not Resolved - Results in Death), Hypothermia (n/a - Not Recovered/Not Resolved - Results in Death), Myalgia (n/a - Unknown - Results in Death), Nervous system disorder (n/a - Fatal - Results in Death), Parkinsonism (n/a - Fatal - Results in Death), Pneumonia aspiration (n/a - Fatal - Results in Death), Thrombocytopenia (19d - Recovered/Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	LUMIGAN [BIMATOPROST] (C - n/a - Unknown - [n/a - 1{drp} - Ophthalmic]), [ALFUZOSIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1{DF} - Oral]), [BROMAZEPAM] (C - Anxiety - Unknown - [n/a - 1{DF} - Oral]), [PRAVASTATIN SODIUM] (C - n/a - Unknown - [n/a - 1{DF} - Oral]), [TRIMEBUTINE MALEATE] (C - Product used for unknown indication - Drug withdrawn - [n/a - 200mg - Oral])
EU-EC-10007663756	690	19.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007663762	691	19.02.2021	More than 85 Years	Not Specified	Female	Cardio-respiratory arrest (1d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007663811	692	19.02.2021	More than 85 Years	Not Specified	Male	Hyperthermia (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported
EU-EC-10007663965	693	19.02.2021	More than 85 Years	Not Specified	Female	Acute respiratory failure (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007664183	694	19.02.2021	More than 85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [BENZBROMARONE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASON PROPRIONATE, SALMETEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [IPRATROPIUM BROMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TIOTROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007664199	695	19.02.2021	65-85 Years	Not Specified	Male	Cardiac death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007664219	696	19.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007664237	697	19.02.2021	Not Specified	Elderly	Female	Fatigue (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [FENTANYL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007664248	698	19.02.2021	More than 85 Years	Not Specified	Female	Dyspnoea (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Injection site pain (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Myalgia (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007664283	699	19.02.2021	More than 85 Years	Not Specified	Female	Nausea (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [NOT AVAILABLE] (S - Pain - Drug withdrawn - [n/a - 5mg - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [MACROGOL, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007664355	700	19.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]), [OXAZEPAM] (S - Anxiety - Not applicable - [n/a - 10mg - Oral])	Not reported
EU-EC-10007664703	701	19.02.2021	18-64 Years	Not Specified	Female	Headache (n/a - Unknown - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]), [DICLOFENAC DIETHYLAMINE, DICLOFENAC SODIUM] (S - Arthralgia - n/a - [n/a - n/a - Cutaneous]), [NAPROXEN SODIUM, NAPROXEN SODIUM ANHYDROUS] (S - Arthralgia - n/a - [n/a - 550mg - Oral])	[ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PRAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007664712	702	19.02.2021	More than 85 Years	Not Specified	Female	Asthenia (n/a - Not Recovered/Not Resolved - Results in Death), Respiratory distress (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	JANUVIA [SITAGLIPTIN, SITAGLIPTIN PHOSPHATE, SITAGLIPTIN PHOSPHATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROXYZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [INSULIN, INSULIN HUMAN] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [PAROXETINE, PAROXETINE HYDROCHLORIDE HEMIHYDRATE, PAROXETINE HYDROCHLORIDE, ANHYDROUS] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007664843	703	19.02.2021	More than 85 Years	Not Specified	Female	Haemorrhagic stroke (3d - Fatal - Results in Death), Hypertension (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007664853	704	19.02.2021	More than 85 Years	Not Specified	Female	Pulmonary oedema (1d - Fatal - Results in Death), Tachycardia (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007664863	705	19.02.2021	More than 85 Years	Not Specified	Female	Pneumonia aspiration (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007664883	706	19.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Life Threatening), Rectal haemorrhage (n/a - Unknown - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007665013	707	19.02.2021	More than 85 Years	Not Specified	Female	Hypotension (1h - Recovered/Resolved - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007665017	708	19.02.2021	More than 85 Years	Not Specified	Female	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[ESCITALOPRAM] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007665048	709	19.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007665169	710	19.02.2021	65-85 Years	Not Specified	Male	Near death experience (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007665187	711	19.02.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007665215	712	19.02.2021	More than 85 Years	Not Specified	Male	Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007665353	713	19.02.2021	65-85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007665651	714	19.02.2021	More than 85 Years	Not Specified	Not Specified	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007665991	715	19.02.2021	More than 85 Years	Not Specified	Female	Pyrexia (0d - Fatal - Results in Death), Respiratory arrest (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 25mg - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - 30mg - n/a]), [OXYCODONE HYDROCHLORIDE, PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007666171	716	19.02.2021	More than 85 Years	Elderly	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	APIXABAN [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), LEVODOPA [LEVODOPA] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LERCANIDIPINE, LERCANIDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MOXONIDINE] (C - n/a - n/a - [n/a - n/a - n/a]), [PRAMIPEXOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007666201	717	19.02.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [23d - n/a - Intramuscular])	[FUROSEMIDE] (C - Cardiac failure - n/a - [10d - n/a - Intravenous (not otherwise specified)])
EU-EC-10007666223	718	19.02.2021	65-85 Years	Elderly	Female	Abdominal pain (4d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pancreatitis acute (4d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Personality change (n/a - Unknown - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Systemic inflammatory response syndrome (4d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	APIXABAN [APIXABAN] (C - Atrial fibrillation - n/a - [n/a - 5mg - Oral]), [DIGITOXIN] (C - Atrial fibrillation - n/a - [n/a - .07mg - Oral]), [METOPROLOL, METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 47.5mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 40mg - Oral]), [RAMIPRIL] (C - Hypertension - n/a - [n/a - 10mg - Oral])
EU-EC-10007666273	719	19.02.2021	65-85 Years	Elderly	Male	Dyspnoea (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007666274	720	19.02.2021	More than 85 Years	Elderly	Female	Fatigue (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	MOVENTIG [NALOXEGOL, NALOXEGOL OXALATE] (C - n/a - n/a - [n/a - n/a - Oral]), [CARBOMER, CARBOMER 980] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [SODIUM PICOFOSFATE, SODIUM PICOSULFATE, SODIUM PICOSULFATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-10007666828	721	19.02.2021	18-64 Years	Not Specified	Male	Aspiration (n/a - Fatal - Results in Death), Epilepsy (n/a - Fatal - Results in Death), Seizure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007666983	722	19.02.2021	18-64 Years	Adult	Female	Acute myocardial infarction (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007667014	723	19.02.2021	65-85 Years	Elderly	Female	Acute coronary syndrome (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007667294	724	19.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007667405	725	19.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007667553	726	19.02.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007668316	727	19.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007668383	728	19.02.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007668406	729	19.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007668458	730	19.02.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007668519	731	19.02.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007668628	732	19.02.2021	65-85 Years	Elderly	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007669009	733	19.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007669064	734	19.02.2021	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported

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EU-EC-10007669068	735	19.02.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007669096	736	19.02.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007669170	737	19.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007669247	738	19.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007669294	739	19.02.2021	65-85 Years	Not Specified	Female	Cerebral haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Urinary incontinence (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007669325	740	19.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007669361	741	19.02.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007670320	742	19.02.2021	65-85 Years	Not Specified	Male	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007671073	743	19.02.2021	More than 85 Years	Not Specified	Not Specified	COVID-19 (n/a - Unknown -), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007671176	744	19.02.2021	More than 85 Years	Not Specified	Not Specified	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007675025	745	19.02.2021	More than 85 Years	Not Specified	Female	Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DF) - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007650489	746	18.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007650704	747	18.02.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Heart rate decreased (n/a - Unknown -), Peripheral coldness (n/a - Unknown -), Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [FENTANYL] (S - Pain - Dose not changed - [n/a - 1{DF} - n/a])	EXFORGE 5 MG/80 MG FILM-COATED TABLETS [VALSARTAN, AMLODIPINE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [ALUMINIUM OXIDE, MAGNESIUM HYDROXIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FENTANYL, FENTANYL CITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARAFFIN] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMINE HYDROCHLORIDE, DEXPANTHENOL, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [VASELINE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007650719	748	18.02.2021	Not Specified	Adult	Female	Basilar artery thrombosis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	LEVETIRACETAM [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CARBAMAZEPINE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007650721	749	18.02.2021	More than 85 Years	Not Specified	Female	Chills (n/a - Fatal - Results in Death), Cystitis (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Hepatic failure (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007650747	750	18.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	XEPLION [PALIPERIDONE PALMITATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007650771	751	18.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - .5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1000mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1000ug - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 25mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 40mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 5600{IU} - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 75mg - n/a]), [CALCIUM CARBONATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [MAGNESIUM CARBONATE HYDROXIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007651225	752	18.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Hypertension - n/a - [n/a - 1.25mg - Oral - More in ICSR]), [BUPRENORPHINE] (C - Back pain - n/a - [n/a - n/a - Transdermal]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Hypertension - n/a - [600d - n/a - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - Pain - n/a - [n/a - 1g - Oral]), [QUETIAPINE] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-10007651246	753	18.02.2021	More than 85 Years	Not Specified	Male	Influenza like illness (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007651431	754	18.02.2021	65-85 Years	Not Specified	Male	Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	NOT AVAILABLE (C - n/a - Unknown - [n/a - n/a - n/a]), [BENSERAZIDE, LEVODOPA] (C - n/a - Unknown - [n/a - n/a - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [TRAZODONE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007651569	755	18.02.2021	65-85 Years	Not Specified	Female	Dyspnoea (0d - Fatal - Results in Death), General physical health deterioration (0d - Fatal - Results in Death), Oxygen saturation decreased (0d - Fatal - Results in Death), Pyrexia (0d - Fatal - Results in Death), Respiratory disorder (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	NOT AVAILABLE (C - n/a - Unknown - [n/a - 1{DF} - n/a]), NOT AVAILABLE (C - n/a - Unknown - [n/a - n/a - n/a]), XARELTO [RIVAROXABAN] (C - n/a - Unknown - [n/a - 15mg - n/a]), [AMLODIPINE, AMLODIPINE MALEATE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [ATORVASTATIN] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [PERINDOPRIL TERT-BUTYLAMINE] (C - n/a - Unknown - [n/a - 1{DF} - n/a])
EU-EC-10007651711	756	18.02.2021	More than 85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death), Fall (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007651717	757	18.02.2021	65-85 Years	Not Specified	Male	Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007651719	758	18.02.2021	65-85 Years	Not Specified	Male	Diarrhoea (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BENDROFLUMETHIAZIDE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [CARMELLOSE] (C - Dry eye - n/a - [n/a - n/a - n/a]), [CLOBETASONE BUTYRATE] (C - Eczema - n/a - [n/a - n/a - n/a]), [DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - Rosacea - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - Prostatism - n/a - [n/a - n/a - n/a])
EU-EC-10007651931	759	18.02.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007651961	760	18.02.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007652042	761	18.02.2021	More than 85 Years	Not Specified	Female	Agitation (n/a - Fatal - Results in Death), Depressed level of consciousness (n/a - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death), Sedation (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYSALICYLIC ACID] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE SODIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [BISOPROLOL FUMARATE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [METHYLPREDNISOLONE, METHYLPREDNISOLONE SODIUM SUCCINATE] (C - n/a - Unknown - [n/a - 1mg - n/a]), [RISPERIDONE] (C - n/a - Unknown - [n/a - .25{DF} - n/a])
EU-EC-10007652238	762	18.02.2021	More than 85 Years	Elderly	Male	COVID-19 (n/a - Fatal - Results in Death, Life Threatening), Cerebrovascular accident (n/a - Fatal - Results in Death, Life Threatening), Drug ineffective (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [1d - n/a - Intramuscular])	Not reported

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EU-EC-10007652574	763	18.02.2021	65-85 Years	Not Specified	Female	Acidosis (1d - Fatal - Results in Death), Chronic obstructive pulmonary disease (1d - Fatal - Results in Death), Cor pulmonale (1d - Fatal - Results in Death), Dyspnoea (1d - Fatal - Results in Death), Hyperkalaemia (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007653658	764	18.02.2021	More than 85 Years	Not Specified	Female	Infection (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007653727	765	18.02.2021	65-85 Years	Not Specified	Male	Coma (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Peripheral coldness (n/a - Fatal - Results in Death), Renal disorder (n/a - Fatal - Results in Death), Respiratory disorder (n/a - Fatal - Results in Death), Thrombocytopenia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	MIRCERA [METHOXY POLYETHYLENE GLYCOL-EPOETIN BETA] (C - n/a - Unknown - [n/a - 50ug - n/a]), NOT AVAILABLE (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [COLECALCIFEROL] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [CYANOCOBALAMIN, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [ENOXAPARIN SODIUM] (C - n/a - Unknown - [n/a - 2{DF} - n/a]), [FOLIC ACID] (C - n/a - Unknown - [n/a - n/a - n/a]), [LORMETAZEPAM] (C - n/a - Unknown - [n/a - 5{DF} - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [PARACETAMOL] (C - n/a - Unknown - [n/a - 1{DF} - n/a])
EU-EC-10007655887	766	18.02.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007656212	767	18.02.2021	65-85 Years	Not Specified	Male	Oxygen saturation decreased (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Sepsis (n/a - Fatal - Results in Death), Tachycardia (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - Atrial fibrillation - n/a - [n/a - 5mg - Oral])
EU-EC-10007656661	768	18.02.2021	18-64 Years	Adult	Male	Death (0d - Fatal - Results in Death), Fibromyalgia (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	PIOGLITAZONE [PIOGLITAZONE] (C - n/a - Unknown - [n/a - n/a - Oral]), [ALLOPURINOL] (C - n/a - Unknown - [n/a - n/a - Oral]), [AMITRIPTYLINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - Oral]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - Unknown - [n/a - n/a - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C n/a - Unknown - [n/a - n/a - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - Unknown - [n/a - n/a - Oral]), [CLONAZEPAM] (C - n/a - Unknown - [n/a - n/a - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - Unknown - [n/a - n/a - Oral])

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EU-EC-10007659003	769	18.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition), Shock (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007660689	770	18.02.2021	More than 85 Years	Elderly	Male	Acute respiratory distress syndrome (1d - Fatal - Results in Death), Depressed level of consciousness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007660769	771	18.02.2021	18-64 Years	Adult	Female	Sudden cardiac death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1{DF} - Intramuscular]), [RISPERIDONE] (S - Psychotic disorder - Not applicable - [6d - .5mg - Oral]), [RISPERIDONE] (S - Psychotic disorder - Not applicable - [n/a - 1mg - Oral])	BUPRENORPHINE [BUPRENORPHINE] (C - Pain - n/a - [n/a - 2{DF} - Transdermal]), [IBUPROFEN] (C - Pain - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - Nervousness - n/a - [n/a - n/a - Oral]), [OXAZEPAM] (C - Restlessness - n/a - [n/a - 7.5mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - n/a])
EU-EC-10007660858	772	18.02.2021	18-64 Years	Adult	Male	Dyspnoea (3d - Fatal - Results in Death), Oxygen saturation decreased (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007660971	773	18.02.2021	More than 85 Years	Elderly	Female	COVID-19 (8d - Fatal - Results in Death), Drug ineffective (8d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported
EU-EC-10007660975	774	18.02.2021	More than 85 Years	Elderly	Female	Confusional state (15d - Fatal - Results in Death), Partial seizures (15d - Fatal - Results in Death), Psychomotor hyperactivity (15d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - Drug withdrawn - [n/a - 5mg - Oral]), [ATORVASTATIN] (C - n/a - Drug withdrawn - [n/a - 20mg - Oral]), [PAROXETINE, PAROXETINE HYDROCHLORIDE HEMIHYDRATE, PAROXETINE HYDROCHLORIDE, ANHYDROUS] (C - n/a - Not applicable - [n/a - 20mg - Oral]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - Drug withdrawn - [n/a - 25mg - Oral]), [TAPENTADOL] (C - n/a - Drug withdrawn - [n/a - 50mg - Oral])
EU-EC-10007635483	775	17.02.2021	65-85 Years	Elderly	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[BROMAZEPAM] (C - Product used for unknown indication - n/a - [n/a - 3mg - n/a]), [INSULIN ASPART] (C - Type 2 diabetes mellitus - n/a - [n/a - n/a - Subcutaneous]), [TAMSULOSIN HYDROCHLORIDE, SOLIFENACIN SUCCINATE] (C - Benign prostatic hyperplasia - n/a - [n/a - 1{DF} - Oral]), [TIMOLOL MALEATE, LATANOPROST] (C - Conjunctivitis - n/a - [n/a - 1{DF} - Intraocular])

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EU-EC-10007637853	776	17.02.2021	More than 85 Years	Not Specified	Male	Death (1d - Fatal - Results in Death), Malaise (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	ABASAGLAR 100 UNITS/ML SOLUTION FOR INJECTION IN A CARTRIDGE [INSULIN GLARGINE] (C - Dementia - n/a - [n/a - 6[iU] - Subcutaneous]), [FLUINDIONE] (C - Arrhythmia - n/a - [n/a - n/a - Oral]), [FUROSEMIDE] (C - Cardiac failure - n/a - [n/a - 1{DF} - Oral]), [MACROGOL 4000] (C - Constipation - n/a - [n/a - 1{DF} - Oral]), [OMEPRAZOLE] (C - Gastric ulcer - n/a - [n/a - 1{DF} - Oral]), [PARACETAMOL] (C - Osteoarthritis - n/a - [n/a - 2{DF} - Oral]), [PAROXETINE] (C - Depression - n/a - [n/a - 1{DF} - Oral]), [RISPERIDONE] (C - Dementia - n/a - [n/a - .5mg - Oral])
EU-EC-10007637963	777	17.02.2021	More than 85 Years	Not Specified	Female	Cardiac failure (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007638483	778	17.02.2021	65-85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007638490	779	17.02.2021	More than 85 Years	Not Specified	Male	Cerebral haemorrhage (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 12mg - n/a])
EU-EC-10007638495	780	17.02.2021	65-85 Years	Not Specified	Male	Hyperpyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NON SPECIFIED BLOEDVERDUNNER [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007638529	781	17.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 1mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1{DF} - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [FLUTICASON PROPIONATE, SALMETEROL] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [IPRATROPIUM BROMIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - .4mg - n/a])
EU-EC-10007638964	782	17.02.2021	65-85 Years	Not Specified	Female	Headache (n/a - Unknown - Life Threatening), Malaise (n/a - Unknown - Life Threatening), Sudden death (n/a - Fatal - Results in Death, Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	ENTACAPONE [ENTACAPONE] (C - n/a - n/a - [n/a - n/a - n/a]), RASAGILINE [RASAGILINE, RASAGILINE TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BENSERAZIDE HYDROCHLORIDE, LEVODOPA, BENSERAZIDE, LEVODOPA] (C - n/a - n/a - [n/a - n/a - n/a]), [BEZAFIBRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FERROUS FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007638966	783	17.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYSALICYLIC ACID] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [BENDROFLUMETHIAZIDE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a])

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EU-EC-10007639044	784	17.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007639370	785	17.02.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	APIXABAN [APIXABAN] (C - n/a - n/a - [n/a - 2.5mg - Oral]), FENTANYL [FENTANYL, FENTANYL CITRATE] (C - n/a - n/a - [n/a - .4mg - Transdermal]), PREGABALIN [PREGABALIN] (C - n/a - n/a - [n/a - 150mg - Oral]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - Oral]), [METAMIZOLE, METAMIZOLE MAGNESIUM, METAMIZOLE SODIUM] (C - n/a - n/a - [n/a - 500mg - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - 5mg - Oral]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 5mg - Oral])
EU-EC-10007639513	786	17.02.2021	More than 85 Years	Elderly	Female	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ileus paralytic (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Microcytic anaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007639530	787	17.02.2021	More than 85 Years	Elderly	Female	Blood pressure decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Body temperature increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Heart rate decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oxygen saturation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1{DF} - n/a])	DULOXETINE [DULOXETINE] (C - n/a - n/a -), ESOMEPRAZOLE [ESOMEPRAZOLE] (C - n/a - n/a -), NEUPRO [ROTIGOTINE] (C - n/a - n/a -), [ACENOCOUMAROL] (C - n/a - n/a -), [CARVEDILOL] (C - n/a - n/a -), [FLUTICASON PROPIONATE, SALMETEROL] (C - n/a - n/a -), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a -), [GABAPENTIN] (C - n/a - n/a -), [SPIRONOLACTONE] (C - n/a - n/a -)
EU-EC-10007639613	788	17.02.2021	65-85 Years	Not Specified	Female	Cardiovascular disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007639674	789	17.02.2021	More than 85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007639836	790	17.02.2021	65-85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death), Confusional state (n/a - Unknown -), Illness (n/a - Unknown -), Migraine (n/a - Unknown -), Muscle fatigue (n/a - Unknown -), Pneumonia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	APIXABAN [APIXABAN] (C - Pulmonary embolism - n/a - [n/a - n/a - n/a]), OLANZAPINE [OLANZAPINE] (C - Mental status changes - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM CARBONATE] (C - Osteoporosis - n/a - [n/a - n/a - n/a]), [INFLUENZA VIRUS] (C - n/a - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - Mental disorder - n/a - [n/a - n/a - n/a]), [TAPENTADOL] (C - Pain in extremity - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - Osteoporosis - n/a - [n/a - n/a - n/a])

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EU-EC-10007640081	791	17.02.2021	18-64 Years	Not Specified	Female	Circulatory collapse (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007640089	792	17.02.2021	More than 85 Years	Not Specified	Male	Pneumonia (n/a - Fatal - Results in Death), Sepsis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007640164	793	17.02.2021	65-85 Years	Not Specified	Male	Depressed level of consciousness (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007640436	794	17.02.2021	65-85 Years	Not Specified	Female	Cerebral haemorrhage (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	APIXABAN [APIXABAN] (C - Atrial fibrillation - n/a - [n/a - n/a - n/a]), ALLOPURINOL (C - n/a - n/a - [n/a - n/a - n/a]), DIGOXIN (C - n/a - n/a - [n/a - n/a - n/a]), ETHANOL (C - n/a - n/a - [n/a - n/a - n/a]), NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]), OMEPRAZOLE (C - n/a - n/a - [n/a - n/a - n/a]), QUININE SULFATE (C - Muscle spasms - n/a - [n/a - n/a - n/a]), THIAMINE (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007640440	795	17.02.2021	65-85 Years	Not Specified	Female	Chest X-ray abnormal (n/a - Unknown -), Dyspnoea (n/a - Fatal - Results in Death, Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007640550	796	17.02.2021	More than 85 Years	Not Specified	Female	Ischaemic cerebral infarction (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007640674	797	17.02.2021	More than 85 Years	Elderly	Male	COVID-19 (9d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - n/a])	Not reported
EU-EC-10007643387	798	17.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007643445	799	17.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007644569	800	17.02.2021	More than 85 Years	Not Specified	Male	Cardiac failure (n/a - Fatal - Results in Death), Confusional state (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Hallucination (n/a - Not Recovered/Not Resolved -), Oedema peripheral (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - n/a - n/a -), BUMETANIDE (C - n/a - n/a -), MORPHINE, MORPHINE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - Subcutaneous]), TRAMADOL, TRAMADOL HYDROCHLORIDE (C - Back pain - n/a - [n/a - n/a - n/a])

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EU-EC-10007644716	801	17.02.2021	65-85 Years	Elderly	Female	Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death), Myocarditis (n/a - Fatal - Results in Death), Septic shock (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007644811	802	17.02.2021	65-85 Years	Not Specified	Male	Cough (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular])	[CINOLAZEPAM] (C - n/a - n/a -), [LORAZEPAM, TETRAZEPAM] (C - n/a - n/a -), [MIRTAZAPINE, MIRTAZAPINE HEMIHYDRATE] (C - n/a - n/a -), [OLANZAPINE] (C - n/a - n/a -), [PAROXETINE, PAROXETINE HYDROCHLORIDE, PAROXETINE HYDROCHLORIDE, ANHYDROUS] (C - n/a - n/a -), [PROCYCLIDINE HYDROCHLORIDE, PROCYCLIDINE HYDROCHLORIDE BP] (C - n/a - n/a -)
EU-EC-10007645637	803	17.02.2021	More than 85 Years	Elderly	Female	Cardiac failure (n/a - Fatal - Results in Death), Emphysema (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007645930	804	17.02.2021	More than 85 Years	Elderly	Male	Pneumonia (n/a - Fatal - Results in Death), Pulmonary infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007646090	805	17.02.2021	More than 85 Years	Not Specified	Female	Anuria (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Fatal - Results in Death), Constipation (n/a - Unknown -), Dehydration (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Fall (n/a - Unknown -), Malaise (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - Myocardial ischaemia - n/a - [n/a - 75mg - n/a]), [ATORVASTATIN] (C - Blood cholesterol increased - n/a - [n/a - 20mg - n/a]), [BETAMETHASONE] (C - Glaucoma - n/a - [n/a - 2{drp} - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 1.25mg - n/a]), [METFORMIN HYDROCHLORIDE] (C - Diabetes mellitus - n/a - [n/a - 4{DF} - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [PARAFFIN, LIGHT LIQUID, PARAFFIN, LIGHT LIQUID, PARAFFIN WHITE SOFT] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007646093	806	17.02.2021	65-85 Years	Not Specified	Female	Asthenia (n/a - Fatal - Results in Death, Life Threatening), Diarrhoea (n/a - Fatal - Results in Death, Life Threatening), Fall (n/a - Fatal - Results in Death, Life Threatening), Hypopnoea (n/a - Fatal - Results in Death, Life Threatening), Illness (n/a - Fatal - Results in Death, Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007646723	807	17.02.2021	65-85 Years	Not Specified	Female	Asthenia (n/a - Recovered/Resolved -), Bladder disorder (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Hyperhidrosis (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Near death experience (n/a - Recovered/Resolved - Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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EU-EC-10007646734	808	17.02.2021	18-64 Years	Not Specified	Female	Aortic stenosis (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardiac failure (n/a - Fatal - Results in Death), Diabetes mellitus (n/a - Fatal - Results in Death), Myocardial ischaemia (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), NOVORAPID [INSULIN ASPART] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), RENAVIT [ASCORBIC ACID, BIOTIN, CALCIUM PANTOTHENATE, FOLIC ACID, NICOTINAMIDE, PYRIDOXINE HYDROCHLORIDE, RIBOFLAVIN, THIAMINE MONONITRATE] (C - Renal failure - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [ALFACALCIDOL] (C - Renal failure - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [CARVEDILOL] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [ERYTHROPOIETIN] (C - Renal failure - n/a - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - Dyspepsia - n/a - [n/a - n/a - n/a]), [LANTHANUM CARBONATE] (C - Renal failure - n/a - [n/a - n/a - n/a]), [NICORANDIL] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [ONDANSETRON] (C - Nausea - n/a - [n/a - n/a - n/a]), [PROCHLORPERAZINE] (C - Nausea - n/a - [n/a - n/a - n/a]), [SENNA ALEXANDRINA LEAF, CASSIA] (C - Constipation - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - Insomnia - n/a - [n/a - n/a - n/a])
EU-EC-10007647256	809	17.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Heart rate decreased (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	KEPPRA [LEVETIRACETAM] (C - Epilepsy - n/a - [n/a - 1500mg - Oral]), LANTUS [INSULIN GLARGINE] (C - Diabetes mellitus - n/a - [n/a - 32[iU] - Subcutaneous]), LURASIDONE HYDROCHLORIDE [LURASIDONE HYDROCHLORIDE] (C - Schizophrenia - n/a - [n/a - 120mg - Oral]), [ACETYLSALICYLIC ACID] (C - Cardiac disorder - n/a - [n/a - 81mg - Oral]), [ATENOLOL, ATENOLOL BP] (C - Essential hypertension - n/a - [n/a - 25mg - Oral]), [ATORVASTATIN CALCIUM] (C - Hyperlipidaemia - n/a - [n/a - 40mg - Oral]), [FINASTERIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - 5mg - Oral]), [HALOPERIDOL] (C - Schizophrenia - n/a - [n/a - 10mg - Oral]), [HYPROMELLOSE, GLYCEROL, MACROGOL 400, POLYVINYL ALCOHOL, PROPYLENE GLYCOL, VASELINE, LIQUID PARAFFIN] (C - Dry eye - n/a - [n/a - 4[drp] - Ophthalmic]), [LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - 88ug - Oral]), [LITHIUM CARBONATE] (C - Schizophrenia - n/a - [n/a - 900mg - Oral]), [LORAZEPAM] (C - Anxiety, Restlessness - n/a - [n/a - 1mg - Oral]), [LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 25mg - Oral]), [OMEPRAZOLE] (C - Gastroesophageal reflux disease - n/a - [n/a - 20mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 3000mg - Oral]), [SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - 200mg - Oral]), [TAMSULOSIN HYDROCHLORIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - .8mg - Oral]), [VITAMIN D] (C - Supplementation therapy - n/a - [n/a - 2000[iU] - Oral])

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EU-EC-10007647526	810	17.02.2021	65-85 Years	Elderly	Male	Condition aggravated (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	XARELTO [RIVAROXABAN] (C - Thrombosis prophylaxis - n/a - [n/a - n/a - n/a]), [FENOTEROL HYDROBROMIDE, IPRATROPIUM BROMIDE, FENOTEROL HYDROBROMIDE, IPRATROPIUM BROMIDE MONOHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 4{DF} - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Diuretic therapy - n/a - [n/a - 80mg - n/a]), [HYOSCINE] (C - Prophylaxis of nausea and vomiting - n/a - [n/a - n/a - n/a]), [MORPHINE SULFATE] (C - Pain - n/a - [n/a - 5mg - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - n/a]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - [n/a - n/a - n/a]), [PREGABALIN] (C - Pain - n/a - [n/a - 100mg - n/a]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [n/a - 20{DF} - n/a])
EU-EC-10007647552	811	17.02.2021	More than 85 Years	Elderly	Male	Chronic obstructive pulmonary disease (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007647570	812	17.02.2021	65-85 Years	Elderly	Male	Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [24d - 1{DF} - Intramuscular])	[FENTANYL] (C - n/a - n/a - [n/a - n/a - n/a]), [MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE HYDROCHLORIDE] (C - Dyspnoea - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - Steroid therapy - n/a - [n/a - n/a - n/a])
EU-EC-10007647809	813	17.02.2021	More than 85 Years	Elderly	Female	Hepatitis acute (4d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular - More in ICSR])	Not reported

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EU-EC-10007647880	814	17.02.2021	18-64 Years	Adult	Male	Haemophagocytic lymphohistiocytosis (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hepatitis acute (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), TOCILIZUMAB [TOCILIZUMAB] (S - COVID-19 pneumonia - Not applicable - [n/a - n/a - n/a]), [AMOXICILLIN SODIUM, POTASSIUM CLAVULANATE, AMOXICILLIN, CLAVULANIC ACID] (S - n/a - Not applicable [n/a - 1{DF} - Oral]), [DEKETOPIROFEN, DEXKETOPROFEN TROMETAMOL] (S - n/a - Not applicable - [1d - n/a - n/a]), [METAMIZOLE MAGNESIUM] (S - n/a - Not applicable - [1d - n/a - n/a]), [METAMIZOLE MAGNESIUM] (S - n/a - Not applicable - [n/a - 1{DF} - Oral]), [METHYLPREDNISOLONE, METHYLPREDNISOLONE ACETATE, METHYLPREDNISOLONE SODIUM HEMISUCCINATE] (S - n/a - Not applicable - [1d - n/a - n/a])	SERFIS - SUERO FISIOLÓGICO (SIN ESPECIFICAR) [NOT AVAILABLE] (C - n/a - n/a - [1d - n/a - n/a]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - n/a - Unknown - [n/a - n/a - Respiratory (inhalation)]), [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [1d - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - n/a - Unknown - [n/a - n/a - Respiratory (inhalation)]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [1d - n/a - n/a])
EU-EC-10007623527	815	16.02.2021	More than 85 Years	Not Specified	Female	Coma (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007625339	816	16.02.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Lung disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007625426	817	16.02.2021	More than 85 Years	Not Specified	Female	Dyspnoea (1d - Fatal - Results in Death), Malaise (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular])	Not reported
EU-EC-10007625650	818	16.02.2021	More than 85 Years	Not Specified	Female	Acute coronary syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypotension (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007625653	819	16.02.2021	More than 85 Years	Not Specified	Female	Bradycardia (n/a - Not Recovered/Not Resolved - Results in Death), Respiratory distress (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007625670	820	16.02.2021	65-85 Years	Not Specified	Male	Asthenia (12h - Recovered/Resolved -), Hot flush (12h - Recovered/Resolved -), Muscle spasms (12h - Recovered/Resolved -), Near death experience (12h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007625788	821	16.02.2021	More than 85 Years	Not Specified	Male	Chest discomfort (n/a - Unknown - Results in Death), Death (n/a - Fatal - Results in Death), Vertigo (n/a - Unknown - Results in Death), Vomiting (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007625843	822	16.02.2021	65-85 Years	Not Specified	Male	Acute pulmonary oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007625855	823	16.02.2021	More than 85 Years	Not Specified	Female	Asthenia (2d - Recovered/Resolved - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	INSULIN GLARGINE [INSULIN GLARGINE] (C - n/a - n/a - [n/a - n/a - n/a]), INSULIN GLULISINE [INSULIN GLULISINE] (C - n/a - n/a - [n/a - n/a - n/a]), IRBESARTAN [IRBESARTAN] (C - n/a - n/a - [n/a - n/a - n/a]), XARELTO 20 MG FILM-COATED TABLETS [RIVAROXBAN] (C - n/a - n/a - [n/a - n/a - n/a]), [ALUMINIUM HYDROXIDE GEL, DRIED, MAGNESIUM CARBONATE, SODIUM CARBONATE, ALGINIC ACID, ALUMINIUM HYDROXIDE, SODIUM CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE, ALUMINIUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, ALGINIC ACID, ALUMINIUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, ALGINIC ACID, ALUMINIUM HYDROXIDE GEL, DRIED USP, SODIUM HYDROGEN CARBONATE, ALGINIC ACID, SODIUM ALGINATE, ALUMINIUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, ALUMINIUM HYDROXIDE GEL, CALCIUM CARBONATE, SODIUM ALGINATE, SODIUM HYDROGEN CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE, SODIUM HYDROGEN CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE, ALUMINIUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, SODIUM ALGINATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DIGOXIN] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [NICARDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [URAPIDIL, URAPIDIL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007625869	824	16.02.2021	65-85 Years	Not Specified	Male	Cardiac failure (1d - Fatal - Results in Death), Chest pain (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular])	Not reported

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EU-EC-10007625872	825	16.02.2021	65-85 Years	Not Specified	Female	Respiratory distress (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular])	Not reported
EU-EC-10007625879	826	16.02.2021	More than 85 Years	Not Specified	Female	Acute kidney injury (19d - Fatal - Results in Death), Agitation (19d - Fatal - Results in Death), General physical health deterioration (19d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - Intramuscular])	Not reported
EU-EC-10007625992	827	16.02.2021	More than 85 Years	Not Specified	Female	Lung disorder (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Tongue oedema (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007626278	828	16.02.2021	More than 85 Years	Not Specified	Male	Seizure (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	LEVETIRACETAM [LEVETIRACETAM] (C - Seizure - n/a - [1d - n/a - n/a]), [ACICLOVIR, ACICLOVIR SODIUM] (C - n/a - n/a - [1d - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [1d - n/a - n/a]), [AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - n/a - n/a - [1d - n/a - n/a]), [CEFTRIAXONE, CEFTRIAXONE SODIUM] (C - n/a - n/a - [1d - n/a - n/a]), [FERROUS FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYOSCINE BUTYLBROMIDE] (C - n/a - n/a - [1d - n/a - n/a]), [METARAMINOL] (C - n/a - n/a - [1d - n/a - n/a]), [PERINDOPRIL, PERINDOPRIL TERT-BUTYLAMINE] (C - Hypertension - n/a - [1d - n/a - n/a])
EU-EC-10007626283	829	16.02.2021	65-85 Years	Not Specified	Male	Cardiac failure (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007626286	830	16.02.2021	More than 85 Years	Not Specified	Female	Agitation (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Neuropsychiatric symptoms (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007626321	831	16.02.2021	More than 85 Years	Not Specified	Male	Coronary artery disease (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	(YAMAGATA LINEAGE)-LIKE VIRUS ANTIGEN, B (VICTORIA LINEAGE)-LIKE VIRUS ANTIGEN, A/BRISBANE/02/2018 (H1N1)PDM09 - LIKE STRAIN (A/IDAHO/07/2018), A/KANSAS/14/2017 (H3N2) - LIKE STRAIN (A/INDIANA/08/2018), B/PHUKET/3073/2013-LIKE VIRUS (B/SINGAPORE/INF11-16-0610/2016, WILD TYPE), B/COLORADO/06/2017 - LIKE STRAIN (B/IOWA/06/2017)) (C - Influenza immunisation - n/a - [n/a - n/a - n/a]), OXYBUTYNIN [OXYBUTYNIN, OXYBUTYNIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 20mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 20mg - n/a]), [BETAMETHASONE DIPROPIONATE, CLOTRIMAZOLE, BETAMETHASONE, CLOTRIMAZOLE PH. EUR., BETAMETHASONE DIPROPIONATE (PH. EUR.)) (C - n/a - n/a - [n/a - n/a - n/a]), [CASSIA] (C - n/a - n/a - [n/a - n/a - n/a]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [FERROUS SULFATE] (C - n/a - n/a - [n/a - 200mg - n/a]), [FINASTERIDE] (C - n/a - n/a - [n/a - 5mg - n/a]), [FLUCLOXACILLIN, FLUCLOXACILLIN SODIUM, FLUCLOXACILLIN SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - n/a - n/a - [n/a - 100mg - n/a]), [HYPROMELLOSE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 50mg - n/a]), [MACROGOL, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]),
EU-EC-10007626505	832	16.02.2021	65-85 Years	Not Specified	Female	Brain injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007626621	833	16.02.2021	More than 85 Years	Elderly	Male	COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007627114	834	16.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007627122	835	16.02.2021	More than 85 Years	Not Specified	Male	Arthralgia (n/a - Unknown -), COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Delusion (n/a - Not Recovered/Not Resolved -), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gastric haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ATENOLOL, ATENOLOL BP] (C - Blood pressure measurement - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISONE] (C - Giant cell arteritis - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - Oedema - n/a - [n/a - n/a - n/a])
EU-EC-10007627154	836	16.02.2021	More than 85 Years	Not Specified	Female	COVID-19 pneumonia (6d - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007627253	837	16.02.2021	65-85 Years	Not Specified	Female	Pyrexia (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - Unknown - [n/a - n/a - n/a]), [BENSERAZIDE, LEVODOPA] (C - n/a - Unknown - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [OLMESARTAN MEDOXOMIL, HYDROCHLOROTHIAZIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007627266	838	16.02.2021	65-85 Years	Not Specified	Male	Ischaemic stroke (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Disabling)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - 75mg - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - 100mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 80mg - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - 30mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [PERINDOPRIL, PERINDOPRIL TERT-BUTYLAMINE] (C - n/a - n/a - [n/a - 8mg - n/a])
EU-EC-10007627333	839	16.02.2021	65-85 Years	Elderly	Female	Administration site pain (6d - Unknown -), Death (0d - Fatal - Results in Death), Somnolence (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - Intramuscular])	[ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Hypercholesterolaemia - n/a - [n/a - n/a - Oral])
EU-EC-10007627357	840	16.02.2021	Not Specified	Elderly	Not Specified	General physical health deterioration (n/a - Fatal - Results in Death), SARS-CoV-2 test positive (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007627468	841	16.02.2021	18-64 Years	Not Specified	Female	Foetal death (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown - Other Medically Important Condition), Product use issue (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - 150mg - n/a - More in ICSR])
EU-EC-10007627857	842	16.02.2021	65-85 Years	Not Specified	Male	Aspiration (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007628986	843	16.02.2021	More than 85 Years	Elderly	Male	Asthenia (n/a - Unknown -), COVID-19 pneumonia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Unknown -), Cough (n/a - Unknown -), Decreased appetite (n/a - Unknown -), Pyrexia (n/a - Unknown - Life Threatening), Respiratory failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C n/a - n/a - [n/a - 10mg - Oral]), [CITALOPRAM HYDROBROMIDE] (C - n/a - n/a - [n/a - 20mg - Oral]), [PERINDOPRIL ARGININE] (C - n/a - n/a - [n/a - 5mg - Oral]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007629592	844	16.02.2021	18-64 Years	Not Specified	Male	COVID-19 (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007630089	845	16.02.2021	More than 85 Years	Not Specified	Female	Atrial fibrillation (n/a - Fatal - Results in Death), Cardiac failure congestive (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007630250	846	16.02.2021	More than 85 Years	Elderly	Female	Chronic obstructive pulmonary disease (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007630544	847	16.02.2021	More than 85 Years	Not Specified	Female	Blood glucose decreased (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular])	NOVORAPID [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), TRAJENTA 5 MG FILM-COATED TABLETS [LINAGLIPTIN] (C - n/a - n/a - [n/a - 5mg - n/a]), [AMLODIPINE] (C - n/a - n/a - [n/a - 5mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 40mg - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [CANDESARTAN CILEXETIL] (C - n/a - n/a - [n/a - 8mg - n/a]), [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - 75mg - n/a]), [ECONAZOLE NITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FERROUS SULFATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 500mg - n/a]), [PANTOPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007630604	848	16.02.2021	More than 85 Years	Not Specified	Male	Pyrexia (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007630619	849	16.02.2021	More than 85 Years	Elderly	Female	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007630961	850	16.02.2021	65-85 Years	Not Specified	Male	Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007631210	851	16.02.2021	More than 85 Years	Elderly	Male	Cerebrovascular accident (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	BETMIGA 25 MG PROLONGED-RELEASE TABLETS [MIRABEGRON] (C - n/a - Not applicable -), ELIQUIS 5 MG [APIXABAN] (C - n/a - Not applicable -), INCRUSE ELLIPTA 55 MICROGRAMS [UMECLIDINIUM BROMIDE] (C - n/a - Not applicable -), [ALLOPURINOL] (C - n/a - Not applicable -), [FINASTERIDE] (C - n/a - Not applicable -), [FOLIC ACID] (C - n/a - Not applicable -), [FUROSEMIDE] (C - n/a - Not applicable -), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - n/a - Not applicable -)
EU-EC-10007631642	852	16.02.2021	2 Months - 2 Years	Elderly	Female	COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Communication disorder (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypersomnia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007631700	853	16.02.2021	65-85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	EBIXA 5 MG/PUMP ORAL SOLUTION [MEMANTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - Oral]), [BUPRENORPHINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CIPROFLOXACIN, CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE] (C - n/a - n/a - [n/a - 250mg - n/a]), [CLOMETHIAZOLE, CLOMETHIAZOLE EDISILATE] (C - n/a - n/a - [n/a - 12mL - n/a]), [KETOPROFEN] (C - n/a - n/a - [n/a - n/a - n/a]), [MACROGOL, MACROGOL 4000] (C - n/a - n/a - [n/a - 10g - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 15mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - .75mg - n/a]), [UREA] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007631846	854	16.02.2021	65-85 Years	Elderly	Female	COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007633065	855	16.02.2021	65-85 Years	Not Specified	Female	Blood pressure immeasurable (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular])	[ALPRAZOLAM] (C - n/a - n/a -), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a -), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a -), [CITALOPRAM, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a -), [LOSARTAN POTASSIUM] (C - n/a - n/a -), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a -)
EU-EC-10007633545	856	16.02.2021	65-85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	RIVAROXABAN [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007633569	857	16.02.2021	65-85 Years	Not Specified	Female	Asthenia (n/a - Not Recovered/Not Resolved -), Balance disorder (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Fatal - Results in Death), Faeces discoloured (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a])	Not reported
EU-EC-10007633814	858	16.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007634279	859	16.02.2021	More than 85 Years	Elderly	Male	Malaise (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[FLUTICASONE PROPIONATE, SALMETEROL, FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE] (C - Lung disorder - n/a - [n/a - 2{DF} - Respiratory (inhalation)]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Prophylaxis against gastrointestinal ulcer - n/a - [n/a - 40mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - Oral]), [PAROXETINE, PAROXETINE HYDROCHLORIDE, ANHYDROUS] (C - Anxiety - n/a - [n/a - 20mg - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Bronchospasm - n/a - [n/a - .2mg - Respiratory (inhalation)]), [TIOTROPIUM, TIOTROPIUM BROMIDE, TIOTROPIUM BROMIDE MONOHYDRATE] (C - Lung disorder - n/a - [n/a - 5ug - Respiratory (inhalation)]), [VITAMIN D, CALCIUM] (C - Mineral supplementation - n/a - [n/a - 1{DF} - Oral])
EU-EC-10007634282	860	16.02.2021	65-85 Years	Elderly	Male	Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007634373	861	16.02.2021	65-85 Years	Elderly	Female	Sudden death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [27d - 1{DF} - n/a])	[ACETYLSALICYLIC ACID] (C - Anticoagulant therapy - n/a - [n/a - 75mg - Oral]), [ALENDRONATE SODIUM, ALENDRONIC ACID] (C - Osteoporosis - n/a - [n/a - 70mg - Oral]), [AMLODIPINE BESILATE] (C - Hypertension - n/a - [n/a - 10mg - Oral]), [ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - Muscle spasms - n/a - [n/a - 360mg - Oral]), [BENDROFLUMETHIAZIDE, POTASSIUM CHLORIDE] (C - Diuretic therapy - n/a - [n/a - 1{DF} - Oral]), [BENSERAZIDE HYDROCHLORIDE, LEVODOPA, BENSERAZIDE, LEVODOPA] (C - Parkinson's disease - n/a - [n/a - 2{DF} - Oral]), [BENSERAZIDE, LEVODOPA] (C - Musculoskeletal stiffness - n/a - [n/a - 1{DF} - Oral]), [BIPERIDEN, BIPERIDEN HYDROCHLORIDE, BIPERIDEN LACTATE] (C - Dystonia - n/a - [n/a - 1mg - Oral]), [CYANOCOBALAMIN] (C - Vitamin B12 deficiency - n/a - [n/a - 1mg - Oral]), [DOMPERIDONE, DOMPERIDONE MALEATE] (C - Nausea - n/a - [n/a - 10mg - Oral]), [ESOMEPRAZOLE, ESOMEPRAZOLE SODIUM] (C - Gastroesophageal reflux disease - n/a - [n/a - 20mg - Oral]), [GLYCERYL TRINITRATE] (C - Angina pectoris - n/a - [n/a - .4mg - Sublingual]), [LACTULOSE, SODIUM PICOSULFATE] (C - Constipation - n/a - [n/a - n/a - Oral]), [MORPHINE SULFATE] (C - Pain - n/a - [n/a - n/a - Oral]), [NICOTINE, NICOTINE POLACRILEX] (C - Smoking cessation therapy - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - Oral]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - [n/a - 1500mg - Oral]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 1{DF} - Oral]), [VITAMIN D] (C - Vitamin D deficiency - n/a - [n/a - 70ug - Oral])
EU-EC-10007634657	862	16.02.2021	More than 85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007634681	863	16.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007617639	864	15.02.2021	65-85 Years	Not Specified	Male	Asthenia (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007617765	865	15.02.2021	18-64 Years	Not Specified	Male	Blood pressure abnormal (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Heart rate increased (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Lymphadenopathy (n/a - Unknown - Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007618072	866	15.02.2021	More than 85 Years	Elderly	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	APIXABAN [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), LEVODOPA [LEVODOPA] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LERCANIDIPINE, LERCANIDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MOXONIDINE] (C - n/a - n/a - [n/a - n/a - n/a]), [PRAMIPEXOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007618264	867	15.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007618491	868	15.02.2021	65-85 Years	Not Specified	Male	Pneumonia (4wk - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007618573	869	15.02.2021	More than 85 Years	Elderly	Female	Cardiac failure acute (5d - Fatal - Results in Death), Cardiogenic shock (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007618630	870	15.02.2021	More than 85 Years	Elderly	Female	Pyrexia (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Somnolence (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	MIRAPEXIN 0.18 MG [PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE] (C - n/a - n/a - [n/a - .18mg - Oral]), NOVOMIX 30 FLEXPEN [INSULIN ASPART, INSULIN ASPART, INSULIN ASPART PROTAMINE] (C - n/a - n/a - [n/a - 1{DF} - Subcutaneous]), RIVASTIGMINE ACTAVIS [RIVASTIGMINE] (C - n/a - n/a - [n/a - 1{DF} - Transdermal]), XARELTO 15 MG [RIVAROXABAN] (C - n/a - n/a - [n/a - 15mg - Oral]), [CARBIDOPA, LEVODOPA, LEVODOPA, CARBIDOPA MONOHYDRATE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - Oral]), [GLIQUIDONE] (C - n/a - n/a - [n/a - 30mg - Oral]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 850mg - Oral]), [METILDIGOXIN] (C - n/a - n/a - [n/a - .1mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 20mg - Oral]), [PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, PARACETAMOL] (C - n/a - n/a - [n/a - 500mg - Oral])

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EU-EC-10007618860	871	15.02.2021	More than 85 Years	Elderly	Male	Epilepsy (1.5d - Fatal - Results in Death, Life Threatening), Escherichia sepsis (1.5d - Fatal - Results in Death, Life Threatening), Meningitis bacterial (1.5d - Fatal - Results in Death, Life Threatening), Pyrexia (1.5d - Fatal - Results in Death, Life Threatening), Somnolence (1.5d - Fatal - Results in Death, Life Threatening), Vomiting (1.5d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1{DF} - n/a])	[CANDESARTAN, HYDROCHLOROTHIAZIDE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [TIMOLOL, TIMOLOL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007619681	872	15.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	[BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - 25mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 75ug - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 5mg - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOFOSFATE, SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - 50mg - n/a])
EU-EC-10007619861	873	15.02.2021	65-85 Years	Not Specified	Male	Asthenia (4d - Fatal - Results in Death), Fatigue (4d - Fatal - Results in Death), Feeding disorder (4d - Fatal - Results in Death), Pyrexia (4d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - n/a]), [ALPRAZOLAM] (C - n/a - n/a - [n/a - .75mg - n/a]), [CINOLAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [NICERGOLINE] (C - n/a - n/a - [n/a - n/a - n/a]), [PENTOXIFYLLINE] (C - n/a - n/a - [n/a - 1200mg - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - 2mg - n/a])
EU-EC-10007620058	874	15.02.2021	More than 85 Years	Not Specified	Female	Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007620144	875	15.02.2021	Not Specified	Not Specified	Female	Cardiac disorder (n/a - Fatal - Results in Death), Erythema (n/a - Fatal - Results in Death), Injection site erythema (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - Unknown - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [NEBIVOLOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - Unknown - [n/a - 3{DF} - n/a]), [PRAZEPAM] (C - n/a - Unknown - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - Unknown - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [SPIRONOLACTONE, SPIRONOLACTONE BP] (C - n/a - Unknown - [n/a - n/a - n/a]), [TRAMADOL HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 2{DF} - n/a])
EU-EC-10007620170	876	15.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Lividity (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007620391	877	15.02.2021	More than 85 Years	Not Specified	Male	Dyspnoea (6d - Fatal - Results in Death), Dysstasia (6d - Fatal - Results in Death), Fall (6d - Fatal - Results in Death), Fibrin D dimer increased (6d - Fatal - Results in Death), Liver function test abnormal (6d - Fatal - Results in Death), Oxygen saturation decreased (6d - Fatal - Results in Death), Troponin increased (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[DONEPEZIL] (C - n/a - Unknown - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [LERCANIDIPINE, LERCANIDIPINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [LOSARTAN POTASSIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [NEBIVOLOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007621578	878	15.02.2021	More than 85 Years	Not Specified	Female	Brain injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiac arrest (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FELODIPINE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007622335	879	15.02.2021	More than 85 Years	Not Specified	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007622394	880	15.02.2021	65-85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [1d - n/a - Intramuscular])	[ACETYLSALICYLIC ACID, ACETYLSALICYLIC ACID PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [INSULIN, INSULIN HUMAN] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007622579	881	15.02.2021	More than 85 Years	Elderly	Female	Blood pressure immeasurable (n/a - Recovered/Resolved - Other Medically Important Condition), Breath sounds (n/a - Unknown -), Choking (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Recovered/Resolved -), Oxygen saturation immeasurable (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	[LORATADINE] (C - Drug hypersensitivity - n/a - [n/a - 10mg - n/a])
EU-EC-10007622988	882	15.02.2021	65-85 Years	Elderly	Male	Diarrhoea (2d - Fatal - Results in Death), Malaise (2d - Fatal - Results in Death), Muscular weakness (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007623234	883	15.02.2021	More than 85 Years	Not Specified	Female	Headache (1d - Recovered/Resolved -), Nausea (1d - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007623255	884	15.02.2021	More than 85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007611508	885	14.02.2021	More than 85 Years	Not Specified	Female	Body temperature increased (1d - Recovered/Resolved -), Cardiac arrest (n/a - Fatal - Results in Death), Malaise (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ELIQUIS 5 MG FILM-COATED TABLETS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CRANBERRY] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007611817	886	14.02.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - Cough - n/a - [n/a - 100mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Cough - n/a - [n/a - n/a - Respiratory (inhalation)])
EU-EC-10007606632	887	13.02.2021	More than 85 Years	Not Specified	Male	Diarrhoea (11d - Fatal - Results in Death), Hyperpyrexia (11d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - n/a]), [DUTASTERIDE] (C - n/a - n/a - [n/a - .5mg - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - 25mg - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [SODIUM VALPROATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007607447	888	13.02.2021	65-85 Years	Not Specified	Male	Lymphopenia (n/a - Not Recovered/Not Resolved - Results in Death), Septic shock (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007607455	889	13.02.2021	More than 85 Years	Not Specified	Female	Myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007607610	890	13.02.2021	More than 85 Years	Not Specified	Male	Respiratory failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	ENTRESTO [VALSARTAN, SACUBITRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [ALFUZOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [DILTIAZEM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASON PROPRIONATE, SALMETEROL, FLUTICASON PROPRIONATE, SALMETEROL XINAFOATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007607617	891	13.02.2021	65-85 Years	Not Specified	Male	Acute abdomen (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Anaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]), PLAVIX [CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE] (S - Product used for unknown indication - Dose not changed - [n/a - 1{DF} - Oral]), [COLCHICINE] (S - Gouty arthritis - Dose not changed - [n/a - 1{DF} - Oral]), [DILTIAZEM HYDROCHLORIDE] (S - Product used for unknown indication - Dose not changed [n/a - 1{DF} - Oral])	Not reported
EU-EC-10007607762	892	13.02.2021	More than 85 Years	Not Specified	Male	Chest pain (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007607779	893	13.02.2021	More than 85 Years	Not Specified	Female	Pyrexia (n/a - Not Recovered/Not Resolved - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007607789	894	13.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007607854	895	13.02.2021	More than 85 Years	Not Specified	Female	Acute respiratory distress syndrome (n/a - Fatal - Results in Death), Hypertension (n/a - Not Recovered/Not Resolved - Results in Death), Tachycardia (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), FENTANYL [FENTANYL, FENTANYL CITRATE] (S - Pain - Not applicable - [n/a - n/a - Cutaneous])	LEVETIRACETAM [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007607887	896	13.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Subileus (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007608007	897	13.02.2021	More than 85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007608011	898	13.02.2021	More than 85 Years	Not Specified	Female	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CANDESARTAN CILEXETIL] (C - n/a - n/a - [n/a - n/a - n/a]), [DORZOLAMIDE HYDROCHLORIDE, TIMOLOL, DORZOLAMIDE HYDROCHLORIDE, TIMOLOL MALEATE, DORZOLAMIDE, TIMOLOL] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007608020	899	13.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007608029	900	13.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007608030	901	13.02.2021	More than 85 Years	Not Specified	Female	Hypertension (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 20mg - Oral]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [ATENOLOL, ATENOLOL BP] (C - n/a - n/a - [n/a - 25mg - Oral]), [ECONAZOLE, ECONAZOLE NITRATE] (C - n/a - n/a - [n/a - n/a - Cutaneous]), [POTASSIUM CHLORIDE, POTASSIUM CHLORIDE, ETHYLCELLULOSE MICROENCAPSULATED 80-90%] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [URAPIDIL] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [VALSARTAN] (C - n/a - n/a - [n/a - 160mg - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - 1{DF} - Oral])
EU-EC-10007608035	902	13.02.2021	More than 85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	PRADAXA [DABIGATRAN ETEXILATE, DABIGATRAN ETEXILATE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN EMBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007608096	903	13.02.2021	More than 85 Years	Not Specified	Female	Acute pulmonary oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007608350	904	13.02.2021	More than 85 Years	Not Specified	Female	Acute myeloid leukaemia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID, CALCIUM GLUBIONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBIONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - n/a - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [MEMANTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007608434	905	13.02.2021	More than 85 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007608438	906	13.02.2021	More than 85 Years	Not Specified	Male	General physical health deterioration (n/a - Fatal - Results in Death), Muscle disorder (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007608442	907	13.02.2021	More than 85 Years	Not Specified	Female	Cardiac failure (n/a - Fatal - Results in Death), Dementia (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Pain (n/a - Recovered/Resolved -), Respiratory tract infection (n/a - Fatal - Results in Death), Swelling face (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 20mg - Oral]), XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - 20mg - Oral]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - 5mg - Oral])
EU-EC-10007610105	908	13.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death), Drug ineffective (n/a - Fatal - Results in Death), Lower respiratory tract infection (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007610668	909	13.02.2021	Not Specified	Not Specified	Male	Thrombocytopenia (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007588070	910	12.02.2021	More than 85 Years	Not Specified	Male	Sudden death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007589120	911	12.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007589122	912	12.02.2021	65-85 Years	Not Specified	Female	Pneumonia (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007589133	913	12.02.2021	65-85 Years	Not Specified	Male	Lung disorder (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007589407	914	12.02.2021	More than 85 Years	Not Specified	Female	Arrhythmia (n/a - Unknown - Results in Death), Cerebrovascular accident (n/a - Unknown - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007589880	915	12.02.2021	More than 85 Years	Not Specified	Male	Body temperature increased (n/a - Unknown -), Confusional state (n/a - Unknown -), Depressed level of consciousness (n/a - Unknown -), Gastrointestinal haemorrhage (n/a - Fatal - Results in Death), Hypovolaemic shock (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007590904	916	12.02.2021	More than 85 Years	Not Specified	Male	Decreased appetite (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[BUMETANIDE] (C - n/a - n/a -), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BP] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-10007591014	917	12.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007592490	918	12.02.2021	18-64 Years	Not Specified	Not Specified	Asthenia (n/a - Fatal - Results in Death), Carotid artery dissection (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007592581	919	12.02.2021	More than 85 Years	Not Specified	Female	Acute coronary syndrome (15d - Fatal - Results in Death), Deep vein thrombosis (15d - Fatal - Results in Death), Dyspnoea (15d - Fatal - Results in Death), Pulmonary embolism (15d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007592591	920	12.02.2021	65-85 Years	Not Specified	Female	Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007593077	921	12.02.2021	More than 85 Years	Not Specified	Female	Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - 300mg - n/a]), [CLODRONATE DISODIUM, CLODRONATE DISODIUM TETRAHYDRATE] (C - n/a - n/a - [n/a - 200mg - Intramuscular]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 50000{DF} - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 5000ug - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - 30mg - n/a]), [MACROGOL 4000] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SIMETICONE] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - 10mg - n/a]), [URSODEOXYCHOLIC ACID] (C - n/a - n/a - [n/a - 450mg - n/a])
EU-EC-10007594197	922	12.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007594199	923	12.02.2021	65-85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007594275	924	12.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007594292	925	12.02.2021	More than 85 Years	Not Specified	Female	Pyrexia (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007594300	926	12.02.2021	More than 85 Years	Not Specified	Male	Cardiogenic shock (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Drug withdrawn - [n/a - n/a - n/a])	Not reported
EU-EC-10007594325	927	12.02.2021	More than 85 Years	Not Specified	Female	Acute coronary syndrome (n/a - Fatal - Results in Death), Atrial fibrillation (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death), Venous oxygen saturation decreased (n/a - Fatal - Results in Death), Vomiting (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007594349	928	12.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007594370	929	12.02.2021	65-85 Years	Not Specified	Male	Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007595200	930	12.02.2021	65-85 Years	Not Specified	Male	Aortic aneurysm (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown -), Fatigue (n/a - Unknown -), Illness (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - Transient ischaemic attack - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE] (C - Angina pectoris - n/a - [n/a - n/a - n/a]), [ISOSORBIDE MONONITRATE] (C - Angina pectoris - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - Anxiety - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - Blood cholesterol increased - n/a - [n/a - n/a - n/a])
EU-EC-10007595470	931	12.02.2021	More than 85 Years	Not Specified	Female	General physical health deterioration (5d - Fatal - Results in Death), Heart rate increased (5d - Fatal - Results in Death), Loss of consciousness (5d - Fatal - Results in Death), Oxygen saturation decreased (5d - Fatal - Results in Death), Respiratory arrest (5d - Fatal - Results in Death), Terminal state (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - Intramuscular])	OLANZAPINE TEVA [OLANZAPINE] (C - Anxiety, Bipolar disorder - n/a - [227d - 10mg - Oral - More in ICSR]), [ACETYLCYSTEINE] (C - Increased bronchial secretion - n/a - [105d - 200mg - Oral]), [BUMETANIDE] (C - Cardiac failure - n/a - [144d - 1mg - Oral]), [GLYCOPYRRONIUM BROMIDE, GLYCOPYRRONIUM BROMIDE, NEOSTIGMINE METHYLSULFATE] (C - Terminal state - n/a - [5d - .2mg - Subcutaneous]), [LACTULOSE, LACTULOSE, LIQUID] (C - Constipation - n/a - [715d - 15mL - Oral]), [LAMOTRIGINE] (C - Bipolar disorder - n/a - [232d - 100mg - Oral]), [MIDAZOLAM] (C - Terminal state - n/a - [5d - 1mg - Subcutaneous]), [MORPHINE HYDROCHLORIDE] (C - Terminal state - n/a - [5d - 2.5mg - Subcutaneous]), [OXAZEPAM] (C - Anxiety - n/a - [189d - 5mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [417d - 1000mg - Oral]), [WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BP] (C - Heart valve replacement - n/a - [957d - 16{DF} - Oral]), [ZOPICLONE] (C - Insomnia - n/a - [528d - 5mg - Oral])
EU-EC-10007595824	932	12.02.2021	18-64 Years	Not Specified	Male	Aspiration (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown -), Death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - Anticoagulant therapy - n/a - [n/a - n/a - n/a]), DULOXETINE [DULOXETINE] (C - Depression - n/a - [n/a - n/a - n/a]), EPOETIN ZETA [EPOETIN ZETA] (C - Anaemia - n/a - [n/a - n/a - n/a]), LINAGLIPTIN [LINAGLIPTIN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), PREGABALIN [PREGABALIN] (C - Neuralgia - n/a - [n/a - n/a - n/a]), RENAGEL [SEVELAMER, SEVELAMER HYDROCHLORIDE] (C - Hyperphosphataemia - n/a [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - Anticoagulant therapy - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Hypercholesterolaemia - n/a - [n/a - n/a - n/a]), [BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - Polyuria - n/a - [n/a - n/a - n/a]), [GLICLAZIDE] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [IRON, IRON SUCROSE] (C - Iron deficiency - n/a - [n/a - n/a - n/a]), [LANTHANUM CARBONATE] (C - Hyperphosphataemia - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - Asthma - n/a [n/a - n/a - n/a])

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EU-EC-10007596055	933	12.02.2021	More than 85 Years	Elderly	Male	Multi-organ disorder (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007596345	934	12.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007596811	935	12.02.2021	More than 85 Years	Not Specified	Female	Decreased appetite (n/a - Unknown -), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (n/a - Unknown -), Suspected COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Urinary tract infection bacterial (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007597273	936	12.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007597682	937	12.02.2021	More than 85 Years	Not Specified	Male	Death (5d - Fatal - Results in Death), General physical health deterioration (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007597941	938	12.02.2021	65-85 Years	Elderly	Male	Dyspnoea (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Heart rate increased (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Respiratory arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007598032	939	12.02.2021	65-85 Years	Not Specified	Female	Fatigue (n/a - Fatal - Results in Death), Productive cough (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[CARBIDOPA, LEVODOPA] (C - Parkinson's disease - n/a - [n/a - 110.a - Oral]), [CEFTRIAXONE] (C - n/a - n/a - [n/a - n/a - Intravenous (not otherwise specified)]), [SELEGILINE HYDROCHLORIDE] (C - Parkinson's disease - n/a - [n/a - n/a - Oral])

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EU-EC-10007598076	940	12.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Gaze palsy (n/a - Fatal - Results in Death), Opisthotonus (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	EXELON [RIVASTIGMINE] (C - Dementia Alzheimer's type - n/a - [n/a - n/a - Oral]), MELATONIN [MELATONIN] (C - Sleep disorder - n/a - [n/a - n/a - Oral]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - Oral]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Hypertension - n/a - [n/a - n/a - Oral]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - Oral]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM] (C - Gastrointestinal disorder prophylaxis - n/a - [n/a - n/a - Oral]), [ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE] (C - Hypertension - n/a - [n/a - n/a - Oral]), [MEMANTINE] (C - Dementia Alzheimer's type - n/a - [n/a - n/a - Oral]), [MIRTAZAPINE] (C - Insomnia - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral]), [RISPERIDONE] (C - Behaviour disorder - n/a - [n/a - n/a - Oral]), [WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BP] (C - Atrial fibrillation - n/a - [n/a - n/a - Oral])
EU-EC-10007598081	941	12.02.2021	65-85 Years	Elderly	Male	General physical health deterioration (n/a - Fatal - Results in Death), Pneumonia aspiration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [22d - n/a - Intramuscular])	Not reported
EU-EC-10007598105	942	12.02.2021	More than 85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death), Dehydration (n/a - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death), Infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[ACETYSALICYLIC ACID, ACETYSALICYLIC ACID PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007598354	943	12.02.2021	More than 85 Years	Not Specified	Not Specified	Asthenia (n/a - Unknown - Other Medically Important Condition), Cardiac death (n/a - Fatal - Results in Death), Musculoskeletal pain (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007598357	944	12.02.2021	More than 85 Years	Not Specified	Male	Pneumonia (15d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - Pneumonia - n/a - [n/a - 500mg - Oral])
EU-EC-10007598366	945	12.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[FLUCONAZOLE] (C - Fungal infection - n/a - [8d - 100mg - Oral])
EU-EC-10007598367	946	12.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007598373	947	12.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	PRADAXA [DABIGATRAN ETEXILATE, DABIGATRAN ETEXILATE MESILATE] (C - Cerebrovascular accident prophylaxis - n/a - [n/a - 110mg - Oral]), [BUMETANIDE] (C - Diuretic therapy - n/a - [n/a - 1mg - Oral]), [CYANOCOBALAMIN, HYDROXOCOBALAMIN] (C - Vitamin supplementation - n/a - [n/a - 1mg - Oral]), [FERROUS CHLORIDE TETRAHYDRATE, FERROUS ION] (C - n/a - n/a - [n/a - 9mg - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - Pain - n/a - [n/a - 1g - Oral]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 1{DF} - Oral]), [QUETIAPINE] (C - Frontotemporal dementia - n/a - [n/a - 50mg - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Dyspnoea - n/a - [n/a - n/a - Respiratory (inhalation)])
EU-EC-10007598507	948	12.02.2021	65-85 Years	Elderly	Male	Cough (12d - Fatal - Results in Death), Diet refusal (9d - Fatal - Results in Death), General physical health deterioration (9d - Fatal - Results in Death), Restlessness (12d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007599036	949	12.02.2021	More than 85 Years	Elderly	Male	Cardiac failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - Dose not changed -)
EU-EC-10007599192	950	12.02.2021	More than 85 Years	Elderly	Female	General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007599392	951	12.02.2021	18-64 Years	Not Specified	Male	Chills (n/a - Unknown -), Dyspnoea (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular])	[OXAZEPAM] (C - Anxiety - n/a - [n/a - 10mg - Oral]), [OXYCODONE HYDROCHLORIDE] (C - Analgesic therapy - n/a - [n/a - 10mg - Oral]), [OXYCODONE HYDROCHLORIDE] (C - Analgesic therapy - n/a - [n/a - 5mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Antacid therapy - n/a - [n/a - 40mg - Oral]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 1{DF} - Oral]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [n/a - 4{drp} - Oral])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007599394	952	12.02.2021	More than 85 Years	Not Specified	Female	Anxiety (3d - Fatal - Results in Death), Chills (2d - Fatal - Results in Death), Depressed level of consciousness (2d - Fatal - Results in Death), Dysphagia (2d - Fatal - Results in Death), Muscle spasms (2d - Fatal - Results in Death), Pain (2d - Fatal - Results in Death), Pruritus (3d - Fatal - Results in Death), Restlessness (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]), [OXYCODONE HYDROCHLORIDE] (S - Pelvic fracture - n/a - [2d - 5mg - Oral])	ELIQUIS [APIXABAN] (C - Atrial fibrillation - n/a - [96d - 2.5mg - Oral]), [BUMETANIDE] (C - Cardiac failure - n/a - [96d - n/a - Oral]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - Osteoporosis - n/a - [2d - 2{DF} - Oral]), [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - Chronic obstructive pulmonary disease n/a - [12d - .5mg - Respiratory (inhalation)]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Cardiac failure - n/a - [89d - 100mg - Oral]), [MIRTAZAPINE] (C - n/a - n/a - [89d - 15mg - Oral]), [OXAZEPAM] (C - Anxiety - n/a - [89d - n/a - Oral]), [OXYGEN] (C - Hypoxia - n/a - [96d - n/a - Respiratory (inhalation)]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Prophylaxis against gastrointestinal ulcer - n/a - [96d - 20mg - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - Pain - n/a - [2d - 1g - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [12d - 5mg - Respiratory (inhalation)]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [145d - n/a - Oral])
EU-EC-10007599728	953	12.02.2021	65-85 Years	Elderly	Female	Apathy (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling, Other Medically Important Condition), Eating disorder (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Fatigue (n/a - Fatal - Results in Death, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Language disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Memory impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007600683	954	12.02.2021	65-85 Years	Not Specified	Male	General symptom (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007600764	955	12.02.2021	More than 85 Years	Not Specified	Male	General physical health deterioration (4d - Fatal - Results in Death), Malnutrition (4d - Fatal - Results in Death), Terminal state (4d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007601297	956	12.02.2021	65-85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007601301	957	12.02.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dementia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Encephalitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death), Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	RANOLAZINE [RANOLAZINE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [TEMAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN, WARFARIN SODIUM] (C - Myocardial infarction - n/a - [n/a - n/a - n/a])
EU-EC-10007601302	958	12.02.2021	More than 85 Years	Not Specified	Male	Asthenia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory tract infection (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007602309	959	12.02.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	[CALCIUM CARBONATE, CHOLECALCIFEROL CONCENTRATE (POWDER FORM), CALCIUM CARBONATE, COLECALCIFEROL CONCENTRATE (POWDER FORM) (SDS), COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OLMESARTAN MEDOXOMIL] (C - n/a - n/a - [n/a - 20mg - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 100mg - n/a])
EU-EC-10007602606	960	12.02.2021	More than 85 Years	Not Specified	Not Specified	General physical health deterioration (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Respiratory tract infection (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	ESOMEPRAZOLE [ESOMEPRAZOLE] (C - n/a - n/a - [n/a - 40mg - n/a]), FENTANYL [FENTANYL, FENTANYL CITRATE] (C - n/a - n/a - [n/a - 12ug - n/a - More in ICSR]), [CARBOMER] (C - n/a - n/a - [n/a - n/a - n/a]), [HYOSCINE BUTYLBROMIDE] (C - n/a - n/a - [n/a - 10mg - Subcutaneous]), [HYOSCINE] (C - n/a - n/a - [n/a - 1.5mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1g - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - 25mg - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a -)

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EU-EC-10007602657	961	12.02.2021	More than 85 Years	Not Specified	Female	Cerebral haemorrhage (n/a - Fatal - Results in Death), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - n/a])
EU-EC-10007603152	962	12.02.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007603914	963	12.02.2021	More than 85 Years	Elderly	Female	COVID-19 (22d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10007604081	964	12.02.2021	More than 85 Years	Elderly	Female	Acute respiratory failure (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007604259	965	12.02.2021	More than 85 Years	Not Specified	Female	Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling, Other Medically Important Condition), Oedema (n/a - Unknown - Life Threatening, Disabling, Other Medically Important Condition), Pleural effusion (n/a - Unknown - Life Threatening, Disabling, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling, Other Medically Important Condition), Renal failure (n/a - Not Recovered/Not Resolved - Life Threatening, Disabling, Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Life Threatening, Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Heart rate - n/a - [n/a - n/a - n/a]), [FERROUS FUMARATE] (C - Anaemia - n/a - [n/a - n/a - n/a]), [ISOSORBIDE MONONITRATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - Blood cholesterol increased - n/a - [n/a - n/a - n/a])
EU-EC-10007573475	966	11.02.2021	More than 85 Years	Not Specified	Female	Anaphylactic shock (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Fatal - Results in Death), Diarrhoea (n/a - Fatal - Results in Death), Faecal vomiting (n/a - Fatal - Results in Death), Gastrointestinal haemorrhage (n/a - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Tachycardia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007573492	967	11.02.2021	More than 85 Years	Not Specified	Male	Pulmonary oedema (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007574895	968	11.02.2021	More than 85 Years	Not Specified	Male	Acute respiratory failure (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007575089	969	11.02.2021	More than 85 Years	Not Specified	Female	Abdominal distension (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening), Anal fistula (n/a - Fatal - Results in Death, Life Threatening), General physical health deterioration (n/a - Not Recovered/Not Resolved - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007578850	970	11.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	COAPROVEL 150 MG/12.5 MG TABLETS [HYDROCHLOROTHIAZIDE, IRBESARTAN] (C - n/a - Dose not changed - [n/a - 1{DF} - Oral]), [MIANSERIN HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - 30mg - Oral]), [NEBIVOLOL] (C - n/a - Dose not changed - [n/a - 1{DF} - Oral]), [OXAZEPAM] (C - n/a - Dose not changed - [n/a - 1{DF} - Oral]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - 75mg - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - 1{DF} - Oral])
EU-EC-10007578890	971	11.02.2021	More than 85 Years	Not Specified	Female	Diarrhoea (4h - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hypotension (4h - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (4h - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (4h - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Tachycardia (4h - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007578922	972	11.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]), KEPPRA 500 MG FILM-COATED TABLETS [LEVETIRACETAM] (S - Product used for unknown indication - Dose not changed - [n/a - 1{DF} - Oral]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (S - Product used for unknown indication - Dose not changed [n/a - 1{DF} - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (S - Product used for unknown indication - Dose not changed [n/a - 1{DF} - Oral]), [FUROSEMIDE] (S - Product used for unknown indication - Dose not changed - [n/a - 1{DF} - Oral]), [METFORMIN, METFORMIN HYDROCHLORIDE] (S - Product used for unknown indication - Dose not changed - [n/a - 1{DF} - Oral]),	Not reported
EU-EC-10007579349	973	11.02.2021	More than 85 Years	Elderly	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007579510	974	11.02.2021	More than 85 Years	Not Specified	Female	General physical health deterioration (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - Intramuscular])	ABILIFY [ARIPRAZOLE] (C - Anxiety - n/a - [n/a - 5mg - Oral]), AVAMYS [FLUTICASON FUROATE] (C - Hypersensitivity - n/a - [n/a - 2{DF} - Nasal]), BETMIGA [MIRABEGRON] (C - Polyuria - n/a - [n/a - 25mg - Oral]), EXELON [RIVASTIGMINE] (C - Dementia Alzheimer's type - n/a - [n/a - 3mg - Oral]), PRADAXA [DABIGATRAN ETEXILATE, DABIGATRAN ETEXILATE MESILATE] (C - Atrial fibrillation - n/a - [n/a - 110mg - Oral]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - Mineral supplementation - n/a - [n/a - 1{DF} - Oral]), [ESTRIOL] (C - n/a - n/a - [n/a - 1{DF} - Vaginal]), [FLECAINIDE ACETATE] (C - n/a - n/a - [n/a - 200mg - Oral]), [LEVOCABASTINE, LEVOCABASTINE HYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - 1{DF} - Ophthalmic]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 100ug - Oral]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 125ug - Oral]), [MICONAZOLE NITRATE, HYDROCORTISONE] (C - Pruritus - n/a - [n/a - 1{DF} - Cutaneous]), [NITRAZEPAM] (C - Insomnia - n/a - [n/a - 2.5mg - Oral]), [OXAZEPAM] (C - Anxiety - n/a - [n/a - 25mg - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - Pain - n/a - [n/a - 1000mg - Oral])
EU-EC-10007579635	975	11.02.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ELIQUIS [APIXABAN] (C - n/a - Unknown - [n/a - n/a - n/a]), [AMIODARONE, AMIODARONE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [BETAHISTINE MESILATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM, OMEPRAZOLE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007579737	976	11.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007579874	977	11.02.2021	More than 85 Years	Not Specified	Female	Cardiac failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007579876	978	11.02.2021	More than 85 Years	Not Specified	Male	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported

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EU-EC-10007580314	979	11.02.2021	More than 85 Years	Not Specified	Female	Infection (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	INSULATARD FLEXPEN [INSULIN HUMAN, INSULIN HUMAN (RDNA), INSULIN HUMAN ISOPHANE (RDNA)] (C - n/a - n/a - [n/a - 30[iU] - n/a]), NOVORAPID FLEXPEN [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - n/a]), [FLUCONAZOLE] (C - n/a - n/a - [n/a - 100mg - n/a]), [OXYCODONE HYDROCHLORIDE] (C - Pain - n/a - [n/a - 5mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 3g - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007580407	980	11.02.2021	65-85 Years	Elderly	Female	General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[DALTEPARIN SODIUM] (C - n/a - n/a - [n/a - n/a - Subcutaneous]), [LEVOTHYROXINE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007580463	981	11.02.2021	More than 85 Years	Not Specified	Female	Cardiovascular disorder (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	BRILIQUE 90 MG [TICAGRELOR] (C - n/a - Unknown - [n/a - 2{DF} - n/a]), EVISTA 60 MG [RALOXIFENE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [ANHYDROUS LEVOTHYROXINE SODIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [BUMETANIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [DRIED FERROUS SULFATE, FERROUS SULFATE, FERROUS SULPHATE SESQUIHYDRATE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [LORMETAZEPAM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [OMEPRAZOLE, OMEPRAZOLE SODIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [PARACETAMOL] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [RAMIPRIL] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - Unknown - [n/a - 1{DF} - n/a])
EU-EC-10007580612	982	11.02.2021	Not Specified	Adult	Male	Cough (n/a - Unknown - Other Medically Important Condition), Haemorrhage (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007581296	983	11.02.2021	65-85 Years	Not Specified	Male	Cold sweat (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	INSUMAN BASAL [INSULIN HUMAN, INSULIN HUMAN ISOPHANE (RDNA)] (C - n/a - Unknown - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - Unknown - [n/a - .5{DF} - n/a]), NOT AVAILABLE (C - n/a - Unknown - [n/a - 1{DF} - n/a]), OZEMPIC 0.25 MG [SEMAGLUTIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [ALLOPURINOL] (C - n/a - Unknown - [n/a - .5{DF} - n/a]), [ATORVASTATIN] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [BENSERAZIDE HYDROCHLORIDE, LEVODOPA, BENSERAZIDE, LEVODOPA] (C - n/a - Unknown - [n/a - 1.5{DF} - n/a]), [BUMETANIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [FENTANYL] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [LORMETAZEPAM] (C - n/a - Unknown - [n/a - .5{DF} - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 2{DF} - n/a]), [PARACETAMOL] (C - n/a - Unknown - [n/a - 2{DF} - n/a]), [PIPAMPERONE, PIPAMPERONE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 30{drp} - n/a]), [TAMSULOSIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a])
EU-EC-10007582271	984	11.02.2021	Not Specified	Elderly	Male	Asthenia (6d - Fatal - Results in Death), Chills (6d - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Malaise (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007582669	985	11.02.2021	65-85 Years	Not Specified	Not Specified	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007582961	986	11.02.2021	More than 85 Years	Not Specified	Male	Asthenia (24h - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), General physical condition abnormal (24h - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007583238	987	11.02.2021	More than 85 Years	Not Specified	Female	General physical health deterioration (4d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007583472	988	11.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007584467	989	11.02.2021	65-85 Years	Not Specified	Male	Diarrhoea (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007584469	990	11.02.2021	More than 85 Years	Not Specified	Male	Cough (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007584512	991	11.02.2021	65-85 Years	Not Specified	Male	Cachexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE, BECLOMETASONE PROPIONATE, FORMOTEROL FUMARATE HYDRATE, FORMOTEROL FUMARATE DIHYDRATE PH.EUR., BECLOMETASONE DIPROPIONATE PH. EUR., FORMOTEROL FUMARATE DIHYDRATE PH.EUR., BECLOMETASONE DIPROPIONATE PH. EUR., FORMOTEROL FUMARATE DIHYDRATE, BECLOMETASONE DIPROPIONATE ANHYDROUS] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE, BISOPROLOL FUMARATE, ACETYLSALICYLIC ACID, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - 500mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 500mg - n/a])
EU-EC-10007584814	992	11.02.2021	18-64 Years	Not Specified	Male	Pyrexia (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death), Urosepsis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007585761	993	11.02.2021	More than 85 Years	Not Specified	Male	Death (0d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - n/a])	[LEVOCETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OLMESARTAN MEDOXOMIL, AMLODIPINE, HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ROSUVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [TIOTROPIUM, TIOTROPIUM BROMIDE, TIOTROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007587136	994	11.02.2021	More than 85 Years	Not Specified	Female	Hypotension (n/a - Fatal - Results in Death), Melaena (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007587714	995	11.02.2021	More than 85 Years	Elderly	Female	Drug ineffective (4d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - Not applicable - [n/a - 75mg - Oral]), ESOMEPRAZOLE [ESOMEPRAZOLE] (C - n/a - Not applicable - [n/a - 20mg - Oral]), [FUROSEMIDE] (C - n/a - Not applicable - [n/a - 40mg - Oral])
EU-EC-10007589613	996	11.02.2021	More than 85 Years	Elderly	Male	Cough (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (2d - Recovered/Resolved - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [23d - 1{DF} - n/a])	MELATONIN [MELATONIN] (C - Insomnia - n/a - [n/a - 3mg - Oral]), TRAJENTA [LINAGLIPTIN] (C - Type 2 diabetes mellitus - n/a - [n/a - 5mg - Oral]), [ACETYLSALICYLIC ACID, ACETYLSALICYLIC ACID, MAGNESIUM OXIDE] (C - Anticoagulant therapy - n/a - [n/a - 75mg - Oral]), [ALLOPURINOL] (C - Gouty arthritis - n/a - [n/a - 100mg - Oral]), [CYANOCOBALAMIN] (C - Vitamin B12 deficiency - n/a - [n/a - 1mg - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Diuretic therapy - n/a - [n/a - 40mg - Oral]), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Heart rate irregular - n/a - [n/a - 50mg - Oral]), [MIRTAZAPINE] (C - Insomnia - n/a - [n/a - 15mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - Oral]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - [n/a - 750mg - Oral]), [TRIMETHOPRIM] (C - Prophylaxis urinary tract infection - n/a - [n/a - 100mg - Oral]), [VITAMIN D] (C - Vitamin supplementation - n/a - [n/a - 50ug - Oral])

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EU-EC-10007589645	997	11.02.2021	More than 85 Years	Elderly	Female	Atrial fibrillation (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ACRIVASTINE, DIPHENHYDRAMINE HYDROCHLORIDE, DIPHENHYDRAMINE HYDROCHLORIDE, ZINC ACETATE] (C - Pruritus - n/a - [n/a - 8mg - Oral]), [ALLOPURINOL] (C - Gouty arthritis - n/a - [n/a - 100mg - Oral]), [BETAHISTINE DIHYDROCHLORIDE, BETAHISTINE HYDROCHLORIDE] (C - Meniere's disease - n/a - [n/a - 8mg - Oral]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE] (C - Depression - n/a - [n/a - 20mg - Oral]), [CYANOCOBALAMIN] (C - Vitamin B12 deficiency - n/a - [n/a - 1mg - Oral]), [EPINEPHRINE BITARTRATE, LIDOCAINE HYDROCHLORIDE, LIDOCAINE, LIDOCAINE HYDROCHLORIDE] (C - Pruritus - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Diuretic therapy - n/a - [n/a - 40mg - Oral]), [FUROSEMIDE] (C - Diuretic therapy - n/a - [n/a - 80mg - Oral]), [GABAPENTIN] (C - Neuralgia - n/a - [n/a - 300mg - Oral]), [GLYCERYL TRINITRATE] (C - Cardiac disorder - n/a - [n/a - 1{DF} - n/a]), [MAGNESIUM OXIDE, MAGNESIUM OXIDE, LIGHT] (C - Constipation - n/a - [n/a - n/a - Oral]), [OXAZEPAM] (C - Sedative therapy - n/a - [n/a - 15mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Gastroesophageal reflux disease - n/a - [n/a - 40mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - Oral]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - [n/a - 1500mg - Oral]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - [n/a - 750mg - Oral]), [POVIDONE, POVIDONE K25] (C - Dry eye - n/a - [n/a - 1{DF} - Ophthalmic]), [PROPRANOLOL HYDROCHLORIDE] (C - Tremor - n/a - [n/a - 20mg - Oral]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 1{DF} - Oral]), [TRAMADOL HYDROCHLORIDE] (C - Pain - n/a - [n/a - 50mg - Oral])
EU-EC-10007565174	998	10.02.2021	65-85 Years	Not Specified	Female	Asthenia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[VALSARTAN, HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007565238	999	10.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Lip oedema (n/a - Recovering/Resolving - Results in Death), Pyrexia (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ALPRAZOLAM] (C - n/a - n/a - [n/a - .125mg - Oral]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 25ug - Oral])
EU-EC-10007565255	1000	10.02.2021	More than 85 Years	Not Specified	Female	Coronavirus infection (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Recovering/Resolving - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007565298	1001	10.02.2021	More than 85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death), Fatigue (n/a - Not Recovered/Not Resolved - Results in Death), Hypoperfusion (n/a - Not Recovered/Not Resolved - Results in Death), Pain in jaw (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007565301	1002	10.02.2021	More than 85 Years	Not Specified	Female	Intracranial haematoma (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007565314	1003	10.02.2021	More than 85 Years	Not Specified	Female	Cholecystitis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007566773	1004	10.02.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007566787	1005	10.02.2021	18-64 Years	Not Specified	Male	Breath sounds abnormal (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypopnoea (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Illness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Respiratory rate increased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007566790	1006	10.02.2021	More than 85 Years	Not Specified	Female	Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Upper respiratory tract infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007567201	1007	10.02.2021	More than 85 Years	Not Specified	Male	COVID-19 pneumonia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007567352	1008	10.02.2021	More than 85 Years	Not Specified	Male	Thrombotic stroke (10d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007568351	1009	10.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[BUPRENORPHINE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007568359	1010	10.02.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular])	PROLIA [DENOSUMAB] (C - n/a - n/a - [n/a - n/a - n/a]), [BUPRENORPHINE] (C - n/a - n/a - [n/a - n/a - Transdermal]), [CARBOMER, CARBOMER 974P] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [FLUTICASONE PROPIONATE, SALMETEROL, FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [LACTULOSE] (C - n/a - n/a - [n/a - n/a - Oral]), [MACROGOL 4000] (C - n/a - n/a - [n/a - n/a - Oral]), [MEMANTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [METOCLOPRAMIDE, METOCLOPRAMIDE HYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [ONDANSETRON, ONDANSETRON HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [OXYCODONE, OXYCODONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - Intravenous (not otherwise specified)]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - Oral]), [THEOPHYLLINE, THEOPHYLLINE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [TIOTROPIUM, TIOTROPIUM BROMIDE, TIOTROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)]), [WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BP] (C - n/a - n/a - [n/a - n/a - Oral]),
EU-EC-10007568391	1011	10.02.2021	65-85 Years	Elderly	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[AMLODIPINE] (C - Hypertension - n/a - [n/a - n/a - Oral]), [CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [MELATONIN] (C - Insomnia - n/a - [n/a - n/a - Oral]), [MEMANTINE HYDROCHLORIDE] (C - Dementia Alzheimer's type - n/a - [n/a - n/a - Oral]), [OXAZEPAM] (C - Restlessness - n/a - [n/a - n/a - Oral]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - Oral])
EU-EC-10007568772	1012	10.02.2021	18-64 Years	Not Specified	Male	Cardiac failure (3d - Fatal - Results in Death), Left ventricular failure (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported

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EU-EC-10007568780	1013	10.02.2021	65-85 Years	Not Specified	Male	Aortic aneurysm (n/a - Fatal - Results in Death), COVID-19 pneumonia (n/a - Fatal - Results in Death), Respiratory failure (n/a - Fatal - Results in Death), Superinfection bacterial (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007568847	1014	10.02.2021	More than 85 Years	Not Specified	Male	Apnoea (4d - Fatal - Results in Death), Cough (4d - Fatal - Results in Death), Pyrexia (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	OLANZAPINE TEVA [OLANZAPINE] (C - n/a - n/a - [19d - 10mg - n/a]), [BUPROPION HYDROCHLORIDE] (C - n/a - n/a - [19d - 300mg - n/a]), [FENTANYL] (C - n/a - n/a - [20d - 1{DF} - Transdermal]), [LACTULOSE] (C - n/a - n/a - [5d - 15mL - n/a]), [SODIUM PICOSULFATE] (C - n/a - n/a - [5d - 15{drp} - n/a])
EU-EC-10007571573	1015	10.02.2021	18-64 Years	Not Specified	Female	Brain injury (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	SEEBRI BREEZHALER [GLYCOPYRRONIUM BROMIDE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Cardiac failure - n/a - [n/a - n/a - n/a]), [PERINDOPRIL, PERINDOPRIL TERT-BUTYLAMINE] (C - Cardiac failure - n/a - [n/a - n/a - n/a]), [SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [SOLIFENACIN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007571961	1016	10.02.2021	More than 85 Years	Elderly	Male	Cardiac arrest (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported
EU-EC-10007573134	1017	10.02.2021	More than 85 Years	Elderly	Male	Haemorrhagic stroke (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), [ACETYLSALICYLIC ACID] (S - n/a - Drug withdrawn - [n/a - n/a - Oral])	[CYANOCOBALAMIN] (C - Vitamin B12 deficiency - n/a - [n/a - n/a - n/a])
EU-EC-10007573139	1018	10.02.2021	Not Specified	Elderly	Male	COVID-19 (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a])	Not reported
EU-EC-10007573190	1019	10.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Hypothermia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	NOT AVAILABLE (C - n/a - Unknown -), [AMIODARONE HYDROCHLORIDE] (C - n/a - Unknown -), [CANDESARTAN CILEXETIL] (C - n/a - Unknown -), [CITICOLINE, CITICOLINE SODIUM] (C - n/a - Unknown -), [FERROUS (II) GLYCINE SULFATE COMPLEX] (C - n/a - Unknown -), [FUROSEMIDE] (C - n/a - Unknown -), [OMEPRAZOLE] (C - n/a - Unknown -), [WARFARIN SODIUM] (C - n/a - Unknown -)

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EU-EC-10007573438	1020	10.02.2021	More than 85 Years	Elderly	Female	Arterial occlusive disease (n/a - Fatal - Results in Death), COVID-19 pneumonia (8d - Fatal - Results in Death), Circulatory collapse (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007573862	1021	10.02.2021	65-85 Years	Not Specified	Male	COVID-19 pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007574145	1022	10.02.2021	More than 85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007574638	1023	10.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [BICALUTAMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [CANDESARTAN CILEXETIL] (C - n/a - n/a - [n/a - n/a - n/a]), [DIGOXIN] (C - n/a - n/a - [n/a - n/a - n/a]), [FINASTERIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007574768	1024	10.02.2021	More than 85 Years	Not Specified	Female	Fall (16d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007575039	1025	10.02.2021	More than 85 Years	Elderly	Female	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ileus paralytic (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Microcytic anaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007575387	1026	10.02.2021	65-85 Years	Not Specified	Male	Haematemesis (n/a - Fatal - Results in Death), Upper gastrointestinal haemorrhage (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007575978	1027	10.02.2021	18-64 Years	Not Specified	Female	Dyspnoea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007576645	1028	10.02.2021	More than 85 Years	Elderly	Female	Asthenia (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Not Recovered/Not Resolved -), Hypotonia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	XARELTO 15 MG [RIVAROXABAN] (C - Atrial fibrillation - n/a - [n/a - 1{DF} - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 1{DF} - n/a])

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EU-EC-10007576711	1029	10.02.2021	More than 85 Years	Not Specified	Female	Circulatory collapse (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007577294	1030	10.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	[ALENDRONATE SODIUM, ALENDRONIC ACID] (C - Osteoporosis - n/a - [n/a - 70mg - Oral]), [CARBOMER, CARBOMER 980] (C - Dry eye - n/a - [n/a - n/a - Subconjunctival]), [CYANOCOBALAMIN] (C - Vitamin B12 deficiency - n/a - [n/a - 1mg - Oral]), [DONEPEZIL HYDROCHLORIDE] (C - Dementia Alzheimer's type - n/a - [n/a - 5mg - Oral]), [METFORMIN HYDROCHLORIDE] (C - Type 2 diabetes mellitus - n/a - [n/a - 500mg - Oral]), [VITAMIN D] (C - Osteoporosis - n/a - [n/a - 25ug - Oral])
EU-EC-10007577296	1031	10.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007577298	1032	10.02.2021	65-85 Years	Elderly	Male	Respiratory failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	XARELTO [RIVAROXABAN] (C - Thrombosis prophylaxis - n/a - [n/a - 15mg - Oral]), [CHLORAMPHENICOL] (C - Eye infection - n/a - [n/a - 1{DF} - Subconjunctival]), [CYANOCOBALAMIN] (C - Vitamin B12 deficiency - n/a - [n/a - 1mg - Oral]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM DIHYDRATE, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE] (C - Gastroesophageal reflux disease - n/a - [n/a - 40mg - Oral]), [IPRATROPIUM BROMIDE, SALBUTAMOL, SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE MONOHYDRATE] (C - Bronchospasm - n/a - [n/a - n/a - Respiratory (inhalation)]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - Oral]), [RISPERIDONE] (C - Mania - n/a - [n/a - 1mg - Oral]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [n/a - 10{drp} - Oral]), [ZOPICLONE] (C - Insomnia - n/a - [n/a - 7.5mg - Oral])
EU-EC-10007577300	1033	10.02.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007577301	1034	10.02.2021	More than 85 Years	Elderly	Male	Respiratory failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE] (C - Hypertension - n/a [n/a - 5mg - Oral]), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [n/a - 2{DF} - Oral]), [FLUORIDE, SODIUM FLUORIDE] (C - Dental caries - n/a - [n/a - n/a - Dental]), [GABAPENTIN] (C - Neuralgia - n/a - [n/a - 300mg - Oral]), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - Pain - n/a - [n/a - 5mg - Subcutaneous]), [NITROFURANTOIN] (C - Prophylaxis urinary tract infection - n/a - [n/a - 50mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - Oral]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 1{DF} - Oral]), [SERTRALINE] (C - Anxiety - n/a - [n/a - 50mg - Oral]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [n/a - 10{drp} - Oral]), [TAMSULOSIN HYDROCHLORIDE] (C - Dysuria - n/a - [n/a - .4mg - Oral])

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EU-EC-10007577309	1035	10.02.2021	More than 85 Years	Elderly	Female	Cerebral thrombosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[ACETYLSALICYLIC ACID, ACETYLSALICYLIC ACID, MAGNESIUM OXIDE] (C - Anticoagulant therapy - n/a - [n/a - 75mg - Oral]), [DIGOXIN] (C - Heart rate irregular - n/a - [n/a - 62.5ug - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Diuretic therapy - n/a - [n/a - 40mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - Oral])
EU-EC-10007577313	1036	10.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007577324	1037	10.02.2021	65-85 Years	Elderly	Male	Pyrexia (n/a - Not Recovered/Not Resolved - Results in Death), Respiratory failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	[BENDROFLUMETHIAZIDE, POTASSIUM CHLORIDE] (C - Oedema - n/a - [n/a - 1{DF} - Oral]), [IBUPROFEN] (C - Pain - n/a - [n/a - 400mg - Oral]), [MAGNESIUM OXIDE, MAGNESIUM OXIDE, LIGHT] (C - Constipation - n/a - [n/a - 1g - Oral]), [MOMETASONE FUROATE] (C - Eczema - n/a - [n/a - 1{DF} - Cutaneous]), [OLANZAPINE] (C - Mental disorder - n/a - [n/a - 5mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Gastroesophageal reflux disease - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1g - Oral]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 1{DF} - Oral]), [SERTRALINE] (C - Depression - n/a - [n/a - 200mg - Oral]), [VITAMIN D, CALCIUM] (C - Vitamin D deficiency - n/a - [n/a - 35ug - Oral])
EU-EC-10007577326	1038	10.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007577327	1039	10.02.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	BETMIGA [MIRABEGRON] (C - Hypertonic bladder - n/a - [n/a - 50mg - Oral]), XARELTO [RIVAROXABAN] (C - Thrombosis prophylaxis - n/a - [n/a - 15mg - Oral]), [BISACODYL] (C - Constipation - n/a - [n/a - 5mg - Oral]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - n/a - Oral]), [FLUORIDE, SODIUM FLUORIDE] (C - Dental disorder prophylaxis - n/a - [n/a - n/a - Dental]), [FUROSEMIDE] (C - Diuretic therapy - n/a - [n/a - 40mg - Oral]), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Heart rate irregular - n/a - [n/a - 50mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Gastroesophageal reflux disease - n/a - [n/a - 40mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - Oral]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - [n/a - 750mg - Oral]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 1{DF} - Oral]), [VITAMIN D, CALCIUM] (C - Mineral supplementation - n/a - [n/a - n/a - Oral])

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EU-EC-10007577329	1040	10.02.2021	More than 85 Years	Elderly	Male	Circulatory collapse (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	AVAMYS [FLUTICASON FUROATE] (C - Rhinitis allergic - n/a - [234d - 55ug - Nasal]), BUPRENORPHINE "TEVA" [BUPRENORPHIN, BUPRENORPHINHYDROCHLORID] (C - Pain n/a - [267d - 1{DF} - n/a]), CIRCADIN [MELATONIN] (C - Insomnia - n/a - [442d - 2mg - Oral]), [DUTASTERIDE] (C - Dysuria - n/a - [1028d - .5mg - Oral]), [MIRTAZAPINE] (C - Depression - n/a - [584d - 7.5mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [2137d - n/a - Oral]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [227d - n/a - Oral]), [SERTRALINE] (C - Depression - n/a - [640d - 50mg - Oral]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [577d - 15{drp} - Oral]), [VITAMIN D, CALCIUM] (C - Vitamin supplementation - n/a - [717d - 1{DF} - Oral])
EU-EC-10007577331	1041	10.02.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007577332	1042	10.02.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007577981	1043	10.02.2021	65-85 Years	Not Specified	Male	Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007579173	1044	10.02.2021	65-85 Years	Not Specified	Male	Myocardial infarction (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007554953	1045	09.02.2021	More than 85 Years	Not Specified	Male	Dyspnoea (n/a - Unknown - Other Medically Important Condition), Haemoptysis (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007555566	1046	09.02.2021	65-85 Years	Elderly	Female	General physical health deterioration (n/a - Fatal - Results in Death), Somnolence (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - n/a])	Not reported
EU-EC-10007555914	1047	09.02.2021	More than 85 Years	Not Specified	Male	Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007556440	1048	09.02.2021	65-85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMITRIPTYLINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [BENDROFLUMETHIAZIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [LISINOPRIL, LISINOPRIL DIHYDRATE] (C - n/a - n/a - [n/a - 1{DF} - n/a])

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EU-EC-10007556452	1049	09.02.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death), Drug ineffective (n/a - Fatal - Results in Death), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -), Virologic failure (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007556468	1050	09.02.2021	More than 85 Years	Not Specified	Male	Pneumonitis (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DIGOXIN] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [QUININE] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN, WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007557025	1051	09.02.2021	65-85 Years	Not Specified	Female	Cardiac failure (n/a - Fatal - Results in Death), Myocardial infarction (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007557069	1052	09.02.2021	65-85 Years	Not Specified	Female	Cardio-respiratory arrest (0d - Fatal - Results in Death), Cardiovascular disorder (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007557115	1053	09.02.2021	More than 85 Years	Not Specified	Female	Fall (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007557236	1054	09.02.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Upper gastrointestinal haemorrhage (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007557613	1055	09.02.2021	More than 85 Years	Elderly	Female	Dyspnoea (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Rales (n/a - Fatal - Results in Death), Respiratory failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - Drug withdrawn - [n/a - 1{DF} - n/a]), [BROMAZEPAM] (C - n/a - Drug withdrawn - [n/a - 1{DF} - n/a]), [COLECALCIFEROL] (C - n/a - Drug withdrawn - [n/a - 1{DF} - n/a]), [HALOPERIDOL] (C - n/a - Drug withdrawn - [n/a - .5{DF} - n/a]), [METHYLPREDNISOLONE] (C - n/a - Drug withdrawn - [n/a - .5{DF} - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - Drug withdrawn - [n/a - 1{DF} - n/a]), [PARACETAMOL] (C - n/a - Drug withdrawn - [n/a - 1{DF} - n/a])
EU-EC-10007557616	1056	09.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007558047	1057	09.02.2021	More than 85 Years	Not Specified	Male	Pulmonary sepsis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007558108	1058	09.02.2021	More than 85 Years	Elderly	Female	COVID-19 (7d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007558332	1059	09.02.2021	More than 85 Years	Not Specified	Female	Bronchopneumopathy (n/a - Fatal - Results in Death), Cardiac failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007558333	1060	09.02.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Unknown - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007558334	1061	09.02.2021	Not Specified	Elderly	Male	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dehydration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia bacterial (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007558440	1062	09.02.2021	More than 85 Years	Not Specified	Male	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007558544	1063	09.02.2021	65-85 Years	Elderly	Male	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007558601	1064	09.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007558643	1065	09.02.2021	More than 85 Years	Not Specified	Female	Acute pulmonary oedema (n/a - Fatal - Results in Death), Cardiac failure acute (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	LYRICA 75 MG HARD CAPSULES [PREGABALIN] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [VERAPAMIL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007558678	1066	09.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007558807	1067	09.02.2021	More than 85 Years	Not Specified	Female	Dehydration (1d - Fatal - Results in Death), Depressed level of consciousness (1d - Fatal - Results in Death), Diarrhoea (1d - Fatal - Results in Death), Erythema (1d - Fatal - Results in Death), Respiratory distress (1d - Fatal - Results in Death), Vomiting (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007558883	1068	09.02.2021	More than 85 Years	Not Specified	Male	Myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007558909	1069	09.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007558916	1070	09.02.2021	More than 85 Years	Not Specified	Female	Myalgia (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007559149	1071	09.02.2021	65-85 Years	Not Specified	Female	Cardiogenic shock (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocardial infarction (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[COLECALCIFEROL] (C - n/a - n/a - [n/a - 800[iU] - Oral]), [CYANOCOBALAMIN, HYDROXOCOBALAMIN] (C - n/a - n/a - [n/a - 2mg - Oral]), [FOLIC ACID] (C - n/a - n/a - [n/a - 1mg - Oral]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (C - n/a - n/a - [n/a - 1mg - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - 7.5mg - Oral])
EU-EC-10007559165	1072	09.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	BUPRENORPHINE [BUPRENORPHINE] (C - n/a - n/a - [n/a - n/a - n/a]), MIDAZOLAM [MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [CLOMETHIAZOLE, CLOMETHIAZOLE EDISILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCOPYRRONIUM BROMIDE, GLYCOPYRRONIUM BROMIDE, NEOSTIGMINE METHYLSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MEMANTINE] (C - n/a - n/a - [n/a - n/a - n/a]), [METHENAMINE HIPPURATE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007559180	1073	09.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[ALENDRONATE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [BUDESONIDE, BUDESONIDE, MICRONISED] (C - n/a - n/a - [n/a - n/a - n/a]), [CALCIUM, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007560067	1074	09.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007560068	1075	09.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	[LACTULOSE] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007560443	1076	09.02.2021	More than 85 Years	Not Specified	Male	Acute myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	HUMALOG [INSULIN LISPRO] (C - Diabetes mellitus - n/a - [n/a - n/a - Subcutaneous]), LANTUS [INSULIN GLARGINE] (C - Diabetes mellitus - n/a - [n/a - 8[iU] - Intramuscular]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - 20mg - Oral]), [ATORVASTATIN CALCIUM] (C - n/a - n/a - [n/a - 8[iU] - n/a]), [CLONAZEPAM] (C - n/a - n/a - [n/a - 5{DF} - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [SIMVASTATIN] (C - n/a - n/a - [n/a - 20mg - Oral]), [SULODEXIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 75mg - Oral])
EU-EC-10007560832	1077	09.02.2021	65-85 Years	Not Specified	Female	Sepsis (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - 1{DF} - Oral]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 40mg - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - Oral]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [LACTULOSE] (C - n/a - n/a - [n/a - 15mL - n/a]), [METOCLOPRAMIDE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [NIFEDIPINE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON HYDROCHLORIDE DIHYDRATE] (C - n/a - n/a - [n/a - 4mg - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg/m3 - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1g - n/a]), [POTASSIUM CHLORIDE] (C - n/a - n/a -), [PREDNISOLONE] (C - n/a - n/a - [n/a - 10mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007561004	1078	09.02.2021	More than 85 Years	Not Specified	Not Specified	Dysuria (1d - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (3d - Fatal - Results in Death), Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	[FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 25mg - Oral]), [RAMIPRIL] (C - n/a - n/a - [n/a - 5mg - Oral])

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EU-EC-10007561109	1079	09.02.2021	More than 85 Years	Not Specified	Male	Asthenia (3d - Fatal - Results in Death, Other Medically Important Condition), Death (0d - Fatal - Results in Death), Fall (3d - Fatal - Results in Death, Other Medically Important Condition), Restlessness (1d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007561548	1080	09.02.2021	65-85 Years	Not Specified	Female	Pulmonary artery thrombosis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007562142	1081	09.02.2021	More than 85 Years	Not Specified	Female	Abdominal pain upper (n/a - Fatal - Results in Death, Life Threatening), Intestinal perforation (n/a - Fatal - Results in Death, Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CARBIDOPA, LEVODOPA, LEVODOPA, CARBIDOPA MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DICLOFENAC, DICLOFENAC POTASSIUM, DICLOFENAC SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [GLUCOSAMINE, GLUCOSAMINE SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MEMANTINE] (C - n/a - n/a - [n/a - 20mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1300mg - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - 12.5mg - n/a])
EU-EC-10007562199	1082	09.02.2021	65-85 Years	Not Specified	Male	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Diarrhoea (1d - Recovered/Resolved - Other Medically Important Condition), Gait disturbance (n/a - Unknown - Other Medically Important Condition), Hypoaesthesia (0d - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (0d - Recovered/Resolved - Life Threatening, Disabling), Nausea (1d - Recovered/Resolved - Other Medically Important Condition), Near death experience (n/a - Unknown - Other Medically Important Condition), Palpitations (0d - Recovered/Resolved - Life Threatening), Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007562592	1083	09.02.2021	65-85 Years	Not Specified	Female	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Pneumonitis (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	EDOXABAN [EDOXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRIMIPRAMINE, TRIMIPRAMINE MALEATE] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007563659	1084	09.02.2021	65-85 Years	Elderly	Female	General physical health deterioration (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	CIRCADIN [MELATONIN] (C - Insomnia - n/a - [n/a - 2mg - Oral]), MEMANTINE RATIOPHARM [MEMANTINE HYDROCHLORIDE] (C - Dementia Alzheimer's type - n/a - [n/a - 20mg - Oral]), [BUPRENORPHINE] (C - Pain - n/a - [6d - 1{DF} - Cutaneous]), [MECILLINAM, PIVMECILLINAM, PIVMECILLINAM HYDROCHLORIDE] (C - Urinary tract infection - n/a - [n/a - 400mg - Oral]), [MIANSERIN HYDROCHLORIDE] (C - Restlessness - n/a - [n/a - 10mg - Oral]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 1{DF} - Oral]), [QUININE HYDROCHLORIDE] (C - Muscle spasms - n/a - [n/a - 100mg - Oral]), [RISPERIDONE] (C - Mental disorder - n/a - [n/a - n/a - Oral])
EU-EC-10007564012	1085	09.02.2021	65-85 Years	Not Specified	Male	Pneumonitis (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DONEPEZIL] (C - n/a - n/a - [n/a - n/a - n/a]), [FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LOPERAMIDE, LOPERAMIDE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007564118	1086	09.02.2021	18-64 Years	Adult	Male	Sudden death (1d - Fatal - Results in Death)	ADALIMUMAB [ADALIMUMAB] (S - Crohn's disease - Drug withdrawn - [325d - 40mg - Subcutaneous]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported
EU-EC-10007564737	1087	09.02.2021	More than 85 Years	Not Specified	Female	Dyspnoea (15min - Unknown -), Pallor (15min - Unknown -), Sudden cardiac death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007564755	1088	09.02.2021	More than 85 Years	Not Specified	Female	Cerebrovascular accident (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	KOELZALF / BRAND NAME NOT SPECIFIED [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), NOVOMIX 30 FLEXPEN 100 UNITS/ML SUSPENSION FOR INJECTION IN PRE-FILLED PEN [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007541938	1089	08.02.2021	More than 85 Years	Not Specified	Female	Hypertension (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007542039	1090	08.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Panic attack (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - Anxiety - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [SOTALOL, SOTALOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN, WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007542902	1091	08.02.2021	65-85 Years	Not Specified	Female	Food refusal (10d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[BISOPROLOL FUMARATE] (C - Hypertension - n/a - [n/a - 2.5mg - Oral]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - Osteoporosis - n/a - [n/a - 1{DF} - Oral]), [LATANOPROST] (C - Glaucoma - n/a - [n/a - n/a - Ophthalmic]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 20mg - Oral])
EU-EC-10007542918	1092	08.02.2021	65-85 Years	Not Specified	Female	Decreased appetite (5d - Fatal - Results in Death), Depressed level of consciousness (5d - Fatal - Results in Death), General physical health deterioration (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007542921	1093	08.02.2021	More than 85 Years	Not Specified	Female	Bedridden (21d - Fatal - Results in Death), Death (1d - Fatal - Results in Death), Hypophagia (21d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	XARELTO [RIVAROXABAN] (C - n/a - n/a -), [BUDESONIDE, BUDESONIDE, MICRONISED] (C - n/a - n/a -), [DONEPEZIL HYDROCHLORIDE] (C - n/a - n/a -), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a -), [FUROSEMIDE] (C - n/a - n/a -), [HYDROXOCOBALAMIN] (C - n/a - n/a -), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a -), [MIRTAZAPINE] (C - n/a - n/a -), [PARACETAMOL] (C - n/a - n/a -), [POTASSIUM CHLORIDE] (C - n/a - n/a -), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a -), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a -)
EU-EC-10007542923	1094	08.02.2021	More than 85 Years	Not Specified	Female	Bedridden (17d - Fatal - Results in Death), Fatigue (17d - Fatal - Results in Death), General physical health deterioration (7d - Fatal - Results in Death), Pneumonia aspiration (10d - Fatal - Results in Death), Productive cough (7d - Fatal - Results in Death), Pyrexia (1d - Recovered/Resolved With Sequelae - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved With Sequelae - Other Medically Important Condition), Vomiting (7d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007542925	1095	08.02.2021	More than 85 Years	Not Specified	Male	General physical health deterioration (5d - Fatal - Results in Death), Pyrexia (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - Atrial fibrillation - n/a - [n/a - 2.5mg - Oral]), [FLUTICASON PROPRIONATE] (C - Asthma - n/a - [n/a - 125ug - Respiratory (inhalation)])

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EU-EC-10007542928	1096	08.02.2021	More than 85 Years	Not Specified	Female	Apnoea (6d - Fatal - Results in Death), Bedridden (6d - Fatal - Results in Death), Dizziness (1d - Fatal - Results in Death), Dyspnoea (11d - Fatal - Results in Death), General physical health deterioration (14d - Fatal - Results in Death), Muscular weakness (11d - Fatal - Results in Death), Syncope (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007542952	1097	08.02.2021	More than 85 Years	Not Specified	Male	Heart rate decreased (3d - Fatal - Results in Death), Oxygen saturation decreased (3d - Fatal - Results in Death), Productive cough (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[LACTULOSE] (C - Constipation - n/a - [721d - 15mL - Oral]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [632d - 8{DF} - Oral])
EU-EC-10007542986	1098	08.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007543641	1099	08.02.2021	More than 85 Years	Elderly	Female	Apathy (4d - Fatal - Results in Death, Life Threatening), Bradycardia (4d - Fatal - Results in Death, Life Threatening), Bronchitis (4d - Fatal - Results in Death, Life Threatening), Death (4d - Fatal - Results in Death, Life Threatening), Febrile infection (4d - Fatal - Results in Death, Life Threatening), Rhonchi (4d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007543660	1100	08.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Hypertensive crisis (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007543726	1101	08.02.2021	65-85 Years	Elderly	Female	Sudden cardiac death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007543763	1102	08.02.2021	18-64 Years	Adult	Female	Aneurysm (n/a - Fatal - Results in Death), Subarachnoid haemorrhage (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - n/a - intramuscular])	[AMITRIPTYLINE HYDROCHLORIDE, CHLORDIAZEPOXIDE] (C - Headache - n/a - [n/a - n/a - n/a]), [DESOGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a])
EU-EC-10007543767	1103	08.02.2021	65-85 Years	Not Specified	Female	Abdominal pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Blood lactic acid increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intestinal dilatation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Intestinal ischaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007543856	1104	08.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [NOT AVAILABLE] (S - Ileus - Dose not changed - [n/a - 1000mg - n/a]), [NOT AVAILABLE] (S - Ileus, Pneumonia - Dose increased - [n/a - 1{DF} - n/a]), [NOT AVAILABLE] (S - Palliative care - Dose not changed - [n/a - 10mg - n/a])	Not reported
EU-EC-10007543864	1105	08.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 10mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1{DF} - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 45mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 500mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 7.5mg - n/a]), [CARBIDOPA, LEVODOPA, LEVODOPA, CARBIDOPA MONOHYDRATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [CARBOMER] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [THIAMINE HYDROCHLORIDE, DEXPANTHENOL, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007543875	1106	08.02.2021	65-85 Years	Not Specified	Male	Asthma (n/a - Fatal - Results in Death), Cardiac asthma (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	MELATONIN 1MG TABLET (C - n/a - n/a - [n/a - 1mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 100mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 20mg - n/a]), [FLUTICASON PROPRIONATE] (C - n/a - n/a - [n/a - 250ug - n/a])
EU-EC-10007543904	1107	08.02.2021	More than 85 Years	Not Specified	Male	Agitation (0d - Fatal - Results in Death), Cardiovascular disorder (0d - Fatal - Results in Death), Confusional state (0d - Fatal - Results in Death), Dyspnoea (0d - Fatal - Results in Death), Hypotension (0d - Fatal - Results in Death), Malaise (0d - Fatal - Results in Death), Neutropenia (0d - Fatal - Results in Death), Oxygen saturation decreased (0d - Fatal - Results in Death), Pyrexia (0d - Fatal - Results in Death), Respiratory disorder (0d - Fatal - Results in Death), Tachycardia (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	CIRCADIN PROLONGED-RELEASE TABLETS 2 MG [MELATONIN] (C - n/a - Unknown - [n/a - n/a - n/a]), RELVAR ELLIPTA 92 MICROGRAMS/22 MICROGRAMS INHALATION POWDER, PRE-DISPENSED [FLUTICASON FUROATE, VILANTEROL] (C - n/a - Unknown - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - Unknown - [n/a - n/a - n/a]), [BENSERAZIDE HYDROCHLORIDE, LEVODOPA] (C - n/a - Unknown - [n/a - n/a - n/a]), [BETAMETHASONE, CALCIPOTRIOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [CYANOCOBALAMIN] (C - n/a - Unknown - [n/a - n/a - n/a]), [ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [MOLSIDOMINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [NANDROLONE DECANOATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [PERINDOPRIL ARGININE] (C - n/a - Unknown - [n/a - n/a - n/a]), [TAMSULOSIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007544752	1108	08.02.2021	65-85 Years	Not Specified	Female	Malaise (0d - Fatal - Results in Death), Sudden death (0d - Fatal - Results in Death), Vomiting (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported

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EU-EC-10007545629	1109	08.02.2021	More than 85 Years	Not Specified	Female	Acute myocardial infarction (n/a - Fatal - Results in Death), Arteriosclerosis (n/a - Fatal - Results in Death), Arteriosclerosis coronary artery (n/a - Fatal - Results in Death), Atrophy (n/a - Fatal - Results in Death), Chronic obstructive pulmonary disease (n/a - Fatal - Results in Death), Embolism (n/a - Fatal - Results in Death), Gastric disorder (n/a - Fatal - Results in Death), Hepatic cirrhosis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	XARELTO [RIVAROXABAN] (C - Deep vein thrombosis - n/a - [n/a - n/a - n/a]), [MORPHINE, MORPHINE POLY(STYRENE-CO-DIVINYLBENZENE) SULFONATE, MORPHINE SULFATE, MORPHINE SULFATE PENTAHYDRATE, MORPHINE SULFATE PH. EUR.] (C - Dyspnoea, Pain - n/a - [5d - 60mg - n/a])
EU-EC-10007546319	1110	08.02.2021	More than 85 Years	Elderly	Male	Pneumonia (n/a - Fatal - Results in Death), Shock (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007546548	1111	08.02.2021	More than 85 Years	Not Specified	Female	Cardiac failure (7d - Fatal - Results in Death), Diet refusal (7d - Fatal - Results in Death), Disturbance in attention (7d - Fatal - Results in Death), Hyporesponsive to stimuli (7d - Fatal - Results in Death), Hypotension (7d - Fatal - Results in Death), Stupor (7d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007546642	1112	08.02.2021	18-64 Years	Not Specified	Male	Respiratory failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007547320	1113	08.02.2021	More than 85 Years	Not Specified	Female	Cyanosis (n/a - Recovered/Resolved -), Death (n/a - Fatal - Results in Death), Depressed level of consciousness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	EXELON [RIVASTIGMINE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOMER] (C - n/a - n/a - [n/a - .6mL - n/a]), [CASSIA, SENNA PODS] (C - n/a - n/a - [n/a - n/a - n/a]), [FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE, ANHYDROUS AMILORIDE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a -), [HALOPERIDOL, HALOPERIDOL BP] (C - n/a - n/a - [n/a - n/a - n/a]), [HALOPERIDOL] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - n/a - n/a -), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [MEMANTINE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARAFFIN] (C - n/a - n/a -), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a -), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [SOLIFENACIN SUCCINATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - n/a - n/a -), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007547940	1114	08.02.2021	More than 85 Years	Not Specified	Male	Atrial fibrillation (n/a - Fatal - Results in Death), Bronchitis (n/a - Fatal - Results in Death), Depressed level of consciousness (n/a - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	[CARBIDOPA, LEVODOPA, LEVODOPA, ANHYDROUS CARBIDOPA, LEVODOPA, CARBIDOPA MONOHYDRATE] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [CARBIDOPA, LEVODOPA] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [DIGOXIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 80mg - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 50mg - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - 29mg - n/a]), [WARFARIN, WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007548049	1115	08.02.2021	More than 85 Years	Not Specified	Female	Acute myocardial infarction (8d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	n/a -), PLAVIX [CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE] (C - Cardiovascular disorder - n/a -), RIVAROXABAN [RIVAROXABAN] (C - Cardiovascular disorder - n/a -), [ACETYLCYSTEINE] (C - Obstructive airways disorder - n/a -), [BUPRENORPHINE] (C - Pain - n/a -), [CINCHOCINE HYDROCHLORIDE, PREDNISOLONE, CINCHOCINE HYDROCHLORIDE, PREDNISOLONE CAPROATE] (C - n/a - n/a -), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a -), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Oedema - n/a -), [GLYCERYL TRINITRATE] (C - Cardiovascular disorder - n/a -), [ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE] (C - Cardiac disorder - n/a -), [LACTULOSE] (C - Constipation - n/a -), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hyperthyroidism - n/a -), [MACROGOL 3350, SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL 70%, LIQUID (CRYSTALLISING), SODIUM CITRATE, SORBITOL (E420), SODIUM LAURYL SULFOACETATE, SODIUM CITRATE, SORBITOL SOLUTION 70% (CRYSTALLISING) (PH. EUR.), SODIUM LAURYL SULFOACETATE, SODIUM LAURYL SULFOACETATE, TRISODIUM CITRATE, SORBITOL 70%, LIQUID (CRYSTALLISING), SORBITOL (E420), SODIUM LAURYL SULFOACETATE, SORBITOL (E420), SODIUM LAURYL SULFOACETATE, SODIUM CITRATE DIHYDRATE, SORBITOL, LIQUID (CRYSTALLISING), SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL, LIQUID (CRYSTALLISING), SODIUM CITRATE, SODIUM LAURYL SULFOACETATE 70%] (C - Constipation - n/a -), [METHENAMINE HIPPURATE] (C - Urinary tract infection - n/a -), [METOCLOPRAMIDE HYDROCHLORIDE] (C - Nausea - n/a -), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C -
EU-EC-10007548481	1116	08.02.2021	More than 85 Years	Elderly	Female	Asthenia (n/a - Unknown -), Cerebral haemorrhage (0d - Fatal - Results in Death, Other Medically Important Condition), Death (0d - Fatal - Results in Death, Other Medically Important Condition), Fatigue (n/a - Unknown -), Malaise (n/a - Unknown -), Myalgia (n/a - Unknown -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	PANTOPRAZOLE - GASTRO-RESISTANT TABLET (C - n/a - Not applicable - [n/a - n/a - Oral]), [AMLODIPINE, AMLODIPINE BESILATE] (C - Hypertension - Not applicable - [n/a - n/a - Oral]), [PARACETAMOL, CAFFEINE, CODEINE PHOSPHATE] (C - Rheumatoid arthritis - Not applicable - [n/a - n/a - Oral]), [PREDNISOLONE] (C - Rheumatoid arthritis - Not applicable - [n/a - n/a - Oral])

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EU-EC-10007548767	1117	08.02.2021	65-85 Years	Elderly	Female	Haemorrhagic stroke (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Headache (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular]), XARELTO [RIVAROXABAN] (S - n/a - n/a - [n/a - 10mg - n/a])	Not reported
EU-EC-10007549203	1118	08.02.2021	65-85 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007549625	1119	08.02.2021	65-85 Years	Not Specified	Not Specified	Aortic aneurysm rupture (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - n/a])	Not reported
EU-EC-10007550035	1120	08.02.2021	65-85 Years	Not Specified	Male	Cough (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Malaise (n/a - Unknown -), Myocardial infarction (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	LEVEMIR [INSULIN DETEMIR] (C - n/a - n/a - [n/a - n/a - n/a]), NOVORAPID [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASON PROPRIONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007550042	1121	08.02.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Life Threatening), Drug ineffective (n/a - Fatal - Results in Death, Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007551142	1122	08.02.2021	More than 85 Years	Not Specified	Male	Arrhythmia (n/a - Fatal - Results in Death), COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ASCORBIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ZINC] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007551626	1123	08.02.2021	More than 85 Years	Elderly	Female	COVID-19 pneumonia (29d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007540748	1124	07.02.2021	Not Specified	Not Specified	Not Specified	Paralysis (n/a - Fatal - Results in Death, Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007540753	1125	07.02.2021	Not Specified	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death), Chest pain (n/a - Recovered/Resolved -), Incontinence (n/a - Not Recovered/Not Resolved -), Muscular weakness (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007540868	1126	07.02.2021	More than 85 Years	Not Specified	Female	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	LANTUS [INSULIN GLARGINE] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), SITAGLIPTIN [SITAGLIPTIN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - Angina pectoris - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Angina pectoris - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Angina pectoris - n/a - [n/a - n/a - n/a]), [FELODIPINE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE] (C - Angina pectoris - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Osteoarthritis - n/a - [n/a - n/a - n/a])
EU-EC-10007540964	1127	07.02.2021	65-85 Years	Not Specified	Male	Hypertension (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Unknown - Other Medically Important Condition), Sudden death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ALFUZOSIN] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Hypertension - n/a - [n/a - n/a - n/a]), [FINASTERIDE] (C - Prostatism - n/a - [n/a - n/a - n/a]), [INDAPAMIDE, INDAPAMIDE HEMIHYDRATE] (C - Hypertension - n/a - [n/a - n/a - n/a])
EU-EC-10007535205	1128	06.02.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a n/a - [n/a - n/a - n/a]), [ACENOCOUMAROL] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [MACROGOL 4000] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007535306	1129	06.02.2021	65-85 Years	Not Specified	Not Specified	Haematemesis (1d - Fatal - Results in Death), Pneumonia aspiration (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007535469	1130	06.02.2021	65-85 Years	Not Specified	Female	Laryngeal dyspnoea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Seizure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	FEBUXOSTAT [FEBUXOSTAT] (C - n/a - n/a - [n/a - 80mg - Oral]), [CLOMIPRAMINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 75mg - Oral]), [INDAPAMIDE] (C - n/a - n/a - [n/a - 1.5mg - Oral]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - 15mg - Oral]), [LERCANIDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - Oral]), [MACROGOL 4000] (C - n/a - n/a - [n/a - 10g - Oral]), [MAGNESIUM, MAGNESIUM CARBONATE, MAGNESIUM PIDOLATE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 200mg - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - 10mg - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - 500mg - Oral]), [PERINDOPRIL ARGININE] (C - n/a - n/a - [n/a - 4mg - Oral]), [THIAMAZOLE] (C - n/a - n/a - [n/a - 10mg - Oral])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007536258	1131	06.02.2021	More than 85 Years	Elderly	Female	Myocardial infarction (n/a - Fatal - Results in Death), Nausea (n/a - Recovered/Resolved -), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	ELIQUIS 5 MG FILM-COATED TABLETS [APIXABAN] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [LACTULOSE] (C - n/a - n/a - [n/a - n/a - n/a]), [METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - 20{drp} - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [PANTOPRAZOLE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [POTASSIUM CHLORIDE, SODIUM CHLORIDE, CALCIUM CHLORIDE DIHYDRATE, SODIUM LACTATE] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007537763	1132	06.02.2021	65-85 Years	Not Specified	Male	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	TOUJEO 300 UNITS/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN [INSULIN GLARGINE] (C - n/a - n/a - [n/a - n/a - Subcutaneous]), [D,L-LYSINE ACETYLSALICYLATE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [FOLIC ACID] (C - n/a - n/a - [n/a - 5mg - Oral]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - Type 2 diabetes mellitus - n/a - [n/a - 850mg - Oral]), [PAROXETINE] (C - n/a - n/a - [n/a - 20mg - Oral]), [PRAVASTATIN SODIUM] (C - n/a - n/a - [n/a - 20mg - Oral]), [RAMIPRIL] (C - n/a - n/a - [n/a - 5mg - Oral])
EU-EC-10007538569	1133	06.02.2021	More than 85 Years	Not Specified	Female	Body temperature increased (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE] (C - n/a - n/a - [n/a - 10mg - n/a])
EU-EC-10007522843	1134	05.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Headache (n/a - Not Recovered/Not Resolved - Results in Death), Vomiting (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007523214	1135	05.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	XARELTO [RIVAROXABAN] (C - Atrial fibrillation - n/a - [n/a - n/a - n/a])
EU-EC-10007524390	1136	05.02.2021	65-85 Years	Not Specified	Female	Acute respiratory failure (6d - Fatal - Results in Death), Generalised oedema (15d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]), GALVUS 50 MG TABLETS [VILDAGLIPTIN] (S - Type 2 diabetes mellitus - n/a - [n/a - 50mg - Oral])	NOVORAPID FLEXPEN [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYGEN] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM POLYSTYRENE SULPHONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [VALPROIC ACID, SODIUM VALPROATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007524454	1137	05.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007524469	1138	05.02.2021	65-85 Years	Not Specified	Male	Cardiac arrest (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007524506	1139	05.02.2021	65-85 Years	Not Specified	Female	COVID-19 (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007524533	1140	05.02.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007526658	1141	05.02.2021	65-85 Years	Not Specified	Female	Cardiac failure (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Vaccination site pain (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007526731	1142	05.02.2021	More than 85 Years	Not Specified	Male	Decreased appetite (5d - Fatal - Results in Death), Dysphagia (5d - Fatal - Results in Death), Fatigue (5d - Fatal - Results in Death), General physical health deterioration (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - Vascular dementia - n/a - [2165d - 5mg - Oral]), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [228d - 800[iU] - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - Pain - n/a - [n/a - 2g - Oral])
EU-EC-10007526750	1143	05.02.2021	More than 85 Years	Not Specified	Female	Condition aggravated (n/a - Fatal - Results in Death), General physical health deterioration (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007526767	1144	05.02.2021	65-85 Years	Not Specified	Female	Oxygen saturation decreased (1d - Fatal - Results in Death), Urinary tract infection (1d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported

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EU-EC-10007526844	1145	05.02.2021	More than 85 Years	Not Specified	Female	Anxiety (1d - Unknown -), Cold sweat (1d - Fatal - Results in Death), Dyspnoea (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - Atrial fibrillation - n/a - [n/a - 5mg - Oral]), [CARBOMER, CARBOMER 980] (C - Dry eye - n/a - [n/a - 3{DF} - Ophthalmic]), [CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE HYDROCHLORIDE] (C - Hypovitaminosis n/a - [n/a - 1{DF} - Oral]), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - Iron deficiency - n/a - [n/a - 200mg Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Diuretic therapy - n/a - [n/a - 60mg - Oral]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Atrial fibrillation - n/a - [n/a - 50mg - Oral]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - 10mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Dyspepsia - n/a - [n/a - 20mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 500mg - Oral]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 1{DF} - Iontophoresis]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - 8{DF} - Respiratory (inhalation)]), [TIOTROPIUM, OLODATEROL] (C - Asthma - n/a - [n/a - 2{DF} - Respiratory (inhalation)])
EU-EC-10007526890	1146	05.02.2021	More than 85 Years	Not Specified	Female	Fatigue (n/a - Unknown - Other Medically Important Condition), Heart rate increased (2d - Fatal - Results in Death), Loss of consciousness (2d - Fatal - Results in Death), Pallor (n/a - Unknown - Other Medically Important Condition), Pupil fixed (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Respiratory rate increased (2d - Fatal - Results in Death), Somnolence (n/a - Unknown - Other Medically Important Condition), Tremor (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - Anticoagulant therapy - n/a - [n/a - 5mg - Oral]), [BUPRENORPHINE] (C - Pain - n/a - [n/a - n/a - Transdermal]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - Pain - n/a - [n/a - 3g - n/a]), [PREDNISOLONE] (C - Polymyalgia rheumatica - n/a - [n/a - 10mg - Oral])
EU-EC-10007527303	1147	05.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007527560	1148	05.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 1mg - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - 50mg - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007527829	1149	05.02.2021	More than 85 Years	Not Specified	Male	Lung disorder (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007527990	1150	05.02.2021	More than 85 Years	Not Specified	Male	Dyspnoea (5d - Fatal - Results in Death), Loss of consciousness (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	[AMLODIPINE, AMLODIPINE BESILATE] (C - Hypertension - n/a - [3y - 5mg - Oral]), [ASCORBIC ACID, COLECALCIFEROL] (C - Vitamin supplementation - n/a - [2y - 1{DF} - Oral]), [BISACODYL] (C - Constipation - n/a - [6y - 5mg - Oral]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - Mineral supplementation - n/a - [3y - 1{DF} - Oral]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM] (C - Gastrooesophageal reflux disease - n/a - [2y - 20mg - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Dyspnoea - n/a - [3d - 40mg - Oral]), [MIANSERIN HYDROCHLORIDE] (C - Insomnia - n/a - [2y - 10mg - Oral]), [NITRAZEPAM] (C - Insomnia - n/a - [1y - 5mg - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - Pain - n/a - [1y - 1000mg - Oral])
EU-EC-10007528009	1151	05.02.2021	More than 85 Years	Not Specified	Female	Bedridden (n/a - Fatal - Results in Death), Dyspnoea (1a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death), Oxygen saturation decreased (1a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[BUMETANIDE] (C - Cardiac failure - n/a - [7y - 1mg - Oral]), [CEFOTAXIME] (C - Dyspnoea - n/a - [3d - 2g - Intravenous (not otherwise specified)]), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [219d - 800[iU] - Oral]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Cardiac failure - n/a - [7y - 25mg - Oral]), [PHENOXYMETHYLPENICILLIN, PHENOXYMETHYLPENICILLIN POTASSIUM] (C - Dyspnoea - n/a - [10d - 1.3g - Oral])
EU-EC-10007528105	1152	05.02.2021	More than 85 Years	Elderly	Female	Cardiogenic shock (n/a - Fatal - Results in Death), Respiratory failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007528194	1153	05.02.2021	65-85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007528378	1154	05.02.2021	More than 85 Years	Elderly	Female	Atrial fibrillation (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardiac failure (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypernatraemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Interleukin level increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Leukocytosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007528461	1155	05.02.2021	More than 85 Years	Not Specified	Male	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007528631	1156	05.02.2021	More than 85 Years	Elderly	Female	Upper respiratory tract infection (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007528718	1157	05.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMILORIDE HYDROCHLORIDE, HYDROCHLOROTHIAZIDE, AMILORIDE, HYDROCHLOROTHIAZIDE, HYDROCHLOROTHIAZIDE, AMILORIDE HYDROCHLORIDE DIHYDRATE, HYDROCHLOROTHIAZIDE, ANHYDROUS AMILORIDE HYDROCHLORIDE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007528827	1158	05.02.2021	65-85 Years	Not Specified	Male	General physical condition abnormal (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007530163	1159	05.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007530369	1160	05.02.2021	65-85 Years	Elderly	Female	Acute respiratory distress syndrome (n/a - Fatal - Results in Death), COVID-19 pneumonia (n/a - Fatal - Results in Death), SARS-CoV-2 sepsis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007530686	1161	05.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	[CITALOPRAM, CITALOPRAM HYDROBROMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a]), [EPINEPHRINE] (C - n/a - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTULOSE, LACTULOSE, LIQUID] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007531045	1162	05.02.2021	65-85 Years	Not Specified	Female	Anaphylactic reaction (2d - Fatal - Results in Death), Cardio-respiratory arrest (2d - Fatal - Results in Death), Dyspnoea (2d - Fatal - Results in Death), Hypotension (2d - Fatal - Results in Death), Malaise (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [BENSERAZIDE, LEVODOPA] (C - n/a - Unknown - [n/a - 1.5{DF} - n/a]), [ENOXAPARIN SODIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [ESTRIOL] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [MELATONIN] (C - n/a - Unknown - [n/a - 2mg - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [SODIUM ASCORBATE, FERROUS SULFATE] (C - n/a - Unknown - [n/a - 1{DF} - n/a])
EU-EC-10007532191	1163	05.02.2021	65-85 Years	Not Specified	Female	Dyspnoea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	FENTANYL [FENTANYL, FENTANYL CITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), NEUPRO [ROTIGOTINE] (C - n/a - n/a - [n/a - n/a - n/a]), PREGABALIN [PREGABALIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BENSERAZIDE HYDROCHLORIDE, LEVODOPA, BENSERAZIDE, LEVODOPA] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 100mg - n/a]), [SODIUM PICOFOSSFATE, SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [STERCULIA, STERCULIA GUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007534113	1164	05.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	CELLCEPT [MYCOPHENOLATE MOFETIL] (C - Renal transplant - n/a - [n/a - 2g - n/a]), CICLOSPORIN [CICLOSPORIN] (C - Renal transplant - n/a - [n/a - 75mg - n/a]), NOT AVAILABLE (C - Aorta coarctation repair - n/a - [n/a - n/a - n/a]), VALSARTAN, SACUBITRIL [VALSARTAN, SACUBITRIL] (C - Hypertension - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Hypertension - n/a - [n/a - 5mg - n/a]), [METHYLPREDNISOLONE, METHYLPREDNISOLONE SODIUM SUCCINATE] (C - Renal transplant - n/a - [n/a - 2mg - n/a]), [TORASEMIDE] (C - Cardiac failure - n/a - [n/a - 10mg - n/a])
EU-EC-10007534293	1165	05.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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EU-EC-10007534563	1166	05.02.2021	More than 85 Years	Not Specified	Female	Cough (n/a - Unknown -), Fatigue (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Nausea (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Urinary tract infection (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[GALANTAMINE] (C - Dementia - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hyperthyroidism - n/a - [n/a - n/a - n/a])
EU-EC-10007534567	1167	05.02.2021	65-85 Years	Not Specified	Male	Body temperature increased (n/a - Unknown -), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown -), Fatigue (n/a - Unknown -), Lethargy (n/a - Unknown -), Nausea (n/a - Unknown -), Sudden death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007534947	1168	05.02.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	ABILIFY [ARIPRAZOLE] (C - Neuropsychiatric symptoms - n/a - [873d - n/a - n/a]), ELIQUIS [APIXABAN] (C - Atrial fibrillation - n/a - [873d - 2.5mg - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Atrial fibrillation - n/a - [873d - 2.5mg - n/a]), [TRIAZOLAM] (C - Insomnia - n/a - [873d - .25mg - n/a])
EU-EC-10007535504	1169	05.02.2021	More than 85 Years	Elderly	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	ELIQUIS [APIXABAN] (C - Atrial fibrillation - n/a - [n/a - 2.5mg - Oral]), FENTANYL [FENTANYL, FENTANYL CITRATE] (C - Pain - n/a - [n/a - 1{DF} - Transdermal]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - 25mg - Oral])
EU-EC-10007512509	1170	04.02.2021	More than 85 Years	Not Specified	Male	Body temperature increased (n/a - Fatal - Results in Death), Chills (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), PREGABALIN [PREGABALIN] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBASALATE CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [MACROGOL 400] (C - n/a - n/a - [n/a - n/a - n/a]), [TEMAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007514810	1171	04.02.2021	More than 85 Years	Not Specified	Female	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Asthenia (n/a - Not Recovered/Not Resolved -), Crying (n/a - Unknown -), Dizziness (n/a - Not Recovered/Not Resolved -), Feeling abnormal (n/a - Unknown -), Feeling hot (n/a - Unknown -), Gastric ulcer (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown -), Near death experience (n/a - Unknown - Other Medically Important Condition), Presyncope (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[OXYCODONE HYDROCHLORIDE, PARACETAMOL] (C - Pain in extremity - n/a - [n/a - n/a - n/a])
EU-EC-10007515738	1172	04.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007515744	1173	04.02.2021	More than 85 Years	Not Specified	Female	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007515751	1174	04.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007515860	1175	04.02.2021	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007515888	1176	04.02.2021	65-85 Years	Not Specified	Male	Adult failure to thrive (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007515914	1177	04.02.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	ABILIFY 10 MG TABLETS [ARIPIRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROXYCHLOROQUINE SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [NICARDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007515962	1178	04.02.2021	More than 85 Years	Not Specified	Female	Myocardial infarction (45min - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007516030	1179	04.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007516122	1180	04.02.2021	65-85 Years	Not Specified	Female	Cardiac failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007516151	1181	04.02.2021	More than 85 Years	Not Specified	Female	Myocardial infarction (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007516334	1182	04.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007516399	1183	04.02.2021	More than 85 Years	Not Specified	Female	Dyspnoea (n/a - Fatal - Results in Death), Productive cough (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[GLYCOPYRRONIUM BROMIDE, GLYCOPYRRONIUM BROMIDE, NEOSTIGMINE METHYLSULFATE] (C - Dyspnoea - n/a - [n/a - n/a - Intramuscular])

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EU-EC-10007516401	1184	04.02.2021	65-85 Years	Not Specified	Female	Respiratory failure (9d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007516406	1185	04.02.2021	65-85 Years	Not Specified	Male	Pneumonia (11d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	EBIXA [MEMANTINE HYDROCHLORIDE] (C - n/a - n/a -), [AMBROXOL HYDROCHLORIDE, TIMOLOL MALEATE, LATANOPROST] (C - n/a - n/a -), [CARBOMER, CARBOMER 980] (C - n/a - n/a -), [DONEPEZIL, DONEPEZIL HYDROCHLORIDE, DONEPEZIL HYDROCHLORIDE MONOHYDRATE] (C - n/a - n/a -), [METHENAMINE HIPPURATE] (C - n/a - n/a -), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a -)
EU-EC-10007516465	1186	04.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007516473	1187	04.02.2021	65-85 Years	Not Specified	Female	Pulmonary embolism (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	EXELON [RIVASTIGMINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBAMAZEPINE, CARBAMAZEPINE (PH. EUR.)] (C - n/a - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [MEMANTINE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007518276	1188	04.02.2021	65-85 Years	Not Specified	Male	Bradycardia (n/a - Unknown - Other Medically Important Condition), Bundle branch block right (n/a - Unknown -), Cardiac arrest (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cyanosis (n/a - Unknown -), Hypothermia (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved -), Pulseless electrical activity (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ANORO [UMECLIDINIUM BROMIDE, VILANTEROL] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), APIXABAN [APIXABAN] (C - Pulmonary embolism - n/a - [n/a - n/a - n/a]), DULOXETINE [DULOXETINE] (C - Diabetic neuropathy - n/a - [n/a - n/a - n/a]), [ALLOPURINOL] (C - Gout - n/a - [n/a - n/a - n/a]), [AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Cardiac failure - n/a - [n/a - n/a - n/a]), [CARBOCISTEINE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - Cardiac failure - n/a - [n/a - n/a - n/a]), [GUARAPROLOSE] (C - Dry eye - n/a - [n/a - n/a - Ophthalmic]), [INSULIN HUMAN ISOPHANE] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE] (C - Angina pectoris - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - Dyspepsia - n/a - [n/a - n/a - n/a]), [PARACETAMOL, CODEINE PHOSPHATE] (C - Analgesic therapy - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [SENNA ALEXANDRIAN] (C - Constipation - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - Hypercholesterolaemia - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - n/a - n/a])
EU-EC-10007518287	1189	04.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Psoriasis (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007518409	1190	04.02.2021	More than 85 Years	Not Specified	Female	Chronic kidney disease (n/a - Fatal - Results in Death), Confusional state (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Urticaria (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - n/a - n/a - [n/a - 500mg - Oral])
EU-EC-10007518556	1191	04.02.2021	65-85 Years	Adult	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[BISOPROLOL FUMARATE, BISOPROLOL FUMARATE PH. EUR.] (C - Congestive cardiomyopathy - n/a - [n/a - n/a - Oral]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - Oral]), [ENALAPRIL MALEATE] (C - Congestive cardiomyopathy - n/a - [n/a - n/a - Oral]), [ISOSORBIDE MONONITRATE] (C - Congestive cardiomyopathy - n/a - [n/a - n/a - Oral]), [MELATONIN] (C - Sleep disorder - n/a - [n/a - n/a - Oral]), [MEMANTINE HYDROCHLORIDE] (C - Dementia Alzheimer's type - n/a - [n/a - n/a - Oral]), [MIANSERIN HYDROCHLORIDE] (C - Sleep disorder - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral]), [RISPERIDONE] (C - Sleep disorder - n/a - [n/a - n/a - Oral])

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EU-EC-10007519764	1192	04.02.2021	More than 85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007519820	1193	04.02.2021	18-64 Years	Not Specified	Male	Acute myocardial infarction (0d - Fatal - Results in Death), Death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a -), [DIHYDROXYALUMINUM SODIUM CARBONATE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a -), [NEBIVOLOL, NEBIVOLOL HYDROCHLORIDE] (C - n/a - n/a -), [PERINDOPRIL, PERINDOPRIL ARGININE, PERINDOPRIL TERT-BUTYLAMINE] (C - n/a - n/a -), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - n/a - n/a -), [TRIMETAZIDINE DIHYDROCHLORIDE] (C - n/a - n/a -)
EU-EC-10007520630	1194	04.02.2021	More than 85 Years	Not Specified	Female	Blood lactic acid increased (n/a - Fatal - Results in Death), Depressed level of consciousness (n/a - Fatal - Results in Death), Livedo reticularis (n/a - Fatal - Results in Death), Liver function test abnormal (n/a - Fatal - Results in Death), Pleural effusion (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death), Respiration abnormal (n/a - Fatal - Results in Death), Sedation (n/a - Fatal - Results in Death), Troponin increased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007520916	1195	04.02.2021	65-85 Years	Elderly	Male	Acute kidney injury (n/a - Fatal - Results in Death), Hypernatraemia (n/a - Fatal - Results in Death), Lung disorder (n/a - Fatal - Results in Death), Sepsis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), NOVORAPID [INSULIN ASPART] (S - n/a - n/a - [n/a - n/a - n/a]), [CEFTRIAXONE] (S - Lung disorder - Dose not changed - [n/a - 2g - Intravenous (not otherwise specified)])	FORXIGA 10 MG [DAPAGLIFLOZIN] (C - n/a - Unknown - [n/a - 10mg - n/a]), LANTUS [INSULIN GLARGINE] (C - n/a - Unknown - [n/a - 12{IU} - n/a]), TRAJENTA 5 MG [LINAGLIPTIN] (C - n/a - Unknown - [n/a - 5mg - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - Unknown - [n/a - 80mg - n/a]), [ALLOPURINOL] (C - n/a - Unknown - [n/a - 300mg - n/a]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - Unknown - [n/a - 10mg - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - Unknown - [n/a - 10mg - n/a]), [FOLIC ACID] (C - n/a - Unknown - [n/a - 4mg - n/a]), [INDAPAMIDE, INDAPAMIDE HEMIHYDRATE] (C - n/a - Unknown - [n/a - 3.75mg - n/a]), [MOXONIDINE] (C - n/a - Unknown - [n/a - .2mg - n/a]), [NEBIVOLOL] (C - n/a - Unknown - [n/a - 5mg - n/a]), [PERINDOPRIL ARGININE] (C - n/a - Unknown - [n/a - 10mg - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - Unknown - [n/a - 25mg - n/a])
EU-EC-10007520937	1196	04.02.2021	Not Specified	Not Specified	Male	Haemorrhagic stroke (n/a - Fatal - Results in Death), Platelet count decreased (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007502281	1197	03.02.2021	More than 85 Years	Not Specified	Female	Myocardial infarction (0d - Fatal - Results in Death), Renal failure (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007502904	1198	03.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007502908	1199	03.02.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Lower respiratory tract infection (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007502929	1200	03.02.2021	65-85 Years	Not Specified	Male	Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[PARACETAMOL] (C - Blood pressure abnormal - n/a - [n/a - n/a - n/a]), [ROSUVASTATIN] (C - Blood cholesterol - n/a - [n/a - n/a - n/a])
EU-EC-10007503110	1201	03.02.2021	65-85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007503112	1202	03.02.2021	Not Specified	Not Specified	Male	Back pain (n/a - Unknown -), COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007503114	1203	03.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	RIVAROXABAN [RIVAROXABAN] (C - Atrial fibrillation - n/a - [n/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDRALAZINE] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007503324	1204	03.02.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death), Drug ineffective (n/a - Fatal - Results in Death), Lower respiratory tract infection (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007503335	1205	03.02.2021	More than 85 Years	Not Specified	Female	Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Gastritis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007503896	1206	03.02.2021	More than 85 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Dysphagia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INSULIN ASPART] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a])
EU-EC-10007503900	1207	03.02.2021	More than 85 Years	Not Specified	Female	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Abdominal tenderness (n/a - Unknown - Other Medically Important Condition), Blood creatinine increased (n/a - Unknown - Other Medically Important Condition), Blood urea increased (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Unknown - Other Medically Important Condition), Hyponatraemia (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Intestinal perforation (n/a - Fatal - Results in Death), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Memory impairment (n/a - Unknown - Other Medically Important Condition), Movement disorder (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007504344	1208	03.02.2021	65-85 Years	Elderly	Male	Incorrect route of product administration (n/a - Unknown -), Pyrexia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Staphylococcal sepsis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous])	Not reported

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EU-EC-10007504572	1209	03.02.2021	More than 85 Years	Not Specified	Female	Cerebrovascular accident (7d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	INCRUSE [UMECLIDINIUM BROMIDE] (C - n/a - n/a -), INCRUSE [UMECLIDINIUM BROMIDE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)]), RELVAR ELLIPTA [FLUTICASONE FUROATE, VILANTEROL] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - Oral]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - n/a - Oral]), [MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - n/a - [n/a - n/a - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-10007505560	1210	03.02.2021	65-85 Years	Not Specified	Female	Anxiety (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007505562	1211	03.02.2021	65-85 Years	Not Specified	Male	Anal incontinence (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urinary incontinence (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	DULOXETINE [DULOXETINE] (C - Depression - n/a - [n/a - 60mg - n/a]), [ALLOPURINOL] (C - Gout - n/a - [n/a - 100mg - n/a]), [DOSULEPIN, DOSULEPIN HYDROCHLORIDE] (C - n/a - n/a - [43d - n/a - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - 50mg - n/a]), [PROMETHAZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1[DF] - n/a])
EU-EC-10007506077	1212	03.02.2021	65-85 Years	Elderly	Female	Asthenia (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Poor quality sleep (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death), Vaccination site pain (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007506497	1213	03.02.2021	65-85 Years	Not Specified	Male	Acute kidney injury (1d - Fatal - Results in Death), Resuscitation (1d - Fatal - Results in Death), Toxicity to various agents (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007506524	1214	03.02.2021	65-85 Years	Not Specified	Female	SARS-CoV-2 test positive (1d - Fatal - Results in Death), Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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EU-EC-10007506691	1215	03.02.2021	65-85 Years	Not Specified	Female	General physical health deterioration (0d - Fatal - Results in Death), Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ANORO [UMECLIDINIUM BROMIDE, VILANTEROL] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), EXELON 9.5 MG/24 H TRANSDERMAL PATCH [RIVASTIGMINE] (C - n/a - Unknown - [n/a - n/a - n/a]), NOT AVAILABLE (C - Chronic obstructive pulmonary disease - Unknown - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [BISOPROLOL FUMARATE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [LORMETAZEPAM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [PARACETAMOL] (C - n/a - Unknown - [n/a - 3{DF} - n/a]), [VENLAFAXINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a])
EU-EC-10007507351	1216	03.02.2021	More than 85 Years	Elderly	Male	Cardiac failure (3d - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Hyperpyrexia (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007507436	1217	03.02.2021	65-85 Years	Not Specified	Male	Sudden death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), OLANZAPINE 10 MG [OLANZAPINE] (S - n/a - Unknown - [n/a - n/a - n/a]), [NOT AVAILABLE] (S - n/a - Unknown - [n/a - n/a - n/a]), [TRAZODONE HYDROCHLORIDE] (S - n/a - Unknown - [n/a - n/a - n/a])	[CALCIUM CARBONATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007508102	1218	03.02.2021	More than 85 Years	Elderly	Female	Acute myocardial infarction (n/a - Fatal - Results in Death), C-reactive protein increased (n/a - Fatal - Results in Death), Increased upper airway secretion (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	TRAJENTA [LINAGLIPTIN] (C - n/a - n/a - [n/a - n/a - Oral]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - n/a - Oral]), [BROMHEXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [CARBOMER, CARBOMER 974P] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [CHLORHEXIDINE GLUCONATE, HYDROCORTISONE] (C - n/a - n/a - [n/a - n/a - Topical]), [DIGOXIN] (C - n/a - n/a - [n/a - n/a - Oral]), [DONEPEZIL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [LACTULOSE] (C - n/a - n/a - [n/a - n/a - Oral]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)]), [WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BP] (C - Atrial fibrillation - n/a - [n/a - n/a - Oral])
EU-EC-10007508322	1219	03.02.2021	More than 85 Years	Not Specified	Male	Pulmonary oedema (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007508333	1220	03.02.2021	More than 85 Years	Not Specified	Female	Cardiac failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	ELIQUIS 5 MG FILM-COATED TABLETS [APIXABAN] (C - n/a - n/a - [n/a - 5mg - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [CANDESARTAN CILEXETIL] (C - n/a - n/a - [n/a - 8mg - n/a]), [CLOMETHIAZOLE EDISILATE] (C - n/a - n/a - [n/a - 600mg - n/a]), [DULOXETINE] (C - n/a - n/a - [n/a - 60mg - n/a]), [ECONAZOLE NITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 1mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - n/a]), [KETOCONAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [MICONAZOLE NITRATE, HYDROCORTISONE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 30mg - n/a]), [OLANZAPINE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a])
EU-EC-10007508427	1221	03.02.2021	More than 85 Years	Not Specified	Female	Dyspnoea (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular])	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007508687	1222	03.02.2021	More than 85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007509181	1223	03.02.2021	More than 85 Years	Not Specified	Female	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007511116	1224	03.02.2021	18-64 Years	Adult	Female	Acute myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cardiogenic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Chills (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), Hypotension (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007489053	1225	02.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007489104	1226	02.02.2021	More than 85 Years	Not Specified	Female	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - Intramuscular])	Not reported
EU-EC-10007489118	1227	02.02.2021	65-85 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007489164	1228	02.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007489257	1229	02.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007489318	1230	02.02.2021	More than 85 Years	Not Specified	Female	Acute pulmonary oedema (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007489609	1231	02.02.2021	65-85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [CANDESARTAN CILEXETIL] (C - n/a - n/a - [n/a - n/a - n/a]), [CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [CYCLOBENZAPRINE, CYCLOBENZAPRINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FENOFIBRATE, FENOFIBRATE MICRONISED] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [INSULIN, INSULIN HUMAN] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYGEN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007489762	1232	02.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	TRESIBA [INSULIN DEGLUDEC] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE, LISINAPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL, CODEINE PHOSPHATE HEMIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007489777	1233	02.02.2021	More than 85 Years	Not Specified	Male	Altered state of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Chills (1d - Recovered/Resolved - Other Medically Important Condition), Diarrhoea (1d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (0d - Recovered/Resolved - Other Medically Important Condition), Dysuria (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Rash (1d - Recovered/Resolved -), Rash macular (n/a - Unknown -), Retching (1d - Recovered/Resolved -), Vascular dementia (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007490106	1234	02.02.2021	More than 85 Years	Elderly	Female	Dyspnoea (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [INSULIN INJECTION SOLUBLE] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM HYDROGEN CARBONATE, CITRIC ACID ANHYDROUS, POTASSIUM CITRATE, POTASSIUM HYDROGEN CARBONATE, POTASSIUM CITRATE PH. EUR., CITRIC ACID, POTASSIUM HYDROGEN CARBONATE, POTASSIUM CITRATE, CITRIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007490160	1235	02.02.2021	More than 85 Years	Not Specified	Female	Ischaemic stroke (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [208d - 75mg - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM TRIHYDRATE] (C - n/a - n/a - [9d - 20mg - Oral]), [BUPRENORPHINE] (C - Pain - n/a - [9d - 15ug - Transdermal]), [CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [ENALAPRIL MALEATE, HYDROCHLOROTHIAZIDE] (C - Hypertension - n/a - [129d - 20mg - Oral]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM DIHYDRATE, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE] (C - Gastric ulcer - n/a - [156d - 20mg - Oral]), [FELODIPINE] (C - Hypertension - n/a - [n/a - 10mg - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - Pain - n/a - [208d - 1g - Oral])
EU-EC-10007490332	1236	02.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007490333	1237	02.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007490614	1238	02.02.2021	65-85 Years	Not Specified	Male	Disease recurrence (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CODEINE] (C - n/a - n/a - [n/a - n/a - n/a]), [EZETIMIBE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE 5 MONONITRATE, ISOSORBIDE DINITRATE, ISOSORBIDE MONONITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007490618	1239	02.02.2021	More than 85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[BUPRENORPHINE] (C - Pain - n/a - [n/a - 1{DF} - Cutaneous]), [CARBOMER, CARBOMER 980] (C - Dry eye - n/a - [n/a - 3{drp} - Ophthalmic]), [LACTULOSE] (C - Constipation - n/a - [n/a - 40mL - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 3g - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Restlessness - n/a - [n/a - 25mg - Oral]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [n/a - 20{DF} - Oral]), [VITAMIN D] (C - n/a - n/a - [n/a - 40ug - n/a])
EU-EC-10007490642	1240	02.02.2021	65-85 Years	Elderly	Female	Hypersensitivity (4d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007490796	1241	02.02.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[LISINAPRIL] (C - Hypertension - n/a - [n/a - 5mg - Oral]), [METAMIZOLE SODIUM] (C - Analgesic therapy, Antiinflammatory therapy - n/a - [2d - 20{drp} - Oral]), [METOCLOPRAMIDE HYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE] (C - n/a - n/a - [1d - 20{drp} - Oral]), [OXYCODONE HYDROCHLORIDE, NALOXONE HYDROCHLORIDE DIHYDRATE] (C - Analgesic therapy, Antiinflammatory therapy - n/a - [1d - 1{DF} - Oral]), [PARACETAMOL] (C - Analgesic therapy, Antiinflammatory therapy - n/a - [n/a - 500mg - Oral]), [QUETIAPINE] (C - Agitation - n/a - [2d - 25mg - Oral - More in ICSR]), [SULFAMETHOXAZOLE, TRIMETHOPRIM] (C - Antibiotic therapy - n/a - [n/a - 2{DF} - Oral]), [TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 4mg - Oral]), [TRAMADOL HYDROCHLORIDE] (C - Analgesic therapy, Antiinflammatory therapy - n/a - [1d - 20{drp} - Oral - More in ICSR])
EU-EC-10007492097	1242	02.02.2021	Not Specified	Not Specified	Male	Pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007492099	1243	02.02.2021	More than 85 Years	Not Specified	Female	Intestinal ischaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Volvulus (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported

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EU-EC-10007493167	1244	02.02.2021	More than 85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007493213	1245	02.02.2021	More than 85 Years	Not Specified	Female	General physical health deterioration (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Fatal - Results in Death), Sepsis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	LEVETIRACETAM [LEVETIRACETAM] (C - n/a - n/a - [n/a - 500mg - Oral]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - Oral]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 40mg - Oral]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1mg - Oral]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FELODIPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [KETOBEMIDONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 5mg - Oral]), [METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - Oral])
EU-EC-10007493759	1246	02.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	[HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007494036	1247	02.02.2021	More than 85 Years	Elderly	Female	Asthenia (0d - Fatal - Results in Death), Cardiac failure (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a 1{DF} - n/a])	[COLECALCIFEROL] (C - n/a - n/a - [n/a - 35{drp} - n/a]), [ENOXAPARIN, ENOXAPARIN SODIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [EXTRACT OF IBERIS AMARA (1 : 1.5 - 2.5), EXTRACTING AGENT: ETHANOL 50 % (V/V), EXTRACT OF ANGELICA ROOT (1 : 2.5 - 3.5), EXTRACTING AGENT: ETHANOL 30 % (V/V), LIQUID EXTRACT OF CARAWAY FRUIT (1 : 2.5 - 3.5), EXTRACTING AGENT: ETHANOL 30 % (V/V), EXTRACT OF CELANDINE HERB (1 : 2.5 - 3.5), EXTRACTING AGENT: ETHANOL 30 % (V/V), LIQUID EXTRACT OF MATRICARIA FLOWER (1 : 2 - 4), EXTRACTING AGENT: ETHANOL 30 % (V/V), LIQUID EXTRACT OF PEPPERMINT LEAF (1 : 2.5 - 3.5), EXTRACTING AGENT: ETHANOL 30 % (V/V), LIQUID EXTRACT OF MILK THISTLE FRUIT (1 : 2.5 - 3.5), EXTRACTING AGENT: ETHANOL 30 % (V/V), LIQUID EXTRACT FROM LIQUORICE ROOT (1:2,5-3,5), EXTRACTION SOLVENT: ETHANOL 30% V/V, LIQUID EXTRACT FROM MELISSA LEAF (1:2,5-3,5), EXTRACTION SOLVENT: ETHANOL 30% V/V, EXTRACT OF IBERIS AMARA (1 : 1.5 - 2.5), EXTRACTING AGENT: ETHANOL 50 % (V/V), EXTRACT OF ANGELICA ROOT (1 : 2.5 - 3.5), EXTRACTING AGENT: ETHANOL 30 % (V/V), LIQUID EXTRACT OF CARAWAY FRUIT (1 : 2.5 - 3.5), EXTRACTING AGENT: ETHANOL 30 % (V/V), LIQUID EXTRACT OF MATRICARIA FLOWER (1 : 2 - 4), EXTRACTING AGENT: ETHANOL 30 % (V/V), LIQUID EXTRACT OF PEPPERMINT LEAF (1 : 2.5 - 3.5), EXTRACTING AGENT: ETHANOL 30 % (V/V), LIQUID EXTRACT OF MILK THISTLE FRUIT (1 : 2.5 - 3.5), EXTRACTING AGENT: ETHANOL 30 % (V/V), LIQUID EXTRACT FROM GREATER CELANDINE AERIAL PARTS (1:2,5-3,5), EXTRACTION SOLVENT: ETHANOL 30% V/V, LIQUID EXTRACT FROM LIQUORICE ROOT (1:2,5-3,5), EXTRACTION SOLVENT: ETHANOL 30% V/V, LIQUID EXTRACT FROM MELISSA LEAF (1:2,5-3,5), EXTRACTION SOLVENT: ETHANOL 30% V/V, MELISSA LEAF, MILK THISTLE FRUIT EXTRACT, BITTER CANDYTUFT FRESH PLANT EXTRACT, MATRICARIA LIQUID EXTRACT, MENTHAE PIPERITAE FOLIUM, CHELIDONII HERBA, EXTRACTUM LIQUIDUM, ANGELICA ROOT EXTRACT, MELISSAE FOLII DRY AQUEOUS EXTRACT, GLYCYRRHIZA GLABRA ROOT, CARVI EXTRACTUM FLUIDUM] (C - n/a - n/a - [n/a - 15{drp} - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 5mg - n/a]),
EU-EC-10007494159	1248	02.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007494357	1249	02.02.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Loss of consciousness (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007494527	1250	02.02.2021	More than 85 Years	Elderly	Female	Cerebrovascular accident (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [METAMIZOLE, METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007494983	1251	02.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007498202	1252	02.02.2021	18-64 Years	Not Specified	Male	Bradycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cardiac arrest (1d - Fatal - Results in Death), Fatigue (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007498569	1253	02.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[CLOMETHIAZOLE, CLOMETHIAZOLE EDISILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007499124	1254	02.02.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular])	TRAJENTA 5 MG FILM-COATED TABLETS [LINAGLIPTIN] (C - n/a - n/a - [n/a - 5mg - n/a]), [BENSERAZIDE HYDROCHLORIDE, LEVODOPA, BENSERAZIDE, LEVODOPA] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CINCHOCAINE HYDROCHLORIDE, PREDNISOLONE CAPROATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 800{iU} - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [FERROUS SULFATE] (C - n/a - n/a - [n/a - 100mg - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 1mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - n/a]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTULOSE, LACTULOSE, LIQUID] (C - n/a - n/a - [n/a - n/a - n/a]), [MAGNESIUM CITRATE, MAGNESIUM LACTATE] (C - n/a - n/a - [n/a - 120mg - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [PROPYLENE GLYCOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOFOSFATE, SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TIOTROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007499182	1255	02.02.2021	More than 85 Years	Not Specified	Male	Confusional state (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007499387	1256	02.02.2021	65-85 Years	Elderly	Male	Malaise (n/a - Unknown - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Pyrexia (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1{DF} - Intramuscular])	[IBUPROFEN] (C - Pain - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - Prophylaxis against gastrointestinal ulcer - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - Depression - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - Hypercholesterolaemia - n/a - [n/a - n/a - n/a]), [TOLTERODINE TARTRATE] (C - Pollakiuria - n/a - [n/a - n/a - n/a])
EU-EC-10007477956	1257	01.02.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[MORPHINE, MORPHINE HYDROCHLORIDE] (C - Pain - n/a - [n/a - n/a - n/a]), [OXYGEN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007477988	1258	01.02.2021	65-85 Years	Not Specified	Male	Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	AREDS [ASCORBIC ACID, TOCOPHERYL ACETATE, XANTOXYL, ZEAXANTHIN, ZINC] (C - n/a - n/a - [n/a - n/a - n/a]), PLAVIX [CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - n/a - n/a]), [AMIODARONE, AMIODARONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FERRIC CITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007477990	1259	01.02.2021	65-85 Years	Not Specified	Female	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Pulse abnormal (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	XARELTO [RIVAROXABAN] (C - Deep vein thrombosis - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE, LISINAPRIL] (C - Hypertension - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISONE] (C - Myasthenia gravis - n/a - [n/a - n/a - n/a]), [PYRIDOSTIGMINE, PYRIDOSTIGMINE BROMIDE] (C - Myasthenia gravis - n/a - [n/a - n/a - n/a]), [TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - Spinal operation - n/a - [n/a - n/a - n/a])
EU-EC-10007478004	1260	01.02.2021	65-85 Years	Not Specified	Male	Arteriosclerosis (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardiovascular disorder (n/a - Fatal - Results in Death, Other Medically Important Condition), Dizziness (n/a - Unknown -), Headache (n/a - Unknown -), Nausea (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007478203	1261	01.02.2021	More than 85 Years	Not Specified	Female	Anaphylactic reaction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cerebellar haemorrhage (n/a - Fatal - Results in Death), Coma scale abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Dermatitis exfoliative generalised (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Systolic hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Urticaria (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	BRINTELLIX [VORTIOXETINE] (C - n/a - n/a - [n/a - 10mg - n/a]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 40mg - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - n/a]), [ALENDRONIC ACID] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 5mg - n/a]), [PERICIAZINE] (C - n/a - n/a - [n/a - 10{drp} - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10{drp} - n/a]), [VALSARTAN] (C - n/a - n/a - [n/a - 80mg - n/a])
EU-EC-10007478358	1262	01.02.2021	65-85 Years	Not Specified	Female	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - Results in Death, Other Medically Important Condition), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a])
EU-EC-10007478364	1263	01.02.2021	More than 85 Years	Not Specified	Female	Cerebrovascular accident (n/a - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BISACODYL] (C - n/a - n/a - [n/a - n/a - n/a]), [CLOMIPRAMINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUDROCORTISONE] (C - n/a - n/a - [n/a - n/a - n/a]), [INFLUENZA VIRUS] (C - n/a - n/a - [1d - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007478370	1264	01.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007478374	1265	01.02.2021	Not Specified	Adult	Male	COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[RAMIPRIL] (C - Left ventricular hypertrophy - n/a - [n/a - n/a - n/a])
EU-EC-10007478376	1266	01.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007478383	1267	01.02.2021	More than 85 Years	Not Specified	Male	Abdominal adhesions (n/a - Unknown - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Postoperative ileus (n/a - Unknown - Caused/Prolonged Hospitalisation), Small intestinal obstruction (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[CYANOCOBALAMIN, VITAMIN B12] (C - n/a - n/a - [n/a - n/a - n/a]), [PROPYLENE GLYCOL, MACROGOL, PROPYLENE GLYCOL, MACROGOL 400] (C - n/a - n/a - [n/a - n/a - n/a]), [TIMOLOL, TIMOLOL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007478385	1268	01.02.2021	65-85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune system disorder (1d - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007478388	1269	01.02.2021	More than 85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [NITRAZEPAM, NITRAZEPAM BP] (C - Mental disorder - n/a - [n/a - n/a - n/a])
EU-EC-10007478389	1270	01.02.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007478392	1271	01.02.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death), Drug ineffective (n/a - Fatal - Results in Death), Lower respiratory tract infection (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007478394	1272	01.02.2021	More than 85 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a])

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EU-EC-10007478485	1273	01.02.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Femoral neck fracture (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), General physical health deterioration (n/a - Unknown), Pneumonia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007478505	1274	01.02.2021	More than 85 Years	Not Specified	Female	Pneumonia (n/a - Fatal - Results in Death), Respiratory failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007478598	1275	01.02.2021	Not Specified	Not Specified	Male	Malaise (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Sudden cardiac death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007478748	1276	01.02.2021	65-85 Years	Not Specified	Male	Acute respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypersensitivity pneumonitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Lower respiratory tract infection (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BENDROFLUMETHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PERINDOPRIL, PERINDOPRIL TERT-BUTYLAMINE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007479399	1277	01.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007479649	1278	01.02.2021	More than 85 Years	Not Specified	Male	Abdominal pain (n/a - Unknown -), Anal haemorrhage (n/a - Unknown -), Back pain (n/a - Recovered/Resolved -), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Heart rate decreased (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown -), Oxygen saturation decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition), Tachypnoea (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - Oral]), [HYDROXYCARBAMIDE] (C - Myeloproliferative neoplasm - n/a - [n/a - 1500mg - Oral]), [LISINOPRIL, LISINOPRIL DIHYDRATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [TORASEMIDE SODIUM] (C - n/a - n/a - [n/a - 100mg - Oral])
EU-EC-10007480038	1279	01.02.2021	65-85 Years	Not Specified	Female	Pneumonia (n/a - Fatal - Results in Death), Respiratory tract infection (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007480110	1280	01.02.2021	More than 85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007480165	1281	01.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), General physical condition abnormal (22d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007480253	1282	01.02.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007481458	1283	01.02.2021	Not Specified	Not Specified	Male	Myocardial infarction (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007481754	1284	01.02.2021	More than 85 Years	Elderly	Female	Increased upper airway secretion (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - Atrial fibrillation - n/a - [n/a - n/a - Oral]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - Oral]), [CETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - n/a - Oral]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - Oral]), [FLUTICASON PROPRIONATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]), [FUROSEMIDE] (C - Cardiac failure - n/a - [n/a - n/a - Oral])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007481782	1285	01.02.2021	More than 85 Years	Elderly	Female	Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported
EU-EC-10007481907	1286	01.02.2021	65-85 Years	Elderly	Female	Cardiac failure (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - n/a - n/a - [392d - n/a - Oral]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [26d - n/a - Oral]), [ATORVASTATIN] (C - n/a - n/a - [392d - n/a - Oral]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [392d - n/a - Oral]), [BUPRENORPHINE] (C - n/a - n/a - [392d - n/a - Transdermal]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [392d - n/a - Oral]), [FUROSEMIDE] (C - n/a - n/a - [392d - n/a - Oral]), [ISOSORBIDE MONONITRATE] (C - n/a - n/a - [392d - n/a - Oral]), [MELATONIN] (C - n/a - n/a - [392d - n/a - Oral]), [PARACETAMOL] (C - n/a - n/a - [392d - n/a - Oral])
EU-EC-10007481912	1287	01.02.2021	65-85 Years	Elderly	Female	C-reactive protein increased (n/a - Fatal - Results in Death), Confusional state (n/a - Fatal - Results in Death), Pyelonephritis (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Urinary tract infection (n/a - Fatal - Results in Death), Vaccination site erythema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007481923	1288	01.02.2021	18-64 Years	Adult	Male	Foaming at mouth (n/a - Fatal - Results in Death), Pallor (n/a - Fatal - Results in Death), Rash erythematous (n/a - Fatal - Results in Death), Respiratory tract infection (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007481943	1289	01.02.2021	18-64 Years	Adult	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007481984	1290	01.02.2021	65-85 Years	Not Specified	Male	Cardiac failure (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - Prophylaxis - n/a - [n/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - n/a - n/a]), [ATENOLOL, ATENOLOL BP] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [FENOFIBRATE, FENOFIBRATE MICRONISED] (C - Prophylaxis - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - n/a - n/a]), [PARACETAMOL, CODEINE PHOSPHATE] (C - Spinal decompression - n/a - [n/a - n/a - n/a]), [PROMETHAZINE HYDROCHLORIDE] (C - Poor quality sleep - n/a - [n/a - n/a - n/a]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Hyperlipidaemia - n/a - [n/a - n/a - n/a])
EU-EC-10007482017	1291	01.02.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - Supplementation therapy - n/a - [n/a - n/a - Oral]), [MEMANTINE HYDROCHLORIDE] (C - Dementia Alzheimer's type - n/a - [n/a - n/a - Oral]), [OXAZEPAM] (C - Relaxation therapy, Sleep disorder - n/a - [n/a - n/a - Oral])

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EU-EC-10007483682	1292	01.02.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007484361	1293	01.02.2021	Not Specified	Elderly	Not Specified	Nausea (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007484526	1294	01.02.2021	65-85 Years	Not Specified	Male	Dementia (n/a - Fatal - Results in Death), Dysphagia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramedullar (bone marrow)])	[CARBIDOPA, LEVODOPA, LEVODOPA, ANHYDROUS CARBIDOPA, LEVODOPA, CARBIDOPA MONOHYDRATE] (C - Parkinson's disease - n/a - [n/a - n/a - Oral]), [FENTANYL, FENTANYL CITRATE] (C - Pain - n/a - [n/a - 12ug - Transdermal])
EU-EC-10007485090	1295	01.02.2021	More than 85 Years	Elderly	Male	Oxygen saturation decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	CIRCADIN 2 MG [MELATONIN] (C - n/a - Not applicable - [n/a - 4mg - n/a]), NOT AVAILABLE (C - n/a - Not applicable - [n/a - 200mg - n/a]), [CLOPIDOGREL, CLOPIDOGREL BESILATE, CLOPIDOGREL HYDROGEN SULFATE] (C - n/a - Not applicable - [n/a - 75mg - n/a]), [FUROSEMIDE] (C - n/a - Not applicable - [n/a - 40mg - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - Not applicable - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - Not applicable - [n/a - n/a - n/a]), [MAGNESIUM OXIDE, MAGNESIUM OXIDE, LIGHT] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - Not applicable - [n/a - 30mg - n/a]), [PARACETAMOL] (C - n/a - Not applicable - [n/a - 1g - n/a]), [POTASSIUM CHLORIDE] (C - n/a - Not applicable - [n/a - 1500mg - n/a]), [TRIMETHOPRIM] (C - n/a - Unknown - [n/a - 100mg - n/a])
EU-EC-10007485532	1296	01.02.2021	Not Specified	Not Specified	Male	Autoimmune disorder (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007485543	1297	01.02.2021	65-85 Years	Not Specified	Female	Cardiopulmonary failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007485695	1298	01.02.2021	More than 85 Years	Not Specified	Male	Pyrexia (3d - Recovering/Resolving -), Rash (3d - Recovering/Resolving -), Respiratory failure (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[AMITRIPTYLINE HYDROCHLORIDE] (C - Neuralgia - n/a - [13d - 20mg - Oral]), [MIDAZOLAM] (C - Anxiety - n/a - [26d - n/a - n/a]), [OXAZEPAM] (C - Anxiety - n/a - [45d - 20mg - Oral]), [OXYCODONE HYDROCHLORIDE] (C - Pain - n/a - [26d - n/a - n/a]), [ZOPICLONE] (C - Insomnia - n/a - [45d - 5mg - Oral])
EU-EC-10007485871	1299	01.02.2021	65-85 Years	Elderly	Male	Haemorrhagic infarction (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported

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EU-EC-10007486506	1300	01.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	MIDAZOLAM [MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ANTIFOAM M COMPOUND, DIMETICONE, DIMETICONE, COLLOIDAL SILICON DIOXIDE, DIMETICONE, SILICA, COLLOIDAL ANHYDROUS, SILICA, COLLOIDAL ANHYDROUS, DIMETICONE 1000] (C - n/a - n/a - [n/a - n/a - n/a]), [EPINEPHRINE BITARTRATE, LIDOCAINE HYDROCHLORIDE, LIDOCAINE, LIDOCAINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASONE PROPIONATE, FORMOTEROL FUMARATE DIHYDRATE, FLUTICASONE PROPIONATE, FORMOTEROL FUMARATE DIHYDRATE PH.EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCOPYRRONIUM BROMIDE, GLYCOPYRRONIUM BROMIDE, NEOSTIGMINE METHYLSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MOMETASONE FUROATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOFOSFATE, SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007486558	1301	01.02.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Hypertensive emergency (n/a - Recovered/Resolved - Other Medically Important Condition), Pain (1d - Unknown - Other Medically Important Condition), Rales (1d - Unknown -), Somnolence (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007487006	1302	01.02.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Productive cough (n/a - Fatal - Results in Death), Wheezing (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	AZOPT [BRINZOLAMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - n/a]), [CITALOPRAM] (C - n/a - n/a - [n/a - 10mg - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [FENTANYL, FENTANYL CITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 1mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - n/a - n/a - [n/a - 100mg - n/a]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 50mg - n/a]), [MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [UREA] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007487097	1303	01.02.2021	More than 85 Years	Not Specified	Female	Upper gastrointestinal haemorrhage (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - n/a])	ESOMEPRAZOLE [ESOMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN, HYDROXOCOBALAMIN] (C - n/a - n/a - [n/a - n/a - n/a]), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007487604	1304	01.02.2021	More than 85 Years	Not Specified	Not Specified	Diarrhoea (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007477354	1305	31.01.2021	More than 85 Years	Not Specified	Female	Cardiac disorder (n/a - Fatal - Results in Death), Sepsis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), JANUVIA [SITAGLIPTIN, SITAGLIPTIN PHOSPHATE, SITAGLIPTIN PHOSPHATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007477398	1306	31.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007473305	1307	30.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007473313	1308	30.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007473417	1309	30.01.2021	More than 85 Years	Not Specified	Female	Malaise (1d - Not Recovered/Not Resolved - Results in Death), Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007473418	1310	30.01.2021	18-64 Years	Not Specified	Female	Respiratory distress (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FENTANYL] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE SULFATE, MORPHINE SULFATE PENTAHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PRAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007473481	1311	30.01.2021	65-85 Years	Not Specified	Female	Haemorrhagic stroke (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular]), [ACETYSALICYLIC ACID, D,L-LYSINE ACETYSALICYLATE] (S - Myocardial ischaemia - Drug withdrawn - [n/a - 75mg - Oral])	APROVEL [IRBESARTAN] (C - Hypertension - Drug withdrawn - [n/a - 300mg - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - Myocardial ischaemia - Drug withdrawn - [n/a - 40mg - Oral]), [DILTIAZEM] (C - Myocardial ischaemia - Drug withdrawn - [n/a - 90mg - Oral]), [GLYCERYL TRINITRATE] (C - Myocardial ischaemia - Drug withdrawn - [n/a - 5mg - Transdermal])
EU-EC-10007473506	1312	30.01.2021	More than 85 Years	Not Specified	Female	General physical health deterioration (1d - Fatal - Results in Death, Life Threatening), Vomiting (1d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007473507	1313	30.01.2021	65-85 Years	Not Specified	Male	Cardiac arrest (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[CODEINE] (C - n/a - n/a - [n/a - n/a - Oral]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 80000{iU} - Oral]), [GABAPENTIN] (C - n/a - n/a - [n/a - 200mg - Oral]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 25ug - Oral]), [LOXAPINE] (C - n/a - n/a - [n/a - 40{drp} - Oral]), [MACROGOL 3350, POTASSIUM CHLORIDE, SODIUM CARBONATE, SODIUM CHLORIDE, SODIUM SULFATE ANHYDROUS, MACROGOL 3350, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350, SODIUM SULPHATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, SODIUM SULFATE ANHYDROUS, MACROGOL 3350] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [MIANSERIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 30mg - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - 100mg - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - 500mg - Oral]), [TETRABENAZINE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [TROSPIUM, TROSPIUM CHLORIDE] (C - n/a - n/a - [n/a - 20mg - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - 3.75mg - Oral])
EU-EC-10007474006	1314	30.01.2021	65-85 Years	Elderly	Male	Death (23d - Fatal - Results in Death), Pyrexia (23d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - n/a - Intramuscular])	Not reported
EU-EC-10007474085	1315	30.01.2021	More than 85 Years	Elderly	Female	Death (5d - Fatal - Results in Death), General physical health deterioration (5d - Fatal - Results in Death), Influenza like illness (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007461673	1316	29.01.2021	More than 85 Years	Not Specified	Male	Dehydration (n/a - Not Recovered/Not Resolved - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (1d - Recovered/Resolved - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	ELIQUIS 5 MG FILM-COATED TABLETS [APIXABAN] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [ALFUZOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [ALIMEMAZINE TARTRATE] (C - n/a - n/a - [n/a - 15{drp} - Oral]), [DUTASTERIDE] (C - n/a - n/a - [n/a - .5mg - Oral]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - Oral]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 20mg - Oral]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 30mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE, POTASSIUM CHLORIDE, ETHYLCELLULOSE MICROENCAPSULATED 80-90%] (C - n/a - n/a - [n/a - 2{DF} - Oral]), [TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 50mg - Oral]), [TROSPIUM, TROSPIUM CHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - Oral])
EU-EC-10007461769	1317	29.01.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007461779	1318	29.01.2021	65-85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007461907	1319	29.01.2021	65-85 Years	Not Specified	Female	Myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007461911	1320	29.01.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007461994	1321	29.01.2021	More than 85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007462621	1322	29.01.2021	More than 85 Years	Elderly	Male	C-reactive protein increased (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	LIXIANA [EDOXABAN, EDOXABAN TOSYLATE] (C - Cerebrovascular accident prophylaxis - n/a - [n/a - n/a - Oral]), MEMANTINE RATIOPHARM [MEMANTINE HYDROCHLORIDE] (C - Memory impairment n/a - [n/a - n/a - Oral]), [FLUTICASON PROPRIONATE, SALMETEROL, FLUTICASON PROPRIONATE, SALMETEROL XINAFOATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - n/a - Oral])
EU-EC-10007462633	1323	29.01.2021	More than 85 Years	Elderly	Female	General physical health deterioration (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported

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EU-EC-10007462635	1324	29.01.2021	More than 85 Years	Elderly	Male	Dyspnoea (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[AMOXICILLIN] (C - Tooth infection - n/a - [n/a - n/a - Oral]), [OXYCODONE HYDROCHLORIDE] (C - Dyspnoea - n/a - [n/a - n/a - Oral])
EU-EC-10007462774	1325	29.01.2021	Not Specified	Elderly	Male	Dyspnoea (0d - Fatal - Results in Death), General physical health deterioration (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported
EU-EC-10007463020	1326	29.01.2021	More than 85 Years	Elderly	Female	Circulatory collapse (4h - Fatal - Results in Death, Life Threatening), Peripheral vascular disorder (4h - Fatal - Results in Death, Life Threatening), Vomiting (4h - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007463054	1327	29.01.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007463086	1328	29.01.2021	More than 85 Years	Not Specified	Female	Cardiac failure (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007463995	1329	29.01.2021	65-85 Years	Elderly	Not Specified	Body temperature increased (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Tremor (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007464525	1330	29.01.2021	18-64 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	Not reported
EU-EC-10007464544	1331	29.01.2021	More than 85 Years	Elderly	Male	Cyanosis (n/a - Unknown - Results in Death), General physical health deterioration (n/a - Unknown Results in Death), Pneumonia (n/a - Fatal - Results in Death), Respiratory failure (n/a - Unknown - Results in Death), Syncope (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007464769	1332	29.01.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - Anxiety - n/a - [n/a - 5mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Cardiac failure - n/a - [n/a - 20mg - n/a]), [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - Chronic obstructive pulmonary disease n/a -), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a -), [METOPROLOL, METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 25mg - n/a]), [MIRTAZAPINE] (C - Anxiety - n/a - [n/a - 30mg - n/a]), [OXAZEPAM] (C - Anxiety - n/a - [n/a - 10mg - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Prophylaxis against gastrointestinal ulcer - n/a -), [PREDNISOLONE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - 10mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a -)
EU-EC-10007464777	1333	29.01.2021	More than 85 Years	Not Specified	Male	Abdominal pain upper (6d - Fatal - Results in Death), Diarrhoea (2d - Fatal - Results in Death), General physical health deterioration (9d - Fatal - Results in Death), Nausea (6d - Fatal - Results in Death), Urinary retention (1d - Fatal - Results in Death), Vomiting (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - Oral]), [FOLIC ACID] (C - n/a - n/a - [n/a - 1mg - Oral]), [MIANSERIN HYDROCHLORIDE] (C - Depression - n/a - [n/a - 60mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 40mg - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - n/a - n/a - [n/a - n/a - Oral]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - 750mg - Oral])
EU-EC-10007464783	1334	29.01.2021	More than 85 Years	Not Specified	Male	Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[MORPHINE, MORPHINE HYDROCHLORIDE] (C - Pain - n/a - [n/a - n/a - n/a])
EU-EC-10007464822	1335	29.01.2021	65-85 Years	Elderly	Female	Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007465137	1336	29.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007465196	1337	29.01.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007465596	1338	29.01.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007465770	1339	29.01.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007465789	1340	29.01.2021	More than 85 Years	Not Specified	Female	Pulmonary oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	[FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007465939	1341	29.01.2021	More than 85 Years	Not Specified	Male	Abdominal pain lower (8d - Unknown -), Pyrexia (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007466534	1342	29.01.2021	More than 85 Years	Not Specified	Male	Chronic obstructive pulmonary disease (n/a - Fatal - Results in Death), Cough (n/a - Fatal - Results in Death), Diarrhoea (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Infection (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - [n/a - 100mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 40mg - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 100mg - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 30mg - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - 40mg - n/a]), [TIOTROPIUM, TIOTROPIUM BROMIDE, TIOTROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - 20mg - n/a])
EU-EC-10007466653	1343	29.01.2021	More than 85 Years	Not Specified	Male	Chronic obstructive pulmonary disease (n/a - Fatal - Results in Death), Cough (n/a - Fatal - Results in Death), Diarrhoea (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007467009	1344	29.01.2021	More than 85 Years	Not Specified	Female	Altered state of consciousness (6d - Fatal - Results in Death), Decreased appetite (6d - Fatal - Results in Death), Nausea (2d - Recovered/Resolved -), Pain (2d - Recovered/Resolved -), Pain (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007467137	1345	29.01.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	KETOCONAZOLE [KETOCONAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), PROLIA [DENOSUMAB] (C - n/a - n/a - [n/a - n/a - n/a]), RESOLOR [PRUCALOPRIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [BENSERAZIDE HYDROCHLORIDE, LEVODOPA, BENZERAZIDE, LEVODOPA] (C - n/a - n/a [n/a - n/a - n/a]), [BUPRENORPHINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBIDOPA, LEVODOPA] (C - n/a - n/a - [n/a - n/a - n/a]), [CLOZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - n/a - n/a]), [DOCUSATE SODIUM, SORBITOL (E420)] (C - n/a - n/a - [n/a - n/a - n/a]), [ECONAZOLE, ECONAZOLE NITRATE, ECONAZOLE NITRATE, ZINC OXIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIDODRINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PROPYLENE GLYCOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007467145	1346	29.01.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	BETMIGA [MIRABEGRON] (C - n/a - n/a - [n/a - n/a - n/a]), ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - 5mg - n/a]), [CALCIUM, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 100mg - n/a])
EU-EC-10007467421	1347	29.01.2021	65-85 Years	Not Specified	Female	General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TIOTROPIUM, TIOTROPIUM BROMIDE, TIOTROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007467491	1348	29.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	[CHLORHEXIDINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CITALOPRAM] (C - n/a - n/a - [n/a - 10mg - n/a]), [LACTULOSE, LACTULOSE, LIQUID] (C - n/a - n/a - [n/a - 20mL - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 50ug - n/a]), [MEMANTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - .25mg - n/a]), [SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL (E420), SODIUM LAURYL SULFOACETATE, SODIUM CITRATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - Rectal]), [SODIUM FLUORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TIMOLOL, PILOCARPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [TIMOLOL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007467690	1349	29.01.2021	65-85 Years	Elderly	Female	Arrhythmia (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007467705	1350	29.01.2021	65-85 Years	Not Specified	Male	Pneumonia aspiration (n/a - Fatal - Results in Death), Sepsis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007468439	1351	29.01.2021	More than 85 Years	Not Specified	Female	Nasopharyngitis (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007468930	1352	29.01.2021	More than 85 Years	Not Specified	Female	Condition aggravated (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	COMIRNATY [TOZINAMERAN] (C - COVID-19 immunisation - n/a - [n/a - .3mL - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 1.25mg - n/a]), [CHLORPROMAZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 25mg - n/a]), [LEVOSULPIRIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [LORMETAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007470732	1353	29.01.2021	More than 85 Years	Elderly	Female	Dyspnoea (2h - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - 1{DF} - Intramuscular])	NOT AVAILABLE [LOSARTAN + AMLODIPINA] (C - n/a - n/a - [n/a - n/a - Oral]), [ALENDRONATE SODIUM, ALENDRONIC ACID] (C - n/a - n/a - [n/a - n/a - Oral]), [BETAHISTINE, BETAHISTINE DIHYDROCHLORIDE, BETAHISTINE MESILATE] (C - n/a - n/a - [n/a - n/a - Oral]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CALCIFEDIOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SULPIRIDE] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-10007470767	1354	29.01.2021	18-64 Years	Adult	Male	Death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007471240	1355	29.01.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007450888	1356	28.01.2021	More than 85 Years	Not Specified	Male	Blood pressure inadequately controlled (n/a - Unknown -), Sudden death (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (0d - Recovered/Resolved -)	(S - Colorectal cancer metastatic - Not applicable - [2d - n/a - Intravenous (not otherwise specified)]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [CALCIUM FOLINATE, CALCIUM FOLINATE PENTAHYDRATE, FOLINIC ACID] (S - Colorectal cancer metastatic - Not applicable - [2d - n/a - Intravenous (not otherwise specified)]), [FLUOROURACIL] (S - Colorectal cancer metastatic - Not applicable - [2d - n/a - Intravenous (not otherwise specified)]), [IRINOTECAN, IRINOTECAN HYDROCHLORIDE, IRINOTECAN HYDROCHLORIDE TRIHYDRATE] (S - Colorectal cancer metastatic - Not applicable - [2d - n/a - Intravenous (not otherwise specified)])	Not reported
EU-EC-10007451188	1357	28.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007451255	1358	28.01.2021	More than 85 Years	Not Specified	Female	Cardiac failure (1d - Fatal - Results in Death), Malaise (1d - Not Recovered/Not Resolved - Results in Death), Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007451273	1359	28.01.2021	18-64 Years	Not Specified	Male	Acute respiratory failure (2d - Fatal - Results in Death), Arrhythmia (2d - Fatal - Results in Death), Atrial fibrillation (1d - Recovered/Resolved - Results in Death), Metabolic acidosis (2d - Fatal - Results in Death), Pneumonia aspiration (2d - Fatal - Results in Death), Ventricular fibrillation (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007451287	1360	28.01.2021	65-85 Years	Not Specified	Male	COVID-19 (4d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]), NEOFORDEX [DEXAMETHASONE] (S - Monoclonal gammopathy - Not applicable - [n/a - n/a - Oral]), REVLIMID 5 MG HARD CAPSULES [LENALIDOMIDE] (S - Monoclonal gammopathy - Not applicable - [n/a - 5g - Oral])	ELIQUIS [APIXABAN] (C - Thrombosis prophylaxis - n/a - [n/a - 2.5mg/kg - Oral]), [IVOSIDENIB] (C - Acute myeloid leukaemia - n/a - [n/a - 250mg - Oral]), [LIPIDOSTEROLIC EXTRACT OF SERENOA REPENS, SERENOA REPENS (BARTRAM) SMALL.] (C - Benign prostatic hyperplasia - n/a - [n/a - 160mg - n/a]), [OMEPRAZOLE MAGNESIUM] (C - n/a - n/a - [n/a - n/a - Oral]), [PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 60mg - n/a]), [SULFAMETHOXAZOLE, TRIMETHOPRIM] (C - Prophylaxis - n/a - [n/a - n/a - Oral]), [TAMSULOSIN HYDROCHLORIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - n/a - Oral]), [VALACICLOVIR] (C - Prophylaxis - n/a - [n/a - n/a - Oral])
EU-EC-10007451324	1361	28.01.2021	More than 85 Years	Not Specified	Female	Pneumonia aspiration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[ERGOCALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [MACROGOL 3350, SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL 70%, LIQUID (CRYSTALLISING), SODIUM CITRATE, SORBITOL (E420), SODIUM LAURYL SULFOACETATE, SODIUM CITRATE, SORBITOL SOLUTION 70% (CRYSTALLISING) (PH. EUR.), SODIUM LAURYL SULFOACETATE, SODIUM LAURYL SULFOACETATE, TRISODIUM CITRATE, SORBITOL 70%, LIQUID (CRYSTALLISING), SORBITOL (E420), SODIUM LAURYL SULFOACETATE, SORBITOL (E420), SODIUM LAURYL SULFOACETATE, SODIUM CITRATE DIHYDRATE, SORBITOL, LIQUID (CRYSTALLISING), SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL, LIQUID (CRYSTALLISING), SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL, LIQUID (CRYSTALLISING), SODIUM CITRATE, SODIUM LAURYL SULFOACETATE 70%] (C - n/a - n/a - [n/a - n/a - n/a]), [NEFOPAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [POVIDONE, POLYVINYL ALCOHOL] (C - n/a - n/a - [n/a - n/a - n/a]), [RETINOL, VITAMIN A CONCENTRATE (OILY FORM), SYNTHETIC] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [STERCULIA, STERCULIA GUM, STERCULIA URENS ROXB. GUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007451396	1362	28.01.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007451467	1363	28.01.2021	More than 85 Years	Not Specified	Female	Malaise (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Urosepsis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007451705	1364	28.01.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007451827	1365	28.01.2021	More than 85 Years	Not Specified	Female	Cholecystitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007452321	1366	28.01.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007452619	1367	28.01.2021	More than 85 Years	Not Specified	Male	COVID-19 (14d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[PARACETAMOL, PARACETAMOL, ASPARTAME] (C - Pyrexia - n/a - [n/a - n/a - n/a])
EU-EC-10007452681	1368	28.01.2021	65-85 Years	Elderly	Female	Respiratory distress (9d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007452952	1369	28.01.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007452967	1370	28.01.2021	More than 85 Years	Not Specified	Male	Sepsis (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	JANUVIA [SITAGLIPTIN, SITAGLIPTIN PHOSPHATE, SITAGLIPTIN PHOSPHATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CANDESARTAN] (C - n/a - n/a - [n/a - n/a - n/a]), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOLPIDEM, ZOLPIDEM HEMITARTRATE, ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007453289	1371	28.01.2021	65-85 Years	Elderly	Female	General physical condition abnormal (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [14d - n/a - Subcutaneous])	Not reported
EU-EC-10007453875	1372	28.01.2021	More than 85 Years	Not Specified	Female	Malaise (2d - Fatal - Results in Death), Oxygen saturation decreased (2d - Fatal - Results in Death), Pneumonia (2d - Fatal - Results in Death), Respiratory disorder (2d - Fatal - Results in Death), Sedation (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ELIQUIS 2.5 MG FILM-COATED TABLETS [APIXABAN] (C - n/a - Unknown - [n/a - 2{DF} - n/a]), [AMIODARONE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [BISOPROLOL FUMARATE] (C - n/a - Unknown - [n/a - .5{DF} - n/a]), [CYANOCOBALAMIN, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [QUETIAPINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - Unknown - [n/a - .5{DF} - n/a])

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EU-EC-10007455769	1373	28.01.2021	More than 85 Years	Not Specified	Female	Acute kidney injury (2d - Fatal - Results in Death), Acute respiratory failure (2d - Fatal - Results in Death), General physical health deterioration (2d - Fatal - Results in Death), Hypoxia (0d - Fatal - Results in Death), Oxygen saturation decreased (2d - Fatal - Results in Death), Pneumonia (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	VIMPAT [LACOSAMIDE] (C - n/a - Unknown - [n/a - 2{DF} - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [FERROUS GLUCONATE, FERROUS ION] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [MOXONIDINE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [OMEPRAZOLE, OMEPRAZOLE SODIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [PERINDOPRIL ARGININE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a])
EU-EC-10007455828	1374	28.01.2021	More than 85 Years	Elderly	Female	Circulatory collapse (4h - Fatal - Results in Death), Peripheral vascular disorder (4h - Fatal - Results in Death), Vomiting (4h - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007455924	1375	28.01.2021	More than 85 Years	Elderly	Female	Pneumonia (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007456258	1376	28.01.2021	65-85 Years	Not Specified	Female	Cough (n/a - Fatal - Results in Death), Disease recurrence (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Rales (n/a - Fatal - Results in Death), Respiratory rate increased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[FENTANYL] (C - Pain - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - n/a])
EU-EC-10007456370	1377	28.01.2021	65-85 Years	Not Specified	Female	Acute coronary syndrome (n/a - Fatal - Results in Death), Intracardiac thrombus (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Respiratory rate increased (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [2y - n/a - Oral]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [2y - n/a - Oral]), [CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [2y - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [2y - n/a - n/a]), [LITHIUM, LITHIUM SULPHATE, ANHYDROUS] (C - n/a - n/a - [2y - n/a - Oral]), [SIMVASTATIN] (C - n/a - n/a - [2y - n/a - n/a])
EU-EC-10007456393	1378	28.01.2021	More than 85 Years	Not Specified	Female	Cerebral haemorrhage (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Heart rate increased (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (5d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007456396	1379	28.01.2021	More than 85 Years	Not Specified	Female	Altered state of consciousness (3d - Fatal - Results in Death), Bedridden (3d - Fatal - Results in Death), Decreased appetite (10d - Fatal - Results in Death), Fatigue (10d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[BISACODYL] (C - n/a - n/a -), [CARBIDOPA, LEVODOPA, LEVODOPA, ANHYDROUS CARBIDOPA, LEVODOPA, CARBIDOPA MONOHYDRATE] (C - n/a - n/a -), [OXAZEPAM] (C - n/a - n/a -), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - n/a - n/a -), [ZOPICLONE] (C - n/a - n/a -)
EU-EC-10007456951	1380	28.01.2021	65-85 Years	Elderly	Male	Death (7d - Fatal - Results in Death, Other Medically Important Condition), Influenza like illness (7d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Unknown])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007457033	1381	28.01.2021	65-85 Years	Not Specified	Male	Atrioventricular block complete (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), COVID-19 pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007457256	1382	28.01.2021	More than 85 Years	Not Specified	Female	Anxiety (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [DOMPERIDONE] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported
EU-EC-10007458677	1383	28.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	FIASP [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), TRESIBA [INSULIN DEGLUDEC] (C - n/a - n/a - [n/a - n/a - n/a]), [ATENOLOL, ATENOLOL BP] (C - n/a - n/a - [n/a - n/a - n/a]), [DONEPEZIL] (C - n/a - n/a - [n/a - n/a - n/a]), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LOPERAMIDE HYDROCHLORIDE, LOPERAMIDE OXIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMINE, PYRIDOXINE HYDROCHLORIDE, VITAMIN B] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007458683	1384	28.01.2021	65-85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007440860	1385	27.01.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007440863	1386	27.01.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007440868	1387	27.01.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[AMIODARONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 200mg - Oral]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 1.25mg - Oral]), [FLUINDIONE] (C - n/a - n/a - [n/a - n/a - Oral]), [FLUTICASON PROPIONATE, SALMETEROL, FLUTICASON PROPIONATE, SALMETEROL XINAFOATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - Oral]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [MORPHINE SULFATE] (C - n/a - n/a - [n/a - n/a - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - Oral]), [STERCULIA, STERCULIA GUM, STERCULIA URENS ROXB. GUM] (C - n/a - n/a - [n/a - n/a - Rectal])

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EU-EC-10007441084	1388	27.01.2021	More than 85 Years	Not Specified	Male	Pneumonia (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007441175	1389	27.01.2021	More than 85 Years	Not Specified	Female	Cardiac failure (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007441212	1390	27.01.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Increased bronchial secretion (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]), [FENTANYL] (S - Pain - Dose not changed - [n/a - .012mg - Transdermal])	[ALPRAZOLAM] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [STERCULIA, STERCULIA GUM, STERCULIA URENS ROXB. GUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007442305	1391	27.01.2021	65-85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	OLANZAPINE TEVA [OLANZAPINE] (C - Schizoaffective disorder - n/a - [n/a - 15mg - Oral]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [175d - 500mg - Oral]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - Oral])
EU-EC-10007442317	1392	27.01.2021	More than 85 Years	Not Specified	Female	C-reactive protein increased (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007442460	1393	27.01.2021	65-85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Respiratory arrest (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	LEVEMIR [INSULIN DETEMIR] (C - n/a - n/a - [n/a - n/a - n/a]), NOVORAPID [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), [ALENDRONATE SODIUM, ALENDRONIC ACID] (C - Osteoporosis prophylaxis - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CANDESARTAN] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [DIAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [EZETIMIBE] (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a]), [METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a]), [ROPINIROLE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007442465	1394	27.01.2021	18-64 Years	Not Specified	Female	Acute respiratory failure (n/a - Fatal - Results in Death), Respiratory tract infection (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007442493	1395	27.01.2021	65-85 Years	Not Specified	Female	Contusion (n/a - Fatal - Results in Death), Fall (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007442718	1396	27.01.2021	18-64 Years	Not Specified	Male	Respiratory failure (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007444663	1397	27.01.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	LIXIANA [EDOXABAN, EDOXABAN TOSYLATE] (C - n/a - Dose not changed - [n/a - 30mg n/a]), [COLECALCIFEROL] (C - n/a - n/a -), [FOLIC ACID] (C - n/a - Dose not changed -), [FUROSEMIDE] (C - n/a - Dose not changed - [n/a - 20mg - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - 50mg - n/a]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - n/a - Dose not changed - [n/a - 10mg - n/a])
EU-EC-10007444664	1398	27.01.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Life Threatening), Fatigue (n/a - Fatal - Results in Death, Life Threatening), Somnolence (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - Dose not changed - [n/a - 75mg - n/a]), [LORAZEPAM] (C - n/a - Dose not changed - [n/a - 2.5mg - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - 50mg - n/a])
EU-EC-10007444862	1399	27.01.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	[CANDESARTAN CILEXETIL] (C - n/a - Dose not changed - [n/a - 8mg - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - Dose not changed - [n/a - 12.5mg - n/a])
EU-EC-10007444951	1400	27.01.2021	More than 85 Years	Not Specified	Female	Death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	FENTANYL [FENTANYL, FENTANYL CITRATE] (C - n/a - n/a - [n/a - n/a - Unknown]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - Unknown]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - Unknown]), [CALCIUM CITRATE, MAIZE STARCH, STEARIC ACID, TALC, CALCIUM CITRATE] (C - n/a - n/a - [n/a - n/a - Unknown]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - Unknown]), [ENOXAPARIN SODIUM] (C - n/a - n/a - [n/a - n/a - Unknown]), [FOLIC ACID, DRIED FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - Unknown]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - Unknown]), [ROSUVASTATIN CALCIUM] (C - n/a - n/a - [n/a - n/a - Unknown]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - n/a - Unknown])
EU-EC-10007444997	1401	27.01.2021	More than 85 Years	Not Specified	Female	Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Personality change (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007445158	1402	27.01.2021	More than 85 Years	Not Specified	Female	Infection (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BUPRENORPHINE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE, LOSARTAN] (C - n/a - n/a - [n/a - n/a - n/a]), [MACROGOL 3350, POTASSIUM, SODIUM, CHLORIDE ION, HYDROGEN CARBONATE, POTASSIUM, SODIUM, CHLORINE, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM CITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007445192	1403	27.01.2021	More than 85 Years	Not Specified	Female	Infection (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [BENDROFLUAZIDE, BENDROFLUMETHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [CANDESARTAN CILEXETIL] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007445203	1404	27.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007445211	1405	27.01.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Subcutaneous])	Not reported
EU-EC-10007445236	1406	27.01.2021	More than 85 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	DULOXETINE [DULOXETINE] (C - n/a - n/a - [n/a - n/a - n/a]), INSULATARD [INSULIN HUMAN, INSULIN HUMAN (RDNA), INSULIN HUMAN ISOPHANE (RDNA)] (C - n/a - n/a - [n/a - n/a - n/a]), PREGABALIN [PREGABALIN] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007445290	1407	27.01.2021	More than 85 Years	Not Specified	Female	No reaction on previous exposure to drug (n/a - Fatal Results in Death)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a -), [CLOMETHIAZOLE] (C - n/a - n/a -), [DIAZEPAM] (C - n/a - n/a -), [DONEPEZIL] (C - n/a - n/a -), [HALOPERIDOL] (C - n/a - n/a -)
EU-EC-10007445410	1408	27.01.2021	65-85 Years	Elderly	Female	Death (5d - Fatal - Results in Death), General physical condition abnormal (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007445686	1409	27.01.2021	More than 85 Years	Elderly	Male	Myocardial infarction (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[ACETYLSALICYLIC ACID, ACETYLSALICYLIC ACID PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [NITRENDIPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007445740	1410	27.01.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007446819	1411	27.01.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007446863	1412	27.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	[ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007446873	1413	27.01.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007446887	1414	27.01.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Productive cough (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FINASTERIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYCODONE, OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007448076	1415	27.01.2021	More than 85 Years	Elderly	Male	Acute left ventricular failure (n/a - Fatal - Results in Death), Presyncope (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007448078	1416	27.01.2021	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 1mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 100ug - n/a]), [MEMANTINE] (C - n/a - n/a - [n/a - 20mg - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 15mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - 20mg - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007448400	1417	27.01.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Life Threatening), Condition aggravated (n/a - Fatal - Results in Death, Life Threatening), Drug ineffective (n/a - Fatal - Results in Death, Life Threatening), General physical health deterioration (n/a - Fatal - Results in Death, Life Threatening), Respiratory tract infection (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007449346	1418	27.01.2021	More than 85 Years	Not Specified	Female	Coronary artery disease (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BECLOMETASONE DIPROPIONATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [CALCIUM CARBONATE] (C - Osteoporosis prophylaxis - n/a - [n/a - n/a - n/a]), [FERROUS SULFATE] (C - Mineral supplementation - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM, OMEPRAZOLE SODIUM] (C - Dyspepsia - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Analgesic therapy - n/a - [n/a - n/a - n/a]), [QUININE] (C - Muscle spasms - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])
EU-EC-10007449392	1419	27.01.2021	65-85 Years	Elderly	Female	COVID-19 (n/a - Fatal - Results in Death), Respiratory failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ELIQUIS [APIXABAN] (C - Thrombosis prophylaxis - n/a - [n/a - 2.5mg - Oral]), [ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE, LEVOTHYROXINE SODIUM, LEVOTHYROXINE SODIUM ANHYDROUS EP] (C - Hypometabolism - n/a - [n/a - n/a - Oral]), [ASCORBIC ACID] (C - Vitamin supplementation - n/a - [n/a - 1{DF} - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - Oral]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 1{DF} - Oral]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - 37.5mg - Oral]), [VITAMIN D, CALCIUM] (C - Vitamin D deficiency - n/a - [n/a - 1{DF} - Oral])
EU-EC-10007450134	1420	27.01.2021	18-64 Years	Adult	Male	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007431082	1421	26.01.2021	18-64 Years	Not Specified	Female	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intravenous (not otherwise specified)])	Not reported

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EU-EC-10007431098	1422	26.01.2021	65-85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	JANUVIA 100 MG FILM-COATED TABLETS [SITAGLIPTIN] (C - n/a - n/a - [n/a - n/a - Oral]), MIMPARA 30 MG FILM-COATED TABLETS [CINACALCET, CINACALCET HYDROCHLORIDE] (C - n/a - n/a - [n/a - 30mg - Oral]), [AMOXICILLIN SODIUM, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, POTASSIUM CLAVULANATE, AMOXICILLIN, CLAVULANIC ACID, AMOXICILLIN, POTASSIUM CLAVULANATE] (C - n/a - n/a - [n/a - 1g - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a - [n/a - 20mg - Oral]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [DEXAMETHASONE SODIUM PHOSPHATE] (C - n/a - n/a - [n/a - 6mg - Oral]), [DISODIUM PHOSPHATE, ANHYDROUS, CALCIUM, MAGNESIUM GLYCEROPHOSPHATE, PHOSPHORIC ACID CONCENTRATED, DISODIUM PHOSPHATE, ANHYDROUS, MAGNESIUM GLYCEROPHOSPHATE, PHOSPHORIC ACID CONCENTRATED, CALCIUM BIS(DIHYDROGENPHOSPHATE) MONOHYDRATE, DISODIUM PHOSPHATE, MAGNESIUM GLYCEROPHOSPHATE, PHOSPHORIC ACID CONCENTRATED, CALCIUM BIS(DIHYDROGENPHOSPHATE) MONOHYDRATE] (C - n/a - n/a - [n/a - 50{drp} - Oral]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - 10mg - Oral]), [PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [TINZAPARIN, TINZAPARIN SODIUM] (C - Atrial fibrillation - n/a - [n/a - .7mL - Subcutaneous])
EU-EC-10007431167	1423	26.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007431170	1424	26.01.2021	More than 85 Years	Not Specified	Female	Gastric volvulus (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007431177	1425	26.01.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007431178	1426	26.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported

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EU-EC-10007431298	1427	26.01.2021	65-85 Years	Not Specified	Male	Agitation (n/a - Fatal - Results in Death), Fall (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death), Tachycardia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]), [AMOXICILLIN SODIUM, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, POTASSIUM CLAVULANATE, AMOXICILLIN, CLAVULANIC ACID, AMOXICILLIN, POTASSIUM CLAVULANATE] (S - Bronchitis - n/a - [n/a - 1g - Oral]), [PREDNISOLONE, PREDNISOLONE METASULFOBENZOATE SODIUM] (S - Bronchitis - n/a - [n/a - 40mg - Oral])	Not reported
EU-EC-10007431311	1428	26.01.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007431595	1429	26.01.2021	More than 85 Years	Not Specified	Female	Acute myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown -), Disease recurrence (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ALPRAZOLAM] (C - Dementia - n/a - [n/a - .25mg - Oral]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (C - Dementia - n/a - [n/a - 6{drp} - Oral]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - 50ug - Oral]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Dementia - n/a - [n/a - 25mg - Oral]), [ZOLPIDEM TARTRATE] (C - Dementia - n/a - [n/a - 10mg - Oral])
EU-EC-10007431600	1430	26.01.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Nausea (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [LOPERAMIDE, LOPERAMIDE HYDROCHLORIDE] (C - Diarrhoea - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Reflux gastritis - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a])
EU-EC-10007431602	1431	26.01.2021	More than 85 Years	Not Specified	Male	Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved -), Myocardial infarction (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007431609	1432	26.01.2021	More than 85 Years	Not Specified	Male	Fall (n/a - Fatal - Results in Death), Pneumonia aspiration (n/a - Fatal - Results in Death), Somnolence (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM] (C - Hypovitaminosis - n/a - [n/a - n/a - n/a]), [FERROUS FUMARATE] (C - Blood iron decreased - n/a - [n/a - n/a - n/a]), [FINASTERIDE] (C - Prostatism - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Dyspepsia - n/a - [n/a - n/a - n/a]), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - Prostatism - n/a - [n/a - n/a - n/a])
EU-EC-10007431613	1433	26.01.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	RIVASTIGMINE [RIVASTIGMINE, RIVASTIGMINE HYDROGEN TARTRATE] (C - Parkinson's disease - n/a - [n/a - n/a - n/a])
EU-EC-10007431674	1434	26.01.2021	65-85 Years	Not Specified	Male	Asthenia (n/a - Unknown -), Cardiac arrest (n/a - Fatal - Results in Death), Cardiac failure (n/a - Fatal - Results in Death), Feeling abnormal (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TENOFIVIR] (C - n/a - n/a - [n/a - n/a - n/a]), [TICAGRELOR] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007432271	1435	26.01.2021	65-85 Years	Not Specified	Female	Cerebrovascular accident (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007432502	1436	26.01.2021	More than 85 Years	Elderly	Female	Ventricular fibrillation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007432561	1437	26.01.2021	65-85 Years	Not Specified	Female	Subarachnoid haemorrhage (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	ACLIDINIUM BROMIDE [ACLIDINIUM BROMIDE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a])
EU-EC-10007432705	1438	26.01.2021	65-85 Years	Not Specified	Male	Multiple organ dysfunction syndrome (4d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007433053	1439	26.01.2021	More than 85 Years	Not Specified	Female	Blood pressure immeasurable (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Nausea (n/a - Fatal - Results in Death), Personality change (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death), Unresponsive to stimuli (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007433690	1440	26.01.2021	More than 85 Years	Not Specified	Male	Diarrhoea (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	LANTUS [INSULIN GLARGINE] (C - Diabetes mellitus - n/a - [n/a - 17[iU] - Subcutaneous]), MIDAZOLAM [MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE] (C - Restlessness - n/a - [372d - 1mg - Oral]), [BUTYLSCOPOLAMINE, HYOSCINE BUTYLBROMIDE] (C - Gastrointestinal pain - n/a - [6d - 20mg - Oral]), [FENTANYL, FENTANYL CITRATE] (C - Pain - n/a - [7d - n/a - Transdermal]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (C - Restlessness - n/a - [6d - 1mg - Oral]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 100mg - Oral]), [METOCLOPRAMIDE HYDROCHLORIDE] (C - Nausea - n/a - [6d - 10mg - Oral]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [MORPHINE HYDROCHLORIDE] (C - Pain - n/a - [6d - n/a - n/a]), [OXAZEPAM] (C - Restlessness - n/a - [n/a - 5mg - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - Pain - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral])
EU-EC-10007433899	1441	26.01.2021	65-85 Years	Not Specified	Female	Body temperature increased (n/a - Fatal - Results in Death, Life Threatening), COVID-19 (n/a - Fatal - Results in Death, Life Threatening), Crepitations (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Life Threatening), Food refusal (n/a - Fatal - Results in Death, Life Threatening), General physical health deterioration (n/a - Unknown Other Medically Important Condition), Oxygen saturation decreased (n/a - Fatal - Results in Death, Life Threatening), Pneumonia (n/a - Fatal - Results in Death, Life Threatening), Tachycardia (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007433980	1442	26.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[DORZOLAMIDE, TIMOLOL] (C - n/a - n/a - [n/a - n/a - n/a]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 25ug - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a]), [SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [UREA] (C - n/a - n/a - [n/a - n/a - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007434059	1443	26.01.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007434088	1444	26.01.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Multimorbidity (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007434914	1445	26.01.2021	More than 85 Years	Not Specified	Female	Dyspnoea (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - [n/a - 20mg - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - n/a]), [BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 1.25mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 25mg - n/a]), [LACTULOSE] (C - n/a - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - n/a - n/a - [n/a - 1mg - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007436240	1446	26.01.2021	More than 85 Years	Not Specified	Female	Haemorrhage intracranial (0d - Fatal - Results in Death), Nervous system disorder (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), XARELTO 15 MG [RIVAROXABAN] (S - n/a - Unknown - [n/a - 1{DF} - n/a])	[FUROSEMIDE] (C - n/a - Unknown - [n/a - .5{DF} - n/a]), [MIRTAZAPINE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [PARACETAMOL] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007436275	1447	26.01.2021	65-85 Years	Not Specified	Female	Death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007436350	1448	26.01.2021	More than 85 Years	Not Specified	Male	Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	APROVEL [IRBESARTAN] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MEMANTINE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007436592	1449	26.01.2021	More than 85 Years	Not Specified	Female	Pancreatitis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - 2.5mg - n/a]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 20mg - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 5mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [LAMOTRIGINE] (C - n/a - n/a - [n/a - 25mg - n/a]), [OLMESARTAN MEDOXOMIL] (C - n/a - n/a -), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - n/a - n/a - [n/a - 20mg - n/a]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 75mg - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])

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EU-EC-10007437189	1450	26.01.2021	65-85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	PANTOPRAZOLE 20 MG [PANTOPRAZOLE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [ANHYDROUS LEVOTHYROXINE SODIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [CARVEDILOL] (C - n/a - Unknown - [n/a - .5{DF} - n/a]), [CLONAZEPAM] (C - n/a - Unknown - [n/a - 2{DF} - n/a]), [COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE, CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [FENTANYL] (C - n/a - Unknown - [n/a - n/a - n/a]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (C - n/a - Unknown - [n/a - 15{drp} - n/a]), [NADROPARIN CALCIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [PARACETAMOL, ANHYDROUS CAFFEINE, PARACETAMOL, CAFFEINE, PARACETAMOL, POVIDONE, CAFFEINE] (C - n/a - Unknown - [n/a - 4g - n/a]), [PROTHIPENDYL HYDROCHLORIDE, PROTHIPENDYL HYDROCHLORIDE MONOHYDRATE] (C - n/a - Unknown - [n/a - .5{DF} - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - Unknown - [n/a - 1{DF} - n/a])
EU-EC-10007437448	1451	26.01.2021	More than 85 Years	Not Specified	Female	Myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[CALCITONIN (SALMON)] (C - n/a - n/a - [n/a - 30mL - Oral]), [CASSIA, SENNA PODS] (C - n/a - n/a - [n/a - n/a - Oral]), [FERROUS FUMARATE] (C - n/a - n/a - [n/a - 10mL - Oral]), [FOLIC ACID] (C - n/a - n/a - [n/a - 5mg - Oral]), [HYDROGEN PEROXIDE] (C - n/a - n/a - [n/a - 125mL - Oral]), [MEMANTINE] (C - Dementia - n/a - [n/a - 20mg - Oral]), [PERACETIC ACID] (C - n/a - n/a - [n/a - 125mL - Oral])
EU-EC-10007437454	1452	26.01.2021	More than 85 Years	Elderly	Female	Asthenia (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death), Respiratory depression (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1{DF} - n/a])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM] (C - n/a - n/a - [n/a - 20mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 20mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 75ug - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Psychotic disorder due to a general medical condition - n/a - [n/a - 125mg - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - 40mg - n/a])
EU-EC-10007437695	1453	26.01.2021	More than 85 Years	Not Specified	Male	Dyspnoea (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Respiratory arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[MORPHINE HYDROCHLORIDE] (C - Pain - n/a - [n/a - n/a - Subcutaneous])
EU-EC-10007437846	1454	26.01.2021	More than 85 Years	Not Specified	Female	Cardiac failure (0d - Fatal - Results in Death), Cardiovascular disorder (0d - Fatal - Results in Death), General physical health deterioration (0d - Fatal - Results in Death), Pulmonary oedema (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	LIXIANA 60 MG [EDOXABAN, EDOXABAN TOSYLATE] (C - n/a - Unknown - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - Unknown - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [BUMETANIDE] (C - n/a - Unknown - [n/a - n/a - n/a])

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EU-EC-10007438759	1455	26.01.2021	More than 85 Years	Not Specified	Male	Agitation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - Coronary artery disease - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Coronary artery disease - n/a - [n/a - n/a - n/a]), [FERROUS FUMARATE] (C - Anaemia - n/a - [n/a - n/a - n/a]), [MEMANTINE] (C - Dementia - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - Depression - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Gastritis erosive - n/a - [n/a - n/a - n/a]), [OXYTETRACYCLINE] (C - Rosacea - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - Coronary artery disease - n/a - [n/a - n/a - n/a])
EU-EC-10007439851	1456	26.01.2021	More than 85 Years	Elderly	Female	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - Unknown -), [DRIED FERROUS SULFATE, FERROUS SULPHATE SESQUIHYDRATE] (C - n/a - Unknown -)
EU-EC-10007440246	1457	26.01.2021	18-64 Years	Adult	Female	Aortic dissection (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ATORVASTATIN] (C - Hypercholesterolaemia - Dose not changed - [n/a - 20mg - n/a])
EU-EC-10007420216	1458	25.01.2021	More than 85 Years	Not Specified	Female	Heart rate increased (n/a - Unknown -), Oxygen saturation decreased (n/a - Unknown -), Pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ASCORBIC ACID, CALCIUM GLUBIONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBIONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [DONEPEZIL] (N - n/a - n/a - [n/a - n/a - n/a]), [ERGOCALCIFEROL] (N - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007420566	1459	25.01.2021	More than 85 Years	Not Specified	Male	Coma scale abnormal (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Head injury (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Hypothermia (n/a - Unknown - Other Medically Important Condition), Hypoxia (n/a - Unknown - Other Medically Important Condition), Lung consolidation (n/a - Unknown - Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	APIXABAN [APIXABAN] (C - n/a - n/a - [n/a - 10mg - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [FERRIC CARBOXYMALTOSIDE, IRON] (C - Iron deficiency anaemia - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - 15mg - n/a])

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EU-EC-10007420672	1460	25.01.2021	More than 85 Years	Not Specified	Male	Aortic aneurysm rupture (n/a - Fatal - Results in Death, Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID, ASPIRIN BP] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Coronary artery disease - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - Coronary artery disease - n/a - [n/a - n/a - n/a]), [ISOSORBIDE MONONITRATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [NICORANDIL] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Prophylaxis - n/a - [n/a - n/a - n/a]), [ROPINIROLE] (C - Restless legs syndrome - n/a - [n/a - n/a - n/a])
EU-EC-10007420677	1461	25.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007420697	1462	25.01.2021	18-64 Years	Not Specified	Female	Arrhythmia (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cerebellar haemorrhage (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Thrombosis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007421187	1463	25.01.2021	65-85 Years	Elderly	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007421200	1464	25.01.2021	65-85 Years	Not Specified	Male	Cardiovascular disorder (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - Unknown - [n/a - n/a - n/a]), [BETAHISTINE DIHYDROCHLORIDE, BETAHISTINE HYDROCHLORIDE] (C - n/a - Unknown [n/a - n/a - n/a]), [GLICLAZIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [INDAPAMIDE, INDAPAMIDE HEMIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [LORMETAZEPAM] (C - n/a - Unknown - [n/a - n/a - n/a]), [METFORMIN HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [MOLSIDOMINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - Unknown - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - Unknown - [n/a - n/a - n/a]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [TERAZOSIN] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007421334	1465	25.01.2021	More than 85 Years	Not Specified	Female	Circulatory collapse (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007421999	1466	25.01.2021	65-85 Years	Not Specified	Female	Cardiovascular disorder (n/a - Fatal - Results in Death), Pulmonary embolism (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported

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EU-EC-10007422172	1467	25.01.2021	More than 85 Years	Not Specified	Female	Hypoglycaemia (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ACENOCOUMAROL] (C - n/a - Unknown - [n/a - n/a - n/a]), [ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE SODIUM] (C - n/a - Unknown - [n/a - n/a - n/a]), [MOXIFLOXACIN] (C - n/a - Unknown - [n/a - n/a - n/a]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007422315	1468	25.01.2021	Not Specified	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007422316	1469	25.01.2021	More than 85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007422470	1470	25.01.2021	More than 85 Years	Not Specified	Female	Agitation (2d - Fatal - Results in Death), Death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007422755	1471	25.01.2021	65-85 Years	Not Specified	Female	Cardio-respiratory arrest (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - Unknown - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [CALCIUM CARBONATE] (C - n/a - Unknown - [n/a - n/a - n/a]), [DILTIAZEM, DILTIAZEM HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a]), [METHYLPREDNISOLONE] (C - n/a - Unknown - [n/a - n/a - n/a]), [OLMESARTAN, OLMESARTAN MEDOXOMIL] (C - n/a - Unknown - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - Unknown - [n/a - n/a - n/a]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10007422892	1472	25.01.2021	Not Specified	Not Specified	Male	Cardiac failure (n/a - Fatal - Results in Death), Diabetic complication (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007423159	1473	25.01.2021	More than 85 Years	Not Specified	Female	Dysphoria (0d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (0d - Fatal - Results in Death, Other Medically Important Condition), Sudden death (0d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - intramuscular])	Not reported
EU-EC-10007423215	1474	25.01.2021	65-85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007423267	1475	25.01.2021	More than 85 Years	Elderly	Male	Dyspnoea (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Rash macular (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[BUDESONIDE, BUDESONIDE, MICRONISED] (C - Diarrhoea - n/a - [5d - n/a - Oral]), [LEVOTHYROXINE] (C - Hypothyroidism - n/a - [1970d - n/a - Oral]), [OXAZEPAM] (C - Behaviour disorder - n/a - [307d - n/a - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Prophylaxis against gastrointestinal ulcer - n/a - [81d - n/a - Oral]), [RACECADOTRIL] (C - Diarrhoea - n/a - [5d - n/a - Oral]), [RISPERIDONE] (C - Behaviour disorder - n/a - [341d - n/a - Oral]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Behaviour disorder - n/a - [117d - n/a - Oral])
EU-EC-10007423313	1476	25.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007423721	1477	25.01.2021	Not Specified	Elderly	Male	Death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported
EU-EC-10007423826	1478	25.01.2021	More than 85 Years	Elderly	Female	Asthenia (16d - Fatal - Results in Death), Death (16d - Fatal - Results in Death), General physical condition abnormal (16d - Fatal - Results in Death), Pain (16d - Fatal - Results in Death), Respiratory distress (16d - Fatal - Results in Death), Unresponsive to stimuli (16d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007427048	1479	25.01.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	ADENURIC 80 MG FILM-COATED TABLETS [FEBUXOSTAT] (C - n/a - n/a - [n/a - 1{DF} - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1{DF} - n/a]), NOVOMIX 30 PENFILL [INSULIN ASPART, INSULIN ASPART, INSULIN ASPART PROTAMINE] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - .5{DF} - n/a]), [BETAMETHASONE DIPROPIONATE, GENTAMICIN, BETAMETHASONE DIPROPIONATE, GENTAMICIN SULFATE, GENTAMICIN SULFATE, BETAMETHASONE DIPROPIONATE (PH. EUR.), GENTAMICIN, BETAMETHASONE] (C - n/a - n/a - [n/a - n/a - n/a]), [CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [CLOPIDOGREL] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [D-LIMONENE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE, CANDESARTAN CILEXETIL] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [HYDROXYZINE DIHYDROCHLORIDE, HYDROXYZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [HYPROMELLOSE] (C - n/a - n/a - [n/a - 1{drp} - n/a]), [LIQUID PARAFFIN] (C - n/a - n/a - [n/a - n/a - n/a]), [MELALEUCA ALTERNIFOLIA OIL] (C - n/a - n/a - [n/a - n/a - n/a]), [METHYLPREDNISOLONE, METHYLPREDNISOLONE ACETATE, METHYLPREDNISOLONE SODIUM HEMISUCCINATE] (C - Eczema - n/a - [n/a - .5{DF} - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SOYA BEAN OIL REFINED PH.EUR., SOYA OIL, SOYA-BEAN OIL REFINED] (C - n/a - n/a - [n/a - n/a - n/a]), [VASELINE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007429957	1480	25.01.2021	65-85 Years	Elderly	Male	COVID-19 pneumonia (14d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007429960	1481	25.01.2021	More than 85 Years	Elderly	Male	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	ARANESP [DARBEPOETIN ALFA] (C - Anaemia - Dose increased -), GALVUS 50 MG TABLETS [VILDAGLIPTIN] (C - Diabetes mellitus - Dose not changed - [n/a - 50mg - n/a]), LANTUS [INSULIN GLARGINE] (C - Diabetes mellitus - n/a -), [ALLOPURINOL] (C - n/a - Dose not changed -), [ATORVASTATIN] (C - n/a - Dose not changed -), [CALCIFEDIOL] (C - n/a - Dose not changed -), [CALCIUM POLYSTYRENE SULFONATE] (C - n/a - Dose not changed -), [DRIED FERROUS SULFATE, FERROUS SULFATE, FERROUS SULFATE HYDRATE, FERROUS SULPHATE SESQUIHYDRATE] (C - n/a - Dose not changed -), [FUROSEMIDE] (C - Cardiac failure - Dose not changed - [n/a - 200mg - n/a]), [HYDROCHLOROTHIAZIDE] (C - Hypertension - Dose not changed - [n/a - 25mg - Oral]), [OMEPRAZOLE] (C - n/a - Dose not changed -), [PHENOBARBITAL, PHENOBARBITAL SODIUM] (C - n/a - Drug withdrawn -), [SPIRONOLACTONE] (C - n/a - Dose not changed - [n/a - 50mg - n/a])

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EU-EC-10007430329	1482	25.01.2021	65-85 Years	Elderly	Male	Vomiting (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported
EU-EC-10007416594	1483	23.01.2021	More than 85 Years	Not Specified	Female	Hypotension (1d - Fatal - Results in Death), Increased bronchial secretion (1d - Fatal - Results in Death), Oxygen saturation decreased (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	ESOMEPRAZOLE [ESOMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - Oral]), [ACETYLSALICYLIC ACID, D,L-LYSINE ACETYLSALICYLATE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [FUROSEMIDE] (C - Hypertension - n/a - [n/a - 20mg - Oral]), [LERCANIDIPINE HYDROCHLORIDE] (C - Hypertension - n/a - [n/a - 10mg - Oral]), [PIRACETAM] (C - Epilepsy - n/a - [n/a - 800mg - Oral]), [POTASSIUM CHLORIDE, POTASSIUM CHLORIDE, ETHYLCELLULOSE MICROENCAPSULATED 80-90%] (C - n/a - n/a - [n/a - 1{DF} - Oral])
EU-EC-10007399673	1484	22.01.2021	More than 85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007401669	1485	22.01.2021	More than 85 Years	Not Specified	Female	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[BISOPROLOL FUMARATE] (C - Myocardial ischaemia - n/a - [n/a - 2.5mg - Oral]), [D,L-LYSINE ACETYLSALICYLATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - Oral]), [FUROSEMIDE] (C - Renal failure - n/a - [n/a - 80mg - Oral]), [GLYCEROL] (C - Constipation - n/a - [n/a - 2.1g - Rectal]), [GLYCERYL TRINITRATE] (C - Product used for unknown indication - n/a - [n/a - 10mg - Transdermal]), [LACTULOSE] (C - Constipation - n/a - [n/a - 20g - Oral]), [LIQUID PARAFFIN] (C - Constipation - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1g - n/a]), [RAMIPRIL] (C - Myocardial ischaemia - n/a - [n/a - 1.25mg - Oral]), [RISPERIDONE] (C - Behaviour disorder - n/a - [n/a - .5mg - Oral])
EU-EC-10007403036	1486	22.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), No adverse event (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007403048	1487	22.01.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007403183	1488	22.01.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007403297	1489	22.01.2021	More than 85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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EU-EC-10007403312	1490	22.01.2021	More than 85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardiac failure (n/a - Fatal - Results in Death), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID, ACETYLSALICYLIC ACID PH. EUR.] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [CHOLECALCIFEROL CONCENTRATE (POWDER FORM), COLECALCIFEROL, COLECALCIFEROL CONCENTRATE (OILY FORM)] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [FERROUS (II) GLYCINE SULFATE COMPLEX] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [MELPERONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - .5{DF} - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - .5{DF} - n/a])
EU-EC-10007403462	1491	22.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), RIVAROXABAN [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), SITAGLIPTIN [SITAGLIPTIN] (C - n/a - n/a - [n/a - n/a - n/a]), [DIGITOXIN] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [METAMIZOLE, METAMIZOLE MAGNESIUM, METAMIZOLE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007403602	1492	22.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown -), Malaise (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007403754	1493	22.01.2021	65-85 Years	Elderly	Not Specified	Death (0d - Fatal - Results in Death), Decreased appetite (0d - Fatal - Results in Death), Diet refusal (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007403867	1494	22.01.2021	18-64 Years	Adult	Male	General physical condition abnormal (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007404175	1495	22.01.2021	More than 85 Years	Not Specified	Female	Myocardial infarction (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	ARIPIPRAZOLE [ARIPIPRAZOLE] (C - Dementia - n/a - [n/a - n/a - n/a]), CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [CALCIUM CARBONATE, CHOLECALCIFEROL CONCENTRATE (POWDER FORM)] (C - Bone disorder - n/a - [n/a - n/a - n/a]), [DIAZEPAM] (C - Agitation - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - Oedema peripheral - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Dyspepsia - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [SENN ALEXANDRINA LEAF, CASSIA] (C - Constipation - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - n/a])

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EU-EC-10007404231	1496	22.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007404276	1497	22.01.2021	18-64 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007404543	1498	22.01.2021	More than 85 Years	Elderly	Male	Death (0d - Fatal - Results in Death), Nausea (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007405223	1499	22.01.2021	More than 85 Years	Elderly	Female	Acute myocardial infarction (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007405344	1500	22.01.2021	More than 85 Years	Not Specified	Male	General physical condition abnormal (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007405602	1501	22.01.2021	More than 85 Years	Elderly	Female	Acute kidney injury (8d - Fatal - Results in Death), Disturbance in attention (8d - Fatal - Results in Death), Epilepsy (8d - Fatal - Results in Death), Fall (n/a - Fatal - Results in Death), General physical condition abnormal (n/a - Fatal - Results in Death), Hypercalcaemia (8d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007406874	1502	22.01.2021	More than 85 Years	Elderly	Male	Atrial fibrillation (2d - Fatal - Results in Death, Life Threatening), Cardiac failure (2d - Fatal - Results in Death, Life Threatening), Hyperpyrexia (2d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007407761	1503	22.01.2021	18-64 Years	Adult	Female	Cough (n/a - Fatal - Results in Death), Infective exacerbation of chronic obstructive airways disease (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007407835	1504	22.01.2021	65-85 Years	Not Specified	Male	General physical health deterioration (n/a - Fatal - Results in Death), Respiratory failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007407904	1505	22.01.2021	More than 85 Years	Elderly	Female	Coronavirus infection (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007410192	1506	22.01.2021	18-64 Years	Not Specified	Male	Death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007410538	1507	22.01.2021	More than 85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[BUPRENORPHINE] (C - Pain - n/a - [n/a - 1{DF} - Cutaneous]), [CARBOMER, CARBOMER 980] (C - Dry eye - n/a - [n/a - n/a - Ophthalmic]), [LACTULOSE] (C - Constipation - n/a - [n/a - 20mL - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1g - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Restlessness - n/a - [n/a - 25mg - Oral]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [n/a - 20{DF} - Oral]), [VITAMIN D] (C - n/a - n/a - [n/a - 40ug - n/a])
EU-EC-10007411429	1508	22.01.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007411430	1509	22.01.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007411431	1510	22.01.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (0d - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007414167	1511	22.01.2021	Not Specified	Adult	Female	Cardiac arrest (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	SILDENAFIL [SILDENAFIL] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - n/a - n/a]), [AMILORIDE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [DESOGESTREL] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007414973	1512	22.01.2021	More than 85 Years	Elderly	Female	Acute respiratory failure (4d - Fatal - Results in Death, Life Threatening), Hypotension (2d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007415077	1513	22.01.2021	Not Specified	Elderly	Not Specified	Diarrhoea (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007415655	1514	22.01.2021	More than 85 Years	Not Specified	Female	Acute respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Auscultation (n/a - Unknown -), Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	ABASAGLAR [INSULIN GLARGINE] (C - Diabetes mellitus - n/a - [n/a - n/a - Subcutaneous])

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EU-EC-10007391673	1515	21.01.2021	65-85 Years	Not Specified	Male	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Product used for unknown indication - n/a - [n/a - 20mg - Oral]), [ALFUZOSIN HYDROCHLORIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - 10mg - Oral]), [ALUMINIUM HYDROXIDE GEL, DRIED, MAGNESIUM CARBONATE, SODIUM CARBONATE, ALGINIC ACID, ALUMINIUM HYDROXIDE, SODIUM CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE, ALUMINIUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, ALGINIC ACID, ALUMINIUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, ALGINIC ACID, ALUMINIUM HYDROXIDE GEL, DRIED USP, SODIUM HYDROGEN CARBONATE, ALGINIC ACID, SODIUM ALGINATE, ALUMINIUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, ALUMINIUM HYDROXIDE GEL, CALCIUM CARBONATE, SODIUM ALGINATE, SODIUM HYDROGEN CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE, SODIUM HYDROGEN CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE, SODIUM HYDROGEN CARBONATE, CALCIUM CARBONATE, SODIUM ALGINATE, ALUMINIUM HYDROXIDE, SODIUM HYDROGEN CARBONATE, SODIUM ALGINATE] (C - Gastrointestinal disorder - n/a - [n/a - 1{DF} - Oral]), [ALVERINE CITRATE, SIMETICONE] (C - Gastrointestinal disorder - n/a - [n/a - 1{DF} - Oral]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - Oral]), [BROMAZEPAM] (C - Anxiety - n/a - [n/a - .5mg - Oral]), [D,L-LYSINE ACETYLSALICYLATE] (C - Product used for unknown indication - n/a - [n/a - 1{DF} - Oral]), [GLICLAZIDE] (C - Diabetes mellitus - n/a - [n/a - 90mg - Oral]), [LIQUID PARAFFIN] (C - Constipation - n/a - [n/a - 1{DF} - Oral]), [MACROGOL 4000] (C - Constipation - n/a - [n/a - 1{DF} - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - Diabetes mellitus - n/a - [n/a - 850mg - Oral]),
EU-EC-10007392039	1516	21.01.2021	65-85 Years	Not Specified	Male	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007392244	1517	21.01.2021	More than 85 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death), Cough (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	FLUTICASONE FUROATE [FLUTICASONE FUROATE] (C - Dyspnoea - n/a - [n/a - 110ug - Nasal])
EU-EC-10007393871	1518	21.01.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved -), Cough (n/a - Not Recovered/Not Resolved -), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Hypoxia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007394226	1519	21.01.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	[BISACODYL] (C - Constipation - n/a - [n/a - 20mg - n/a]), [BUPRENORPHINE] (C - Pain - n/a - [n/a - 1{DF} - Cutaneous]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [n/a - 30{DF} - Oral])
EU-EC-10007395394	1520	21.01.2021	65-85 Years	Elderly	Female	Malaise (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	ACTRAPID [INSULIN HUMAN, INSULIN HUMAN (RDNA)] (C - n/a - n/a - [n/a - n/a - n/a]), LANTUS [INSULIN GLARGINE] (C - n/a - n/a - [n/a - n/a - n/a]), LEVETIRACETAM [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [RUPATADINE] (C - n/a - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMINE HYDROCHLORIDE, CYANOCOBALAMIN, LIVER EXTRACT, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007395706	1521	21.01.2021	More than 85 Years	Not Specified	Male	Blood lactic acid increased (6d - Fatal - Results in Death), Cardiovascular disorder (6d - Fatal - Results in Death), Coagulopathy (6d - Fatal - Results in Death), Haemoglobin decreased (6d - Fatal - Results in Death), Hypovolaemic shock (6d - Fatal - Results in Death), Rectal haemorrhage (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	IRON [IRON] (C - n/a - Unknown - [n/a - 326mg - n/a]), NOT AVAILABLE (C - n/a - Unknown - [n/a - 3{DF} - Oral]), [ACETYLSALICYLIC ACID] (C - n/a - Unknown - [n/a - 1{DF} - Oral]), [CALCIUM CARBONATE, CHOLECALCIFEROL CONCENTRATE (POWDER FORM)] (C - n/a - Unknown - [n/a - 1{DF} - Oral]), [PANTOPRAZOLE] (C - n/a - Unknown - [n/a - 2{DF} - n/a]), [PROPYLENE GLYCOL] (C - n/a - Unknown - [n/a - 2{DF} - Ophthalmic]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - Unknown - [n/a - 1{DF} - Oral])
EU-EC-10007396267	1522	21.01.2021	More than 85 Years	Not Specified	Female	Acute respiratory failure (n/a - Fatal - Results in Death), Arrhythmia supraventricular (n/a - Fatal - Results in Death), Atrial fibrillation (n/a - Fatal - Results in Death), Cognitive disorder (n/a - Not Recovered/Not Resolved - Results in Death), Confusional state (n/a - Not Recovered/Not Resolved - Results in Death), Depressed level of consciousness (n/a - Recovered/Resolved - Results in Death), Dysarthria (n/a - Not Recovered/Not Resolved - Results in Death), Fall (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007396892	1523	21.01.2021	18-64 Years	Not Specified	Male	Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ATENOLOL, ATENOLOL BP] (C - n/a - n/a - [n/a - n/a - n/a]), [CHLORTALIDONE] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007397256	1524	21.01.2021	65-85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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EU-EC-10007397576	1525	21.01.2021	65-85 Years	Not Specified	Male	Systemic inflammatory response syndrome (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	BIMATOPROST [BIMATOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), PREGABALIN SANDOZ 25 MG HARD CAPSULES [PREGABALIN] (C - n/a - n/a - [n/a - 25mg - n/a]), [BUPRENORPHINE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [CLOMETHIAZOLE EDISILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DORZOLAMIDE, TIMOLOL] (C - n/a - n/a - [n/a - n/a - n/a]), [MAGNESIUM CHLORIDE HEXAHYDRATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, CALCIUM CHLORIDE DIHYDRATE, SODIUM ACETATE TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - 15mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYCODONE, OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM, MACROGOL 3350] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [UREA] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007398019	1526	21.01.2021	More than 85 Years	Not Specified	Male	Acute respiratory failure (n/a - Fatal - Results in Death), Agitation (1d - Fatal - Results in Death), Amnesia (1d - Fatal - Results in Death), Cardiovascular disorder (1d - Fatal - Results in Death), Confusional state (1d - Fatal - Results in Death), Disorientation (1d - Fatal - Results in Death), General physical health deterioration (1d - Fatal - Results in Death), Hypovolaemic shock (1d - Fatal - Results in Death), Intestinal ischaemia (1d - Fatal - Results in Death), Liver function test abnormal (1d - Fatal - Results in Death), Malaise (1d - Fatal - Results in Death), Metabolic acidosis (1d - Fatal - Results in Death), Nervous system disorder (1d - Fatal - Results in Death), Patient elopement (1d - Fatal - Results in Death), Presyncope (1d - Fatal - Results in Death), Renal disorder (1d - Fatal - Results in Death), Septic shock (1d - Fatal - Results in Death), Staring (1d - Fatal - Results in Death), Tachypnoea (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ARIPIRAZOLE 10 MG (C - n/a - Unknown - [n/a - 1{DF} - n/a]), ARIPIRAZOLE [ARIPIRAZOLE] (C - n/a - Unknown - [n/a - 5{DF} - n/a]), KEPPRA 750 MG [LEVETIRACETAM] (C - n/a - Unknown - [n/a - 2{DF} - n/a]), NOT AVAILABLE (C - n/a - Unknown - [n/a - 2{DF} - n/a]), [ACETYSALICYLIC ACID] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [COLECALCIFEROL] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE, CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [MEBEVERINE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 2{DF} - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [PARACETAMOL] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [SIMVASTATIN] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [SODIUM ASCORBATE, FERROUS SULFATE] (C - n/a - Unknown - [n/a - 1{DF} - n/a]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - n/a - Unknown - [n/a - .5{DF} - n/a])

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EU-EC-10007399016	1527	21.01.2021	65-85 Years	Elderly	Female	Cardio-respiratory arrest (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [0d - .3mL - Intramuscular])	PREGABALIN [PREGABALIN] (C - n/a - Unknown - [n/a - 50mg - Oral]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - Unknown - [n/a - 5mg - Oral]), [BETAHISTINE, BETAHISTINE DIHYDROCHLORIDE, BETAHISTINE MESILATE] (C - n/a - Unknown - [n/a - 24mg - Oral]), [BROMAZEPAM] (C - n/a - Unknown - [n/a - 1.5mg - Oral]), [CANDESARTAN, HYDROCHLOROTHIAZIDE] (C - n/a - Unknown - [n/a - 1{DF} - Oral]), [DIAZEPAM] (C - n/a - Unknown - [n/a - 5mg - Oral]), [PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 10mg - Oral])
EU-EC-10007380381	1528	20.01.2021	18-64 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Poor quality product administered (n/a - Unknown -), Wrong technique in product usage process (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007380406	1529	20.01.2021	More than 85 Years	Not Specified	Female	Asthenia (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Cardiac failure congestive (n/a - Fatal - Results in Death), Condition aggravated (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Unknown Other Medically Important Condition), Myocardial ischaemia (n/a - Fatal - Results in Death), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	APIXABAN [APIXABAN] (C - Atrial fibrillation - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [CARBAMAZEPINE] (C - Epilepsy - n/a - [n/a - n/a - n/a]), [CIMETIDINE] (C - Dyspepsia - n/a - [n/a - n/a - n/a]), [CODEINE] (C - Pain - n/a - [n/a - n/a - n/a]), [DIGOXIN] (C - Atrial fibrillation - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - Cardiac failure congestive - n/a - [n/a - n/a - n/a]), [PERINDOPRIL, PERINDOPRIL TERT-BUTYLAMINE] (C - Cardiac failure congestive - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - n/a])
EU-EC-10007380408	1530	20.01.2021	More than 85 Years	Not Specified	Female	Acidosis (n/a - Not Recovered/Not Resolved -), Blood lactic acid increased (n/a - Not Recovered/Not Resolved -), Confusional state (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Electrocardiogram ST segment elevation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hemiparesis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Right ventricular enlargement (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007380914	1531	20.01.2021	More than 85 Years	Not Specified	Female	Hyperpyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007380982	1532	20.01.2021	More than 85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007381022	1533	20.01.2021	More than 85 Years	Not Specified	Male	Hyperpyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007381075	1534	20.01.2021	18-64 Years	Not Specified	Male	Haemorrhagic stroke (n/a - Fatal - Results in Death), Thrombocytopenia (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007381081	1535	20.01.2021	65-85 Years	Not Specified	Female	Fatigue (n/a - Unknown -), Haematemesis (n/a - Fatal - Results in Death), Illness (n/a - Unknown -), Mobility decreased (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007381256	1536	20.01.2021	65-85 Years	Not Specified	Male	Myocardial infarction (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), ESOMEPRAZOLE [ESOMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007381613	1537	20.01.2021	More than 85 Years	Elderly	Male	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	RIVASTIGMINE [RIVASTIGMINE, RIVASTIGMINE HYDROGEN TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - n/a]), [CANDESARTAN] (C - n/a - n/a - [n/a - 4mg - n/a]), [GLYCERYL TRINITRATE, GLYCERYL TRINITRATE SOLUTION] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE] (C - n/a - n/a - [n/a - 30mg - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 25mg - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - 40mg - n/a])
EU-EC-10007384561	1538	20.01.2021	More than 85 Years	Not Specified	Female	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[ALIMEMAZINE TARTRATE] (C - Dementia - n/a - [n/a - 5{drp} - Oral]), [ETIFOXINE HYDROCHLORIDE] (C - Mixed anxiety and depressive disorder - n/a - [n/a - 50mg - Oral]), [FUROSEMIDE] (C - Hypertension - n/a - [n/a - 20mg - Oral]), [LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - 25{drp} - Oral])
EU-EC-10007384843	1539	20.01.2021	More than 85 Years	Not Specified	Female	Chest pain (n/a - Unknown - Results in Death), Diarrhoea (n/a - Not Recovered/Not Resolved - Results in Death), Sudden death (n/a - Fatal - Results in Death), Vomiting (2d - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[D,L-LYSINE ACETYLSALICYLATE] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [INDAPAMIDE, PERINDOPRIL ARGININE] (C - Hypertension - n/a - [n/a - 1{DF} - Oral]), [MACROGOL 3350, POTASSIUM CHLORIDE, SODIUM CARBONATE, SODIUM CHLORIDE, SODIUM SULFATE ANHYDROUS, MACROGOL 3350, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350, SODIUM SULPHATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, SODIUM SULFATE ANHYDROUS, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [PARACETAMOL] (C - Product used for unknown indication - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007386420	1540	20.01.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death), Drug ineffective (n/a - Fatal - Results in Death), Sepsis (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007386700	1541	20.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007386908	1542	20.01.2021	65-85 Years	Not Specified	Female	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	IRBESARTAN [IRBESARTAN] (C - Hypertension - n/a - [n/a - 150mg - Oral]), JANUVIA 100 MG FILM-COATED TABLETS [SITAGLIPTIN] (C - Type 2 diabetes mellitus - n/a - [n/a - 100mg - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a - [n/a - 10mg - Oral]), [D,L-LYSINE ACETYLSALICYLATE] (C - n/a - n/a - [n/a - 75mg - Oral]), [ESCITALOPRAM] (C - Mixed anxiety and depressive disorder - n/a - [n/a - n/a - Oral]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - Type 2 diabetes mellitus - n/a - [n/a - 1000mg - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - 3.75mg - Oral])
EU-EC-10007388596	1543	20.01.2021	More than 85 Years	Not Specified	Male	Lower respiratory tract infection (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007389407	1544	20.01.2021	More than 85 Years	Elderly	Female	Peripheral ischaemia (3d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported
EU-EC-10007389528	1545	20.01.2021	18-64 Years	Adult	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007389587	1546	20.01.2021	More than 85 Years	Elderly	Male	Intestinal ischaemia (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	NOT AVAILABLE (C - Prostatic adenoma - Drug withdrawn - [162d - 1{DF} - Oral])
EU-EC-10007389955	1547	20.01.2021	18-64 Years	Not Specified	Male	Acute myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported
EU-EC-10007372483	1548	19.01.2021	65-85 Years	Elderly	Male	Hyperpyrexia (4d - Fatal - Results in Death, Life Threatening), Respiratory distress (4d - Fatal - Results in Death, Life Threatening), Unresponsive to stimuli (4d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007372833	1549	19.01.2021	65-85 Years	Not Specified	Female	Cardiac arrest (1d - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007372842	1550	19.01.2021	65-85 Years	Not Specified	Female	Cerebral haemorrhage (n/a - Fatal - Results in Death), Haemorrhagic stroke (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FLUTICASONE PROPIONATE, SALMETEROL, FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - Hypertension - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - n/a])
EU-EC-10007372897	1551	19.01.2021	More than 85 Years	Not Specified	Male	Vomiting (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	TICAGRELOR [TICAGRELOR] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (C - Immunisation - n/a - [1d - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [MORPHINE SULFATE, MORPHINE SULFATE PENTAHYDRATE] (C - Palliative care - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Hyperchlorhydria - n/a - [n/a - n/a - n/a]), [PREDNISONE] (C - Palliative care - n/a - [n/a - n/a - n/a])
EU-EC-10007374218	1552	19.01.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007375096	1553	19.01.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007375223	1554	19.01.2021	65-85 Years	Elderly	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007375382	1555	19.01.2021	More than 85 Years	Elderly	Female	Ventricular fibrillation (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007375666	1556	19.01.2021	More than 85 Years	Not Specified	Female	Oxygen saturation decreased (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[AMLODIPINE, AMLODIPINE BESILATE] (C - Hypertension - n/a - [n/a - 5mg - Oral]), [HYDROXYZINE HYDROCHLORIDE] (C - Pruritus - n/a - [n/a - 25mg - Oral]), [PREDNISOLONE] (C - Pruritus - n/a - [n/a - 5mg - Oral])
EU-EC-10007376224	1557	19.01.2021	65-85 Years	Not Specified	Male	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007376269	1558	19.01.2021	More than 85 Years	Elderly	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007376328	1559	19.01.2021	More than 85 Years	Not Specified	Female	Pneumonia (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007376329	1560	19.01.2021	More than 85 Years	Not Specified	Female	Fatigue (3d - Fatal - Results in Death), General physical health deterioration (3d - Fatal - Results in Death), Pyrexia (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007376516	1561	19.01.2021	65-85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death), Livedo reticularis (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Peripheral coldness (n/a - Fatal - Results in Death), Respiratory rate increased (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous])	BUMETANIDE [BUMETANIDE] (C - n/a - n/a - [n/a - n/a - n/a]), MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CASSIA] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [DIMETICONE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOCUSATE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXYCYCLINE HYCLATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOSORBIDE MONONITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL, CODEINE PHOSPHATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRIACETIN] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007376976	1562	19.01.2021	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[ATORVASTATIN] (C - n/a - n/a - [n/a - 40mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 20mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 75ug - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 100mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007377220	1563	19.01.2021	More than 85 Years	Not Specified	Male	Lower respiratory tract infection (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Heart rate abnormal - n/a - [n/a - n/a - n/a])
EU-EC-10007377560	1564	19.01.2021	More than 85 Years	Not Specified	Male	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	APIXABAN [APIXABAN] (C - Atrial fibrillation - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Prophylaxis - n/a - [n/a - n/a - n/a]), [BECLOMETASONE DIPROPIONATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])
EU-EC-10007377566	1565	19.01.2021	Not Specified	Elderly	Male	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007378130	1566	19.01.2021	More than 85 Years	Elderly	Female	Fluid intake reduced (n/a - Unknown - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Hypophagia (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[BENDROFLUMETHIAZIDE, POTASSIUM CHLORIDE] (C - Diuretic therapy - n/a - [n/a - 1{DF} - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - Oral]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Sedative therapy - n/a - [n/a - 25mg - Oral]), [VITAMIN D, CALCIUM] (C - Mineral supplementation - n/a - [n/a - 1{DF} - Oral])
EU-EC-10007378525	1567	19.01.2021	65-85 Years	Not Specified	Female	Cerebrovascular accident (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	CIRCADIN [MELATONIN] (C - Insomnia - n/a - [n/a - 2mg - Oral]), MICARDIS [TELMISARTAN] (C - Hypertension - n/a - [n/a - 20mg - Oral]), [BUMETANIDE] (C - Oedema - n/a - [n/a - 1mg - Oral]), [BUPRENORPHINE] (C - Pain - n/a - [n/a - 1{DF} - Transdermal]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM] (C - Gastroesophageal reflux disease - n/a - [n/a - 20mg - Oral]), [LACTULOSE] (C - Constipation - n/a - [n/a - 15mL - Oral])
EU-EC-10007378621	1568	19.01.2021	More than 85 Years	Elderly	Female	Cardio-respiratory distress (5d - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (12d - Fatal - Results in Death, Other Medically Important Condition), Malaise (12d - Fatal - Results in Death, Other Medically Important Condition), Pyrexia (12d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported
EU-EC-10007378685	1569	19.01.2021	More than 85 Years	Elderly	Female	Cyanosis (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007363795	1570	18.01.2021	65-85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Pulse absent (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	ABILIFY [ARIPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - n/a - n/a]), [AMIODARONE, AMIODARONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [BUSPIRONE] (C - n/a - n/a - [n/a - n/a - n/a]), [CRANBERRY] (C - n/a - n/a - [n/a - n/a - n/a]), [DILTIAZEM, DILTIAZEM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FAMOTIDINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [IPRATROPIUM, SALBUTAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SENNA ALEXANDRINA LEAF, CASSIA] (C - n/a - n/a - [n/a - n/a - n/a]), [VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007364057	1571	18.01.2021	18-64 Years	Not Specified	Male	Thrombocytopenia (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007364687	1572	18.01.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007364938	1573	18.01.2021	18-64 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007365643	1574	18.01.2021	65-85 Years	Not Specified	Male	Acute cardiac event (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Electrocardiogram ST segment abnormal (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	MIRABEGRON [MIRABEGRON] (C - Micturition urgency - n/a - [n/a - n/a - n/a]), OLANZAPINE [OLANZAPINE] (C - Depression - n/a - [n/a - n/a - n/a]), PREGABALIN [PREGABALIN] (C - Depression - n/a - [n/a - n/a - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (C - Immunisation - n/a - [1d - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - Micturition urgency - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - Micturition urgency - n/a - [n/a - n/a - n/a]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a])
EU-EC-10007365844	1575	18.01.2021	65-85 Years	Elderly	Male	COVID-19 pneumonia (7d - Fatal - Results in Death), Multiple organ dysfunction syndrome (7d - Fatal - Results in Death), Pulmonary sepsis (7d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007366128	1576	18.01.2021	More than 85 Years	Elderly	Male	COVID-19 pneumonia (n/a - Fatal - Results in Death, Life Threatening), Cardiac failure (n/a - Fatal - Results in Death, Life Threatening), Renal failure (n/a - Fatal - Results in Death, Life Threatening), Tachyarrhythmia (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007366245	1577	18.01.2021	65-85 Years	Elderly	Female	Body temperature increased (1d - Fatal - Results in Death, Life Threatening), Diet refusal (8d - Fatal - Results in Death, Life Threatening), Pneumonia (1d - Fatal - Results in Death, Life Threatening), Tachycardia (1d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007366983	1578	18.01.2021	65-85 Years	Not Specified	Female	Depressed level of consciousness (1d - Fatal - Results in Death), Diarrhoea (1d - Fatal - Results in Death), Dyspnoea (1d - Fatal - Results in Death), Malaise (1d - Fatal - Results in Death), Vomiting (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - Atrial fibrillation - n/a - [n/a - n/a - n/a]), ZYPREXA VELOTAB [OLANZAPINE] (C - Anxiety - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BUMETANIDE] (C - Cardiac failure, Oedema - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - Constipation - n/a - [n/a - n/a - n/a]), [LATANOPROST] (C - Glaucoma - n/a - [n/a - n/a - n/a]), [MECILLINAM, PIVMECILLINAM, PIVMECILLINAM HYDROCHLORIDE] (C - Urinary tract infection - n/a - [5d - n/a - n/a]), [MORPHINE SULFATE, MORPHINE SULFATE PENTAHYDRATE] (C - Pain - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Gastric pH decreased - n/a - [n/a - n/a - n/a]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - Back pain - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - Cardiac failure - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - Cardiac failure - n/a - [n/a - n/a - n/a])
EU-EC-10007367303	1579	18.01.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	n/a), ARANESP 30 MICROGRAMS SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE [DARBEPOETIN ALFA] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [ACETYLCYSTEINE] (C - n/a - n/a - [n/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - 100mg - n/a]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOMER] (C - n/a - n/a - [n/a - n/a - n/a]), [DALTEPARIN SODIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [FINASTERIDE] (C - n/a - n/a - [n/a - 5mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 250mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE, GLYCERYL TRINITRATE SOLUTION 10 %] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCOPYRRIUM BROMIDE] (C - n/a - n/a - [n/a - 1mL - n/a]), [HALOPERIDOL] (C - n/a - n/a - [n/a - n/a - n/a]), [HYPROMELLOSE] (C - n/a - n/a - [n/a - n/a - n/a]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [MIDAZOLAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 10mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOFOSFATE, SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM POLYSTYRENE SULPHONATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007367682	1580	18.01.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007368121	1581	18.01.2021	More than 85 Years	Not Specified	Female	Myocardial infarction (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported

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EU-EC-10007368196	1582	18.01.2021	65-85 Years	Not Specified	Male	Acute kidney injury (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007368336	1583	18.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007362839	1584	17.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	TRESIBA [INSULIN DEGLUDEC] (C - n/a - n/a -), [ACETYLSALICYLIC ACID] (C - n/a - n/a -), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a -), [HYDROCHLOROTHIAZIDE, LISINAPRIL, HYDROCHLOROTHIAZIDE, LISINOPRIL ANHYDROUS, LISINOPRIL DIHYDRATE, HYDROCHLOROTHIAZIDE] (C - n/a - n/a -), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a -), [PARACETAMOL, CODEINE PHOSPHATE HEMIHYDRATE] (C - n/a - n/a -), [ZOPICLONE] (C - n/a - n/a -)
EU-EC-10007362988	1585	17.01.2021	More than 85 Years	Not Specified	Female	Apathy (1d - Fatal - Results in Death), Confusional state (1d - Fatal - Results in Death), Coordination abnormal (1d - Fatal - Results in Death), Decreased appetite (2d - Fatal - Results in Death), Injection site inflammation (1d - Fatal - Results in Death), Injection site swelling (2d - Fatal - Results in Death), Vomiting (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	PLAVIX [CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOCLOPRAMIDE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [VERAPAMIL, VERAPAMIL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007362992	1586	17.01.2021	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007362995	1587	17.01.2021	65-85 Years	Not Specified	Male	Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007362997	1588	17.01.2021	More than 85 Years	Not Specified	Female	Concomitant disease aggravated (n/a - Fatal - Results in Death), Feeling hot (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	PRADAXA [DABIGATRAN ETEXILATE, DABIGATRAN ETEXILATE MESILATE] (C - Atrial fibrillation - n/a - [n/a - 110mg - Oral]), [ACETYLCYSTEINE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - 200mg - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Cardiac failure - n/a - [n/a - 40mg - Oral]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (C - Restlessness - n/a - [n/a - .5mg - Oral]), [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - Chronic obstructive pulmonary disease n/a - [n/a - n/a - Respiratory (inhalation)]), [METOPROLOL, METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 50mg - n/a]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - Pain - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - Hypokalaemia - n/a - [n/a - 750mg - Oral]), [SPIRONOLACTONE] (C - Cardiac failure, Oedema - n/a - [n/a - 25mg - Oral]), [ZOPICLONE] (C - Sleep disorder - n/a - [n/a - 5mg - Oral])

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EU-EC-10007363168	1589	17.01.2021	More than 85 Years	Elderly	Female	Pyrexia (1d - Fatal - Results in Death), Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported
EU-EC-10007354958	1590	15.01.2021	More than 85 Years	Not Specified	Male	Sudden death (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [GOSERELIN, GOSERELIN ACETATE] (C - Prostate cancer - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - Hypertension - n/a - [n/a - n/a - n/a])
EU-EC-10007355209	1591	15.01.2021	65-85 Years	Not Specified	Male	Myocardial infarction (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007355213	1592	15.01.2021	More than 85 Years	Not Specified	Male	Acidosis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Acute kidney injury (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Blood creatine phosphokinase increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diabetes mellitus inadequate control (1d - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ALLOPURINOL] (C - Gout - n/a - [n/a - n/a - n/a]), [FELODIPINE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - Hypertension - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a])
EU-EC-10007355287	1593	15.01.2021	18-64 Years	Not Specified	Male	Agitation (n/a - Unknown -), Coordination abnormal (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dehydration (n/a - Unknown -), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Gait disturbance (n/a - Unknown -), Hallucination (n/a - Unknown - Other Medically Important Condition), Hypophagia (n/a - Unknown -), Insomnia (n/a - Unknown -), Intrusive thoughts (n/a - Unknown -), Malaise (n/a - Unknown -), Muscle twitching (n/a - Unknown -), Pallor (n/a - Unknown -), Psychomotor hyperactivity (n/a - Unknown - Other Medically Important Condition), Restlessness (n/a - Unknown - Other Medically Important Condition), Tachyphrenia (n/a - Unknown -), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - 10mg - Oral]), [GLIMEPIRIDE] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - 100mg - Oral])

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EU-EC-10007355932	1594	15.01.2021	More than 85 Years	Elderly	Female	Seizure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007356221	1595	15.01.2021	65-85 Years	Elderly	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), ENTRESTO [VALSARTAN, SACUBITRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [DIGITOXIN] (C - n/a - n/a - [n/a - n/a - n/a]), [METAMIZOLE, METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOCLOPRAMIDE, METOCLOPRAMIDE DIHYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE, METOCLOPRAMIDE HYDROCHLORIDE PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYCODONE, OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMOXIFEN, TAMOXIFEN CITRATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007356588	1596	15.01.2021	18-64 Years	Adult	Female	Huntington's disease (0d - Fatal - Results in Death), Seizure (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007357461	1597	15.01.2021	More than 85 Years	Elderly	Male	Cardiac fibrillation (n/a - Unknown - Results in Death), Death (n/a - Fatal - Results in Death), Malaise (n/a - Unknown - Results in Death), Syncope (n/a - Unknown - Results in Death), Vomiting (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007357684	1598	15.01.2021	More than 85 Years	Elderly	Male	Acute myocardial infarction (n/a - Fatal - Results in Death), Fall (n/a - Fatal - Results in Death), Head injury (n/a - Fatal - Results in Death), Peripheral vascular disorder (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007359067	1599	15.01.2021	More than 85 Years	Elderly	Male	COVID-19 pneumonia (6d - Fatal - Results in Death, Life Threatening), Dyspnoea (6d - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007359848	1600	15.01.2021	65-85 Years	Not Specified	Male	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fall (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

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EU-EC-10007360428	1601	15.01.2021	65-85 Years	Not Specified	Male	Cerebrovascular accident (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CLOPIDOGREL (CLOPIDOGREL, CLOPIDOGREL BESILATE) (C - Transient ischaemic attack - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [NEBIVOLOL] (C - Left ventricular dysfunction - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - Hypercholesterolaemia - n/a - [n/a - n/a - n/a])
EU-EC-10007360893	1602	15.01.2021	65-85 Years	Elderly	Male	General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007360900	1603	15.01.2021	More than 85 Years	Elderly	Female	General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10007360918	1604	15.01.2021	65-85 Years	Elderly	Female	Dyspnoea (n/a - Not Recovered/Not Resolved - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	CIRCADIN [MELATONIN] (C - Insomnia - n/a - [n/a - 2mg - Oral]), [BENSERAZIDE HYDROCHLORIDE, LEVODOPA, BENSERAZIDE, LEVODOPA] (C - Parkinson's disease - n/a - [n/a - 1{DF} - Oral]), [DONEPEZIL, DONEPEZIL HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 10mg - Oral]), [GABAPENTIN] (C - Neuralgia - n/a - [n/a - 300mg - Oral]), [LERCANIDIPINE, LERCANIDIPINE HYDROCHLORIDE] (C - Hypertension - n/a - [n/a - 10mg - Oral]), [METHENAMINE HIPPURATE] (C - Urinary tract disorder prophylaxis - n/a - [n/a - 1mg - Oral])
EU-EC-10007361020	1605	15.01.2021	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported
EU-EC-10007346524	1606	14.01.2021	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007346773	1607	14.01.2021	65-85 Years	Not Specified	Male	Blood pressure decreased (1d - Fatal - Results in Death), Diarrhoea (1d - Fatal - Results in Death), Nausea (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007347050	1608	14.01.2021	65-85 Years	Not Specified	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007348967	1609	14.01.2021	65-85 Years	Elderly	Female	Malaise (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	ACTRAPID [INSULIN HUMAN, INSULIN HUMAN (RDNA)] (C - n/a - n/a - [n/a - n/a - n/a]), LANTUS [INSULIN GLARGINE] (C - n/a - n/a - [n/a - n/a - n/a]), LEVETIRACETAM [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [RUPATADINE] (C - n/a - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMINE HYDROCHLORIDE, CYANOCOBALAMIN, LIVER EXTRACT, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007349769	1610	14.01.2021	Not Specified	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007349774	1611	14.01.2021	Not Specified	Not Specified	Not Specified	COVID-19 (n/a - Fatal - Results in Death), Drug ineffective (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007340771	1612	13.01.2021	65-85 Years	Not Specified	Female	Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007342767	1613	13.01.2021	65-85 Years	Not Specified	Male	Gastrointestinal haemorrhage (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a -), [ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a -), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a -)
EU-EC-10007342795	1614	13.01.2021	More than 85 Years	Not Specified	Female	Acute kidney injury (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Confusional state (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	CIRCADIN [MELATONIN] (C - Sleep disorder - n/a - [n/a - n/a - n/a]), [BUMETANIDE] (C - Oedema - n/a - [n/a - n/a - n/a]), [CODEINE PHOSPHATE SESQUIHYDRATE, PARACETAMOL, PARACETAMOL, CODEINE PHOSPHATE] (C - Analgesic therapy - n/a - [n/a - n/a - n/a]), [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - Dyspnoea - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - Constipation - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Atrial fibrillation - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - Agitation - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Prophylaxis against gastrointestinal ulcer - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Analgesic therapy - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Dyspnoea - n/a - [n/a - n/a - n/a]), [THIAMINE, PYRIDOXINE HYDROCHLORIDE, VITAMIN B] (C - Vitamin supplementation - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - Sleep disorder - n/a - [n/a - n/a - n/a])

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EU-EC-10007343848	1615	13.01.2021	65-85 Years	Elderly	Male	Pneumonia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Sepsis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	MABTHERA [RITUXIMAB] (C - n/a - Unknown -), [PREDNISOLONE] (C - n/a - Unknown -)
EU-EC-10007344737	1616	13.01.2021	More than 85 Years	Elderly	Female	Pulmonary embolism (n/a - Fatal - Results in Death), Urinary retention (0d - Recovered/Resolved -), Vaginal discharge (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - 1{DF} - n/a]), TRAJENTA 5 MG FILM-COATED TABLETS [LINAGLIPTIN] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [AMBROXOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 3mL - n/a]), [BISACODYL] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [CALCIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, CALCIUM CHLORIDE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 40{drp} - n/a]), [DOXAZOSIN MESILATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [ESOMEPRAZOLE MAGNESIUM TRIHYDRATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [LACTULOSE, LACTULOSE CRYSTALLINE] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [MAGNESIUM CARBONATE, LIGHT, MAGNESIUM OXIDE, LIGHT, MAGNESIUM CARBONATE, MAGNESIUM OXIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [MEMANTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - 20{drp} - n/a]), [METOCLOPRAMIDE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [PROTHIPENDYL HYDROCHLORIDE, PROTHIPENDYL HYDROCHLORIDE MONOHYDRATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [RILMENIDINE, RILMENIDINE DIHYDROGEN PHOSPHATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SERTRALINE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - 1{DF} - n/a])
EU-EC-10007346083	1617	13.01.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007347302	1618	13.01.2021	More than 85 Years	Elderly	Female	Respiratory failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Intramuscular)	Not reported

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EU-EC-10007347342	1619	13.01.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	ELIQUIS [APIXABAN] (C - Thrombosis prophylaxis - n/a - [n/a - 5mg - Oral]), [ATORVASTATIN] (C - Cardiovascular event prophylaxis - n/a - [n/a - 80mg - Oral]), [DONEPEZIL HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 10mg - Oral]), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Heart rate irregular - n/a - [n/a - 25mg - Oral]), [RISPERIDONE] (C - Aggression - n/a - [n/a - .25mg - Oral]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - 50mg - Oral]), [TAMSULOSIN HYDROCHLORIDE] (C - Dysuria - n/a - [n/a - .4mg - Oral])
EU-EC-10007347608	1620	13.01.2021	More than 85 Years	Elderly	Male	Headache (2d - Fatal - Results in Death), Malaise (2d - Fatal - Results in Death), Presyncope (1d - Fatal - Results in Death), Pyrexia (2d - Fatal - Results in Death), Vaccination complication (2d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACENOCOUMAROL] (C - Atrial fibrillation - Unknown - [1817d - n/a - n/a]), [DIGOXIN] (C - Atrial fibrillation - Unknown - [1817d - n/a - n/a])
EU-EC-10007347612	1621	13.01.2021	More than 85 Years	Elderly	Female	Acute respiratory failure (2d - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007333312	1622	12.01.2021	65-85 Years	Not Specified	Female	Anxiety (n/a - Unknown -), Fall (n/a - Unknown -), Fear of death (n/a - Unknown -), Huntington's disease (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007333563	1623	12.01.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007335395	1624	12.01.2021	18-64 Years	Adult	Male	Acute myocardial infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Circulatory collapse (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Resuscitation (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007337129	1625	12.01.2021	More than 85 Years	Elderly	Male	Respiration abnormal (n/a - Fatal - Results in Death), Sudden death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported

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EU-EC-10007338402	1626	12.01.2021	65-85 Years	Not Specified	Male	Dyspnoea exertional (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ALFACALCIDOL] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PRAZOSIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [SODIUM HYDROGEN CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007338842	1627	12.01.2021	65-85 Years	Elderly	Male	Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	RILUTEK [RILUZOLE] (C - Amyotrophic lateral sclerosis - n/a - [n/a - 50mg - Oral])
EU-EC-10007339366	1628	12.01.2021	65-85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007326705	1629	11.01.2021	65-85 Years	Not Specified	Female	COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death, Other Medically Important Condition), Respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007329378	1630	11.01.2021	More than 85 Years	Elderly	Male	Dementia of the Alzheimer's type, with delirium (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007331262	1631	11.01.2021	More than 85 Years	Elderly	Male	Pyrexia (n/a - Fatal - Results in Death), Somnolence (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[GLIMEPIRIDE] (C - Type 2 diabetes mellitus - n/a - [n/a - 2mg - Oral]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Renal disorder - n/a - [n/a - 12.5mg - Oral]), [METFORMIN HYDROCHLORIDE] (C - Type 2 diabetes mellitus - n/a - [n/a - 1000mg - Oral])
EU-EC-10007331991	1632	11.01.2021	65-85 Years	Not Specified	Male	Circulatory collapse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (1d - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ALLOPURINOL] (C - n/a - n/a - [n/a - 100mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 80mg - n/a]), [BETAMETHASONE, BETAMETHASONE VALERATE, BETAMETHASONE VALERATE BP] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - 400ug - n/a]), [LOPERAMIDE, LOPERAMIDE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 2mg - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [PHENOXYMETHYLPENICILLIN] (C - n/a - n/a - [n/a - 500mg - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - 1.25mg - n/a])

EU Local Number	#	EV Gateway Receipt Date	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10007332244	1633	11.01.2021	More than 85 Years	Elderly	Female	Sudden death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	[LEVOFLOXACIN] (C - Respiratory tract infection - Dose not changed - [n/a - n/a - n/a])
EU-EC-10007318464	1634	08.01.2021	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	[CARVEDILOL] (C - n/a - n/a - [n/a - 25mg - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 100ug - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a]), [UREA] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10007318579	1635	08.01.2021	More than 85 Years	Elderly	Female	Acute myocardial infarction (2d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[ALPRAZOLAM] (C - Dementia - n/a - [n/a - .25mg - Oral]), [HALOPERIDOL] (C - Dementia - n/a - [n/a - 6{drp} - Oral]), [LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - 50ug - Oral]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 50mg - Oral]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Dementia - n/a - [n/a - 25mg - Oral]), [ZOLPIDEM TARTRATE] (C - Dementia - n/a - [n/a - 10mg - Oral])
EU-EC-10007322669	1636	08.01.2021	65-85 Years	Elderly	Male	Coma (n/a - Unknown - Results in Death, Life Threatening), Depressed level of consciousness (n/a - Unknown - Results in Death, Life Threatening), Fatigue (n/a - Unknown - Results in Death, Life Threatening), Flushing (n/a - Unknown - Results in Death, Life Threatening), Hemiparesis (n/a - Unknown - Results in Death, Life Threatening), Mobility decreased (n/a - Unknown - Results in Death, Life Threatening), Respiratory arrest (n/a - Fatal - Results in Death, Life Threatening), Vomiting (n/a - Unknown - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Gastric ulcer - n/a - [n/a - n/a - n/a]), [ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE, LEVOTHYROXINE SODIUM, LEVOTHYROXINE SODIUM ANHYDROUS EP] (C - Hypothyroidism - n/a - [n/a - n/a - n/a]), [DICLOFENAC, DICLOFENAC DIETHYLAMINE, DICLOFENAC EPOLAMINE, DICLOFENAC POTASSIUM, DICLOFENAC RESINATE, DICLOFENAC SODIUM, DICLOFENAC SODIUM PH. EUR.] (C - Pain - n/a - [n/a - n/a - n/a]), [HYDROCORTISONE, HYDROCORTISONE SODIUM SUCCINATE] (C - Adrenal insufficiency - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - Constipation - n/a - [n/a - n/a - n/a]), [MAGNESIUM OXIDE, MAGNESIUM OXIDE, LIGHT] (C - Constipation - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - Vitamin D deficiency - n/a - [n/a - n/a - n/a]), [WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BP] (C - Anticoagulant therapy - n/a - [n/a - n/a - n/a])
EU-EC-10007313051	1637	07.01.2021	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10007314324	1638	07.01.2021	More than 85 Years	Elderly	Male	Cardiac failure (0d - Fatal - Results in Death, Life Threatening)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

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EU-EC-10007314523	1639	07.01.2021	More than 85 Years	Elderly	Female	Cardiac failure (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Cough (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Disease progression (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10007314728	1640	07.01.2021	18-64 Years	Not Specified	Male	Cardiac arrest (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10007315627	1641	07.01.2021	More than 85 Years	Elderly	Male	Aggression (n/a - Unknown - Results in Death), Aspiration (n/a - Fatal - Results in Death), Malaise (n/a - Unknown - Results in Death), Pneumonia aspiration (n/a - Fatal - Results in Death), Rales (n/a - Unknown - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Peptic ulcer - n/a - [n/a - 40mg - n/a]), [CYANOCOBALAMIN] (C - Vitamin B12 deficiency - n/a - [n/a - 1mg - n/a]), [DICLOXACILLIN] (C - Soft tissue infection - n/a - [n/a - 1000mg - n/a]), [ENALAPRIL MALEATE] (C - Hypertension - n/a - [n/a - 10mg - n/a]), [FINASTERIDE] (C - Prostatomegaly - n/a - [n/a - 5mg - n/a]), [GALANTAMINE] (C - Dementia - n/a - [n/a - 16mg - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - n/a]), [SIMVASTATIN] (C - Hypercholesterolaemia - n/a - [n/a - 40mg - n/a])
EU-EC-10007316044	1642	07.01.2021	More than 85 Years	Elderly	Female	Rectal haemorrhage (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]), [ACENOCOUMAROL] (S - Atrial fibrillation - Drug withdrawn - [3203d - n/a - Oral])	ACTRAPID INNOLET 100 INTERNATIONAL UNITS/ML SOLUTION FOR INJECTION IN PRE-FILLED PEN [INSULIN HUMAN (RDNA)] (C - n/a - Unknown - [n/a - n/a - Subcutaneous]), [AMLODIPINE] (C - n/a - Unknown - [n/a - 5mg - Oral]), [FUROSEMIDE] (C - n/a - Unknown - [n/a - 40mg - Oral]), [METAMIZOLE MAGNESIUM] (C - n/a - Unknown - [n/a - 575mg - Oral]), [METFORMIN HYDROCHLORIDE] (C - Type 2 diabetes mellitus - Unknown - [n/a - 425mg - Oral]), [TIMOLOL MALEATE, LATANOPROST] (C - n/a - Unknown - [n/a - 2[drp] - Ophthalmic]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - n/a - Unknown - [n/a - 50mg - Oral]), [VALSARTAN] (C - n/a - Unknown - [n/a - 320mg - Oral])
EU-EC-10007316092	1643	07.01.2021	65-85 Years	Elderly	Female	Dyspnoea (n/a - Fatal - Results in Death), Hypersensitivity (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported

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EU-EC-10007307981	1644	06.01.2021	More than 85 Years	Elderly	Female	Condition aggravated (n/a - Fatal - Results in Death, Life Threatening), Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	BETMIGA [MIRABEGRON] (C - n/a - Not applicable - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - Not applicable - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [CIPROFLOXACIN, CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [COLECALCIFEROL, CYANOCOBALAMIN, ERGOCALCIFEROL, RETINOL ACETATE, ERGOCALCIFEROL, TOCOPHERYL ACETATE] (C - n/a - Unknown -), [CYANOCOBALAMIN] (C - n/a - Not applicable - [n/a - n/a - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [ESTRADIOL, ESTRADIOL HEMIHYDRATE] (C - n/a - Not applicable -), [FOLIC ACID] (C - n/a - Not applicable - [n/a - n/a - n/a]), [LACTOBACILLUS ACIDOPHILUS, BIFIDOBACTERIUM SPP.] (C - n/a - Not applicable -), [NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - n/a - Not applicable -), [OXAZEPAM] (C - n/a - Not applicable - [n/a - n/a - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - Not applicable -)
EU-EC-10007308259	1645	06.01.2021	65-85 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported
EU-EC-10007298416	1646	05.01.2021	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported

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EU-EC-10007302723	1647	05.01.2021	18-64 Years	Adult	Male	Dyspnoea (n/a - Fatal - Results in Death), Respiratory failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	TRELEGY ELLIPTA [UMECLIDINIUM BROMIDE, FLUTICASON FUROATE, VILANTEROL] (C - Chronic obstructive pulmonary disease - n/a - [n/a - 1{DF} - n/a]), XEPLION [PALIPERIDONE PALMITATE] (C - Psychiatric disorder prophylaxis - n/a - [381d - 100mg - n/a]), [BUPRENORPHINE, NALOXONE, NALOXONE] (C - Drug abuse - n/a - [188d - 2{DF} - n/a]), [IPRATROPIUM BROMIDE, SALBUTAMOL, SALBUTAMOL, IPRATROPIUM BROMIDE MONOHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - 1{DF} - n/a]), [ORPHENADRINE HYDROCHLORIDE] (C - Anxiety - n/a - [398d - 50mg - n/a]), [PARACETAMOL] (C - Pain - n/a - [34d - 1000mg - n/a]), [PREDNISOLONE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - 20mg - n/a]), [PROMETHAZINE, PROMETHAZINE HYDROCHLORIDE] (C - Insomnia - n/a - [101d - 25mg - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE, QUETIAPINE HEMIFUMARATE] (C - Psychiatric symptom - n/a - [141d - 100mg - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE, QUETIAPINE HEMIFUMARATE] (C - Psychiatric symptom - n/a - [18d - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - .2mg - n/a])
EU-EC-10007291936	1648	04.01.2021	More than 85 Years	Elderly	Male	Death (0d - Fatal - Results in Death, Other Medically Important Condition), Influenza like illness (0d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007292008	1649	04.01.2021	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Unknown - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported
EU-EC-10007293100	1650	04.01.2021	65-85 Years	Elderly	Female	Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening), Death (n/a - Fatal - Results in Death, Life Threatening), Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported
EU-EC-10007296035	1651	04.01.2021	65-85 Years	Elderly	Female	Sudden death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	ABASAGLAR 100 UNITS/ML SOLUTION FOR INJECTION IN A PRE-FILLED PEN [INSULIN GLARGINE] (C - Type 2 diabetes mellitus - Dose not changed - [n/a - 48m[iU] - Subcutaneous]), [BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE] (C - Bronchitis chronic - Dose not changed - [n/a - 2{DF} - Respiratory (inhalation)]), [COLCHICINE, DICYCLOVERINE HYDROCHLORIDE] (C - Pericardial effusion - Dose not changed - [n/a - 1{DF} - Oral]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Major depression - Dose not changed - [n/a - 25mg - Oral]), [TIOTROPIUM BROMIDE MONOHYDRATE] (C - Bronchitis chronic - Dose not changed - [n/a - 2{DF} - Respiratory (inhalation)]), [VENLAFAXINE] (C - Major depression - Dose not changed - [n/a - 150mg - Oral])