

Line Listing Report

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EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country/Regulatory Purposes	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Report	Reaction List PT (Duration ? Outcome - Seriousness Criteria)	Suspect/Interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Admitted Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-1000848804	30/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation).	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000849330	30/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), 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])	ELIGUIS (APIXABAN) (C - Arthralgia prophylaxis - n/a - [n/a - n/a - n/a]), MELATONIN (MELATONIN) (C - n/a - n/a - [n/a - n/a - n/a]), AMOXICILLIN (C - Prophylaxis - n/a - [n/a - n/a - n/a]), BIFONAZOLE (CLOTRIMAZOLE) (C - n/a - n/a - [n/a - n/a - n/a]), CARBOMER (CARBOMER 974P) (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]), FURUSEMIDE (C - Cardiac failure - n/a - [n/a - n/a - n/a]), FURUSEMIDE (C - n/a - n/a - [n/a - n/a - n/a]), ISOSORBIDE DINITRATE (C - n/a - n/a - [n/a - n/a - n/a]), LEVOTHYROXINE (C - n/a - n/a - [n/a - n/a - n/a]), MACROGOL 4000 (C - n/a - n/a - [n/a - n/a - n/a]), OXAZEPAM (C - n/a - n/a - [n/a - n/a - n/a]), OXYCODONE, OXYCODONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE TRIHYDRATE (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]), PREDNISOLONE (C - Asthma - n/a - [n/a - n/a - n/a]), ROSUVASTATIN, ROSUVASTATIN CALCIUM, ROSUVASTATIN ZINC (C - n/a - n/a - [n/a - n/a - n/a]), SALBUTAMOL, SALBUTAMOL SULFATE (C - Asthma - n/a - [n/a - n/a - n/a]), SPIRONOLACTONE (C - Cardiac failure - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008490407	30/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10008491205	30/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10008491689	30/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular - More in ICSR])	RIVAROXABAN (RIVAROXABAN) (C - n/a - n/a -), (ALLOPURINOL) (C - n/a - n/a -), (DIGOXIN, DIGOXIN PH. EUR.) (C - n/a - n/a -), (METOPROLOL, METOPROLOL TARTRATE) (C - n/a - n/a -), (SIMVASTATIN) (C - n/a - n/a -)	ICSR
EU-EC-10008492262	30/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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 EAM, OPLOSSING VOOR INJECTIE IN FLACON (INSULIN ASPART) (C - n/a - n/a - [n/a - n/a - n/a]), (INSULIN ASPART, INSULIN DEGLUDEC) (C - n/a - n/a - [n/a - n/a - n/a]), (OMEPRAZOLE MAGNESIUM) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008492512	30/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008493181	30/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	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	ICSR
EU-EC-10008495012	30/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [1d - 3mL - Intramuscular])	ABASGLAR (INSULIN GLARGINE) (C - n/a - n/a -), (ESOMEPRAZOLE (ESOMEPRAZOLE) (C - n/a - n/a -), (ACETYL SALICYLIC ACID, D,L-LYSINE ACETYL SALICYLATE) (C - n/a - n/a -), (BISOPROLOL, HEMIFUMARATE) (C - n/a - n/a -), (LEVOTHYROXINE SODIUM) (C - n/a - n/a -)	ICSR
EU-EC-10008497571	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (0d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008497891	29/04/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Aggression (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Paranoia (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008497810	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10008497946	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 30ug - n/a])	(HYDROCHLOROTHIAZIDE, BAMPICIL) (C - n/a - Unknown - [n/a - 1(Df) - Oral]), (NEBIVOLOL, NEBIVOLOL HYDROCHLORIDE) (C - Essential hypertension - Unknown - [n/a - 2.5mg - Oral])	ICSR
EU-EC-10008497947	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (0d - Fatal - Results in Death), SARS-CoV-2 test positive (0d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008498149	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008498148	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-100084981937	29/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008498298	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	Not reported	ICSR
EU-EC-100084983767	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (0d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-100084982210	28/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Acute kidney injury (n/a - Fatal - Results in Death), Aphasia (n/a - Fatal - Results in Death), C-reactive protein increased (n/a - Fatal - Results in Death), Carotid artery occlusion (n/a - Fatal - Results in Death), Cerebral ischaemia (n/a - Fatal - Results in Death), Cerebral thrombosis (n/a - Fatal - Results in Death), Coagulopathy (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Hemiparesis (n/a - Fatal - Results in Death), Ischaemic stroke (n/a - Fatal - Results in Death), Leukocytosis (n/a - Fatal - Results in Death), Platelet count decreased (n/a - Fatal - Results in Death), Pneumonia aspiration (n/a - Fatal - Results in Death), Respiratory failure (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])	ELIGUIS 5 MG (APIXABAN) (C - n/a - Unknown - [n/a - 2(Df) - n/a]), LANTUS (INSULIN GLARGINE) (C - Type 2 diabetes mellitus - Unknown - [n/a - 1(Df) - Subcutaneous]), NOVORAPID FLEXPEN (INSULIN ASPART) (C - Type 2 diabetes mellitus - Unknown - [n/a - 3(Df) - n/a]), (ACETYL SALICYLIC ACID) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (ATORVASTATIN) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (BISOPROLOL, FUMARATE) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (BUMETANIDE) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (FLUTICASON PROPIONATE, SALMETEROL) (C - n/a - Unknown - [n/a - 2(Df) - n/a]), (METFORMIN HYDROCHLORIDE) (C - n/a - Unknown - [n/a - 2(Df) - n/a]), (SPIRONOLACTONE, SPIRONOLACTONE PF) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (TRAZODONE HYDROCHLORIDE) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (ZOLPIDEM, ZOLPIDEM HEMITARTRATE, ZOLPIDEM TARTRATE) (C - n/a - Unknown - [n/a - 1(Df) - n/a])	ICSR
EU-EC-100084983013	28/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (1d - Fatal - Results in Death), Dysphoria (0d - Fatal - Results in Death), Loss of consciousness (0d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - Intramuscular])	CHOLB (FENOFIBRATE, SIMVASTATIN) (C - n/a - n/a - [n/a - n/a - Oral]), (MANDIPINE DIHYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - Oral]), (VALSARTAN) (C - n/a - n/a - [n/a - n/a - Oral]), (QUETIAPINE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-100084984231	28/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	Cardiac arrest (0d - Fatal - Results in Death, Other Medically Important Condition), Death (0d - Fatal - Results in Death, Other Medically Important Condition), Vomiting (0d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100084986070	28/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Coagulopathy (5d - Fatal - Results in Death), Death (5d - Fatal - Results in Death), Haemorrhagic transformation stroke (5d - Fatal - Results in Death), Hemiplegia (5d - Fatal - Results in Death), Ischaemic stroke (5d - Fatal - Results in Death), Nerve compression (5d - Fatal - Results in Death), Nervous system disorder (5d - Fatal - Results in Death), Thrombocytopenia (5d - Fatal - Results in Death), Thrombosis (5d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	(ANHYDROUS LEVOTHYROXINE SODIUM) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (CLONAZEPAM) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (DENOSUMAB) (C - n/a - Unknown - [n/a - 2(Df) - n/a]), (DOMPERIDONE, DOMPERIDONE MALEATE) (C - n/a - Unknown - [n/a - 3(Df) - n/a]), (FENOFIBRATE, FENOFIBRATE NANONISED) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (GABAPENTIN) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (LERCANIDIPINE HYDROCHLORIDE) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (MICRONISED SPIRONOLACTONE, SPIRONOLACTONE) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (PIANTOPRAZOLE) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (SODIUM ASCORBATE, FERROUS SULFATE) (C - n/a - Unknown - [n/a - 1(Df) - n/a]), (TRAMADOL HYDROCHLORIDE) (C - n/a - Unknown - [n/a - 2(Df) - n/a]), (ZINC) (C - n/a - Unknown - [n/a - n/a - n/a]), (ZOLPIDEM TARTRATE) (C - n/a - Unknown - [n/a - 1(Df) - n/a])	ICSR
EU-EC-100084986640	28/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Aphasia (n/a - Fatal - Results in Death), Bedridden (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Motor dysfunction (n/a - Fatal - Results in Death), Nervous system disorder (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100084986880	28/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Acute kidney injury (2d - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (2d - Fatal - Results in Death), Hemiplegia (1d - Fatal - Results in Death), International normalised ratio increased (2d - Fatal - Results in Death), Ischaemic stroke (1d - Fatal - Results in Death), Pulmonary embolism (1d - Fatal - Results in Death), Thrombocytopenia (2d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	(ACENOCUMAROL) (C - Atrial fibrillation - Unknown - [n/a - n/a - n/a]), (CARVEDILOL) (C - n/a - Unknown - [n/a - n/a - n/a]), (LOSARTAN, LOSARTAN POTASSIUM) (C - n/a - Unknown - [n/a - n/a - n/a]), (QUETIAPINE, QUETIAPINE FUMARATE) (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-100084987121	28/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100084987465	28/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008498922	28/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100084989081	28/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-100084975580	28/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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 reported	ICSR
EU-EC-100084971845	28/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Cardogenic shock (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (49d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100084952362	27/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (0d - Fatal - Results in Death), Malaise (4d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	(ACETYL SALICYLIC ACID) (C - n/a - n/a - [n/a - n/a - n/a]), (ATORVASTATIN) (C - n/a - n/a - [n/a - n/a - n/a]), (PIERINDOPRIL, PERINDOPRIL ARGININE) (C - n/a - n/a - [n/a - n/a - n/a]), (TABULSOLIN HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008494168	27/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008494330	27/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008495448	27/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Female	Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dehydration (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 - [1d - n/a - Intramuscular])	(ACETYL SALICYLIC ACID) (C - n/a - n/a - [n/a - 100mg - n/a]), (LAMOTRIGINE) (C - n/a - n/a - [n/a - 100mg - n/a]), (QUETIAPINE, QUETIAPINE FUMARATE) (C - n/a - n/a - [n/a - 50mg - n/a])	ICSR
EU-EC-10008495775	27/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	Balance disorder (n/a - Recovered/Resolved With Sequelae - Disabling), Death (n/a - Fatal - Results in Death), Dysphagia (n/a - Recovered/Resolved With Sequelae - Disabling), Gait disturbance (n/a - Recovered/Resolved With Sequelae - Disabling), Ischaemic stroke (n/a - Recovered/Resolved With Sequelae - Life Threatening, Disabling, Other Medically Important Condition), Loss of consciousness (0min - Recovered/Resolved With Sequelae - Life Threatening, Disabling, Other Medically Important Condition), Nervous system disorder (n/a - Recovered/Resolved With Sequelae - Disabling), Pyrexia (n/a - Fatal - Results in Death), Seizure (n/a - Recovered/Resolved With Sequelae - Disabling, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	(NABILONE) (C - Dementia - n/a - [n/a - n/a - Oral]), (RISPERIDONE) (C - Dementia - n/a - [n/a - n/a - Oral]), (TRAZODONE, TRAZODONE HYDROCHLORIDE) (C - Dementia - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-100084953305	27/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	Sepsis (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008491886	26/04/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR
EU-EC-10008493188	26/04/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Female	Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Portal vein thrombosis (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Sex	Patient Report	Reaction List (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)	ICSR Form
EU-EC-1000943200	26/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Male	No	Death (n/a - Fatal - Results in Death).	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a] - Intramuscular)	[FLUCONAZOLE] (C - Fungal infection - n/a - [n/a - 100mg - Oral])	ICSR
EU-EC-1000943916	26/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Male	No	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]), [LISINAPRIL LISINAPRIL DHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000943519	26/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death).	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000943526	26/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Dyspnoea (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	ICSR
EU-EC-1000943619	26/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Dyspnoea (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death).	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a] - Intramuscular)	Not reported	ICSR
EU-EC-1000944139	26/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	[ESOMEPRAZOLE] (ESOMEPRAZOLE) (C - n/a - n/a -), [COLECALCIFEROL] (C - n/a - n/a -), [SPAGHULA] (C - n/a - n/a -), [LACTULOSE] (C - n/a - n/a -), [LERCANIDIPINE HYDROCHLORIDE] (C - n/a - n/a -), [POTASSIUM CHLORIDE] (C - n/a - n/a -)	ICSR
EU-EC-1000941525	26/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000942059	26/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Epistaxis (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Unknown -),	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	[HYDROCHLOROTHIAZIDE, RAMPRI] (C - n/a - n/a -), [METAMIZOLE, METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000942164	26/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Acute coronary syndrome (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), 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])	Not reported	ICSR
EU-EC-1000943943	26/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	[CLOPIDOGREL, CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - Thrombosis prophylaxis - n/a - [n/a - 75mg - n/a]), [BUPROPION, BUPROPION HYDROCHLORIDE] (C - Diabetes mellitus - n/a - [n/a - 500mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Diuretic therapy - n/a - [n/a - 40mg - n/a]), [HYDROCOBALAMIN] (C - Pernicious anaemia - n/a - [n/a - 1(Df) - n/a]), [LANSOPRAZOLE] (C - Gastroesophageal reflux disease - n/a - [n/a - 15mg - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 100mg - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - 500mg - n/a]), [SIMVASTATIN] (C - Hypercholesterolaemia - n/a - [n/a - 40mg - n/a])	ICSR
EU-EC-1000942934	25/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009410185	23/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Female	No	Death (0d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000941058	23/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Female	No	Death (n/a - Fatal - Results in Death), Product administered to patient of inappropriate age (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000941097	23/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000941138	23/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Cerebral haemorrhage (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a] - Intravenous (not otherwise specified))	Not reported	ICSR
EU-EC-1000941230	23/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Chest pain (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a] - Intramuscular)	Not reported	ICSR
EU-EC-1000941458	23/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (0d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	[ACETLSAUCYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009414979	23/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [1d - 1(Df) - Intramuscular])	[ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a -), [ETOFXINE HYDROCHLORIDE] (C - n/a - n/a -), [LYSINE ASPIRIN] (C - n/a - n/a -), [PAROXETINE, PAROXETINE HYDROCHLORIDE, PAROXETINE HYDROCHLORIDE ANHYDROUS] (C - n/a - n/a -), [PRAZEPAM] (C - n/a - n/a -), [PROPRANLOL, PROPRANLOL HYDROCHLORIDE] (C - n/a - n/a -)	ICSR
EU-EC-1000941607	23/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	[HYDROXYMETHYLGLUCOSYLAMINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000941813	23/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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]), TRASTUZUMAB, PERTUZUMAB - SOLUTION FOR INJECTION (S - n/a - Not applicable - [n/a - n/a - n/a])	NOT AVAILABLE (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])	ICSR
EU-EC-1000943644	22/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	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])	[RAMPRIL] (C - Left ventricular hypertrophy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000939610	22/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000939621	22/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000939859	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009398123	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Male	Cardiogenic shock (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000939848	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Adult	Female	Agility (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Hyperhidrosis (n/a - Fatal - Results in Death), Hypoxia (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	[ELIQUIS] (APIXIBAN) (C - n/a - n/a - [n/a - 5mg - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM BESQUHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ORAZEPAM] (C - n/a - n/a - [n/a - 1mg - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - 50mg - n/a]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009399371	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (1d - Fatal - Results in Death), Malaise (1d - Fatal - Results in Death), Nausea (1d - Fatal - Results in Death), Vomiting (1d - 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])	ICSR
EU-EC-10009400753	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (0d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009400773	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	Not reported	ICSR
EU-EC-10009400948	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000941573	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Cerebral haemorrhage (2d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (2d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009402256	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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 - n/a - [n/a - n/a] - Intramuscular)	Not reported	ICSR
EU-EC-10009403789	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009405082	22/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	[IRON] (C - Mineral supplementation - n/a - [n/a - n/a - n/a]), [XAGRID] (ANAGRELE, ANAGRELE HYDROCHLORIDE) (C - Blood disorder - n/a - [n/a - n/a - n/a]), [BETAMETHASONE, BETAMETHASONE VALERATE] (C - Wound treatment - n/a - [n/a - n/a - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - Pain - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - n/a]), [VITAMIN D, CALCIUM] (C - Vitamin supplementation - n/a - [n/a - n/a - n/a]), [RIVAROXABAN, RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [SLODOSIN] (SLODOSIN) (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, ENALAPRIL MALEATE] (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]), [NERVOLOL] (C - n/a - 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])	ICSR
EU-EC-10009381303	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (0d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	[MBRUVICA] (BRUTINIB) (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [SULFAMETHOXAZOLE, TRIMETHOPRIM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009382941	21/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	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])	[ENTRESTO 24 MG/6 MG FILM-COATED TABLETS] (VALSARTAN, SACUBITRIL) (C - Cardiomyopathy - Not applicable - [n/a - n/a - n/a]), [LIXIANA 15 MG FILM-COATED TABLETS] (DOXABAN) (C - Atrial fibrillation - Not applicable - [n/a - n/a - n/a]), NOT AVAILABLE (C - Atrial fibrillation, Cardiomyopathy - Not applicable - [n/a - n/a - n/a]), [DOXON] (C - Atrial fibrillation - Not applicable - [n/a - n/a - n/a]), [EPLERENONE] (C - Cardiomyopathy - Not applicable - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - Not applicable - [n/a - n/a - n/a])	ICSR
EU-EC-10009383751	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10009386097	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	[INSULATARD] (INSULIN HUMAN, INSULIN HUMAN (RDNA), INSULIN HUMAN ISOPHANE (RDNA)) (C - n/a - n/a - [n/a - n/a - n/a]), [JANUVIA] (SITAGLIPITIN, SITAGLIPITIN PHOSPHATE, SITAGLIPITIN PHOSPHATE MONOHYDRATE) (C - n/a - n/a - [n/a - 50mg - n/a]), [ACETLSAUCYLIC ACID] (C - n/a - n/a - [n/a - 75mg - n/a]), [ALLORPRIMOL] (C - n/a - n/a - [n/a - 300mg - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 40mg - n/a]), [GLYCERYL TRINITRATE, GLYCERYL TRINITRATE SOLUTION] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - 500mg - n/a]), [VALSARTAN, VALSARTAN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1(Df) - n/a])	ICSR
EU-EC-1000938731	21/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Female	No	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	ICSR
EU-EC-10009388409	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009388496	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10009388821	21/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary embolism (29d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 n/a - [n/a - n/a] - Intramuscular)	[EXELON] (RIVASTIGMINE) (C - Vascular dementia - n/a - [n/a - 1(Df) - Cutaneous]), [ACETLSAUCYLIC ACID] (C - Anticoagulant therapy - n/a - [n/a - 1(Df) - Oral]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 1(Df) - Oral]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - 1(Df) - Cutaneous]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - 50mg - Oral])	ICSR
EU-EC-10009390956	21/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10009394613	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Female	No	COVID-19 (n/a - Unknown -), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009395964	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009398903	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	[ESOMEPRAZOLE, ESOMEPRAZOLE SODIUM] (C - Dyspepsia - n/a - [n/a - 40mg - Oral]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 100mg - Oral]), [OXAZEPAM] (C - Emotional disorder - n/a - [n/a - 25mg - Oral])	ICSR
EU-EC-10009399703	20/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009399726	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	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), Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000937305	20/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009374055	20/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not							

EU Local Number	EV Gateway Received Date	Report Type	Primary Source Country for Regulatory Purposes	Literature Reference	Patent Age Group	Patent Age Group (as per report)	Patent Sex	Parent Child Report	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])	ICSR Form		
EU-EC-10008374451	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(Df) - Intramuscular])	[TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 4mg - n/a]), [NABIFARIN, WARFARIN SODIUM] (C - n/a - n/a - [n/a - 2.5mg - n/a - More in ICSR])	Not reported	ICSR
EU-EC-10008378976	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Unknown - [n/a - 1(Df) - n/a])	OLANZAPINE TEVA ([OLANZAPINE] (C - Schizophrenia - n/a - [n/a - 5mg - Oral]), TREVICTA ([PALIPERIDONE PALMATE]) (C - Mania disorder - n/a - [n/a - 350mg - Intramuscular])		ICSR
EU-EC-1000836238	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Acute respiratory distress syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aortic aneurysm (n/a - Unknown - Other Medically Important Condition), Bacterial sepsis (n/a - Unknown - Other Medically Important Condition), COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown -), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved -), Gastrointestinal infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown -), Malaise (n/a - Recovered/Resolved -), Multiple organ dysfunction syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown -), Nausea (n/a - Unknown -), Off label use (n/a - Unknown -), Pulmonary oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown -), Shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition), Vasculitis (n/a - Unknown - Other Medically Important Condition), Viral sepsis (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR])	[METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BPF] (C - Type 2 diabetes mellitus - n/a - [n/a - n/a - n/a]), [THYROXINE] (C - Hypothyroidism - n/a - [n/a - n/a])		ICSR
EU-EC-10008355591	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - Intramuscular])	[ACETYL SALICYLIC ACID] (C - n/a - Dose not changed - [n/a - 100mg - n/a]), [COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 40mg - n/a]), [METAMIZOLE SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - 350mg - n/a]), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE, METOPROLOL TARTRATE PH. EUR.] (C - n/a - Dose not changed - [n/a - 47.5mg - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [RETINOL, RETINOL PALMITATE, DEXPANTHENOL] (C - n/a - Dose not changed - [n/a - 350mg - n/a])		ICSR
EU-EC-10008362031	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Cerebral haemorrhage (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - Intramuscular])	[PHENPROLOM] (C - n/a - n/a -), [THIAMAZOLE] (C - n/a - n/a -)		ICSR
EU-EC-10008363030	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abnormal 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 hyperemia (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])	[ACETYL SALICYLIC 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 HYDROCHLORIDE] (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 HCLATE, 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]), [PIRATROPIUM 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])		ICSR
EU-EC-10008362031	19/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10008361453	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-10008362794	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (0d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR	
EU-EC-10008362903	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (0d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR	
EU-EC-10008325326	16/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Asthenia (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[ACETYL SALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - Oral]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - 10mg - Oral]), [ATENOLOL] (C - n/a - n/a - [n/a - n/a - Oral]), [PERINDOPRIL, PERINDOPRIL TERZ-BUTYLAMINE] (C - Hypertension - n/a - [n/a - 8mg - Oral])		ICSR
EU-EC-10008329122	16/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	19-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Malaise (n/a - Unknown -), Seizure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-1000831487	16/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000832857	16/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Embolism (n/a - Fatal - Results in Death), Sudden death (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])	[BECLMETHASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLMETHASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [ESTRADIOL] (C - Hormone replacement therapy - n/a - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Depressed mood - n/a - [n/a - n/a - n/a]), [LEVONORGESTREL, LEVONORGESTREL MICRONISED] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Dyspepsia - n/a - [n/a - n/a - n/a])		ICSR
EU-EC-10008339979	16/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	19-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10008339804	16/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Hypertension (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10008313265	16/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Feeling hot (n/a - Unknown -), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Hypophagia (n/a - Unknown - Other Medically Important Condition), Rash macular (n/a - Unknown -), Throat tightness (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ACETYL SALICYLIC 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]), [SABAPENTIN] (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])		ICSR
EU-EC-10008313985	16/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10008314660	16/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	19-64 Years	Not Specified	Male	No	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), Tachypnoea (n/a - Unknown -), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (25h - Recovered/Resolved - 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 - 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 BPF] (C - Diabetes mellitus - n/a - [n/a - 100mg - Oral])		ICSR
EU-EC-10008318141	15/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Influenza like illness (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-10008321695	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Cerebrovascular accident (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Disturbance in attention (n/a - Not Recovered/Not Resolved -), Hemiparesis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Ischaemic stroke (4d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10008300483	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (0d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	[ACETYL SALICYLIC ACID] (C - n/a - n/a -), [ALLOPURINOL] (C - n/a - n/a -), [ALPRAZOLAM] (C - n/a - n/a -), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a -), [AMLODIPINE, INDAPAMIDE, PERINDOPRIL ARGININE, INDAPAMIDE, AMLODIPINE BESILATE, PERINDOPRIL ARGININE] (C - n/a - n/a -), [FENOFIBRATE] (C - n/a - n/a -), [PIRACETAM] (C - n/a - n/a -), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - n/a - n/a -), [URAPIDIL, URAPIDIL HYDROCHLORIDE] (C - n/a - n/a -)		ICSR
EU-EC-10008300946	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10008302075	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10008302079	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10008302082	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10008302231	14/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (34d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10008303647	14/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Delirium (n/a - Fatal - Results in Death), Feeding disorder (n/a - Fatal - Results in Death), Fluid intake reduced (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])	NON SPECIFIED DRUG (NOT AVAILABLE) (C - n/a - n/a - [n/a - n/a - n/a])		ICSR
EU-EC-10008303977	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown -), Dysphagia (n/a - Unknown -), Eating disorder (n/a - Unknown -), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	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 - 650mg - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Sleep disorder - n/a - [n/a - 50mg - Oral])		ICSR
EU-EC-10008309116	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10008309270	14/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR	
EU-EC-10008289528	13/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Arthralgia (n/a - Unknown -), Asthenia (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Diarrhoea (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Sex	Patient Report	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])	ICSR Form
									General physical health deterioration (n/a - Unknown -), Nausea (n/a - Unknown -)			
EU-EC-10008289912	13/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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	ICSR
EU-EC-10008290730	13/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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	ICSR
EU-EC-10008291113	13/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Abdominal pain (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008291948	13/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Peripheral circulatory failure (n/a - Not Recovered/Not Resolved -), Blood pressure fluctuation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Intentional product use issue (n/a - Not Recovered/Not Resolved -), Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumonitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pulse abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Therapeutic product effect incomplete (n/a - Not Recovered/Not Resolved -), Vaccination complication (n/a - Unknown - Caused/Prolonged Hospitalisation)	FIRDAPSE (AMIFAMPRIDINE) (S - Myasthenic syndrome - Dose not changed - [n/a - 10mg - Oral - More in ICSR]), FIRDAPSE (AMIFAMPRIDINE) (S - Myasthenic syndrome - Unknown - [n/a - 30mg - Oral - More in ICSR]), TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE) (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown]), ACETYLSALICYLIC ACID (C - Product used for unknown indication - n/a - [n/a - 15mg - Unknown]), FUROSEMIDE (C - Product used for unknown indication - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-10008292543	13/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 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])	NOT AVAILABLE (C - n/a - Unknown - [n/a - 1(Df) - n/a]), DXYBUTYRAN (DXYBUTYRAN, DXYBUTYRAN HYDROCHLORIDE) (C - n/a - Unknown - [n/a - 10mg - n/a]), [AMHYDROUS LEVOTHYROXINE SODIUM] (C - n/a - Unknown - [n/a - 1(Df) - n/a]), [BISMETANIDE] (C - n/a - Unknown - [n/a - 1(Df) - n/a]), [FOSFOMYCIN FOSFOMYCIN TRIMETAMOL] (C - n/a - Unknown - [n/a - 1(Df) - n/a]), [LORAZEPAM] (C - n/a - Unknown - [n/a - 1(Df) - n/a]), [NEBIVOLOL] (C - n/a - Unknown - [n/a - 5(Df) - n/a]), [PASSIFLORA INCARNATA DRY EXTRACT] (C - n/a - Unknown - [n/a - 1(Df) - n/a]), [PRIMOZIDE] (C - n/a - Unknown - [n/a - 2(Df) - n/a])	ICSR
EU-EC-10008296592	13/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008274909	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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	ICSR
EU-EC-10008276417	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[BUPRENORPHINE] (C - n/a - n/a -)	ICSR
EU-EC-10008276594	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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 FLUMARATE, 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]), [CALCITONIN (SALMON)] (C - n/a - n/a -), [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]), [SODIUM PICOSULFATE] (C - n/a - n/a -)	ICSR
EU-EC-10008276884	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Apnoea (n/a - Unknown - Life Threatening), Blood glucose increased (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Hypotension (n/a - Unknown - Life Threatening), Unresponsive to stimuli (n/a - Unknown - Life Threatening, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	FENTANYL (FENTANYL, FENTANYL CITRATE) (C - n/a - n/a - [n/a - n/a - n/a]), [INSULIN, INSULIN HUMAN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008279311	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10008279527	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008279828	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), 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	ICSR
EU-EC-10008280203	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10008280338	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Life Threatening), Dementia (n/a - Not Recovered/Not Resolved - Life Threatening)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008282838	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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	ICSR
EU-EC-10008283101	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Asthenia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Gait instability (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008283433	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008284895	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	KEPPRA (LEVETIRACETAM) (C - n/a - n/a -)	ICSR
EU-EC-10008284899	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Disorientation (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	AZILECT (RASAGILINE, RASAGILINE MESILATE) (C - n/a - n/a - [n/a - n/a - n/a]), CLOPIDOGREL (CLOPIDOGREL, CLOPIDOGREL BESILATE) (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]), TRESIBA (INSULIN DEGLUDEC) (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])	ICSR
EU-EC-10008290301	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Cardiac arrest (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008290303	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10008290966	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	ICSR
EU-EC-10008294110	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Immune reaction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008294138	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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	ICSR
EU-EC-10008295793	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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 - [1200min - 5mg - n/a]), [MEMANTINE HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 20mg - Oral]), [MORPHINE SULFATE] (C - Dyspnoea, Pain - n/a - [125min - 25mL - Oral]), [PARACETAMOL] (C - Arthralgia - n/a - [n/a - 600mg - n/a]), [PARACETAMOL] (C - Arthralgia - n/a - [n/a - 650mg - Oral])	ICSR
EU-EC-10008298133	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocardial infarction (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	ICSR
EU-EC-10008298359	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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	ICSR
EU-EC-10008298360	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008298361	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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	ICSR
EU-EC-10008298364	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008298369	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008298350	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008298351	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008298354	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008298350	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10008299393	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008294194	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	COVID-19 (n/a - Unknown -), Death (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	ICSR
EU-EC-10008294342	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008294347	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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	ICSR
EU-EC-10008216533	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Internal haemorrhage (n/a - Unknown - Other Medically Important Condition), Kidney infection (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin lesion (n/a - Unknown - Caused/Prolonged Hospitalisation), Itching (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008216599	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	COVID-19 (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (0d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (4d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (4d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY COVID-19 mRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - Immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008218770	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	HYDROCORTISONE (HYDROCORTISONE, HYDROCORTISONE SODIUM SUCCINATE) (C - n/a - n/a - [n/a - n/a - n/a]), [CLEMASTINE, CLEMASTINE FLUMARATE] (C - n/a - n/a - [n/a - 1mg - n/a]), [DIAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [ECONAZOLE NITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ESOMEPRAZOLE MAGNESIUM DIHYDRATE] (C - n/a - n/a - [n/a - 20mg - n/a]), [GABAPENTIN] (C - n/a - n/a - [n/a - 300mg - n/a]), [LACTULOSE, LACTULOSE LIQUID] (C - n/a - n/a - [n/a - 20mL - n/a]), [MOMETASONE FURATE, MOMETASONE FURATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 30mg - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a]), [PROPIOMAZINE, PROPIOMAZINE MALEATE] (C - n/a - n/a - [n/a - 50mg - n/a]),	ICSR

EU Local Number	EV Gateway Received Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patent Age Group	Patent Age Group (as per report)	Patent Sex	Parent Child Report	Reaction List PT (Duration 7 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)	ICSR Form
EU-EC-1000821852	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	19-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - 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]), [ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - 10mg - n/a])	ICSR
EU-EC-1000821920	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (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]), [ATORVASTATIN] (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]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000822065	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000822193	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	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]), [DOLECALFEROL] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [FLUTICASONI PROPIONATE, SALMETEROL] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [PIRATROPIUM BROMIDE] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [TIABULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 4mg - n/a])	ICSR
EU-EC-1000822318	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Chills (n/a - Unknown -), Confusional state (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Respiratory rate increased (n/a - Unknown -), Restlessness (n/a - Unknown -), Suspiciousness (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])	ICSR
EU-EC-1000822654	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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]), [XELOFIN (PALIPERIDONE PALMATE)] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000822826	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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 EML OPLOSSING VOOR INJECTIE IN FLACON (INSULIN ASPART) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000825991	06/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000825994	06/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), General physical health deterioration (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000821061	06/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000821614	06/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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 - Cardiovascular accident prophylaxis - n/a - [n/a - 110mg - Oral]), [BUMETANIDE] (C - Diuretic therapy - n/a - [n/a - 1mg - Oral]), [CYANOCOBALAMIN, HYDROXYCOBALAMIN] (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)]), [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 -), [HYDROXYCOBALAMIN] (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 -), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [0.47d - 40mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [35206 - 0.0mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [25868 - n/a - n/a])	ICSR
EU-EC-1000821381	06/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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])	Not reported	ICSR
EU-EC-1000819332	05/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Recovered/Resolved With Sequela - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Severe (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombotic infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Virus reactivation (n/a - Recovered/Resolved With Sequela - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a -), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [0.47d - 40mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [35206 - 0.0mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [25868 - n/a - n/a])	ICSR
EU-EC-1000819363	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Purpura (n/a - Fatal - Results in Death), Rash macular (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000819369	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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	ICSR
EU-EC-1000819365	05/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	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	ICSR
EU-EC-1000819479	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Blood creatinine increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hepatic enzyme increased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	BRILIQUE (TICAGRELOR) (C - n/a - n/a - [n/a - 90mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 80mg - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - 50mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000819509	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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]), [DOLECALFEROL, CALCIUM CARBONATE] (C - Osteopenia - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Dyspepsia - n/a - [n/a - n/a - n/a]), [RAMPRIL] (C - Hypertension - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000819897	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - Life Threatening), Communication disorder (n/a - Unknown - Life Threatening), Death (1d - Fatal - Results in Death), Fatigue (n/a - Unknown - Life Threatening), Inappropriate schedule of product administration (n/a - Unknown -), Malaise (n/a - Unknown - Life Threatening), Off label use (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[VANCOMYCIN, VANCOMYCIN HYDROCHLORIDE] (C - C-reactive protein increased - n/a - [43d - n/a - n/a])	ICSR
EU-EC-1000819302	04/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	[ROSLIVASTATIN, ROSUVASTATIN CALCIUM] (C - Dyslipidaemia - n/a - [n/a - 1(Df) - Oral])	ICSR
EU-EC-1000817642	03/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000817664	03/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008170619	02/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008171181	02/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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	ICSR
EU-EC-10008171171	02/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10008157160	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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	ICSR
EU-EC-10008159443	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008160584	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	[AMLODIPINE] (C - n/a - n/a - [n/a - 10mg - n/a]), [ATENOLOL] (C - n/a - n/a - [n/a - 50mg - n/a]), [DESLOFATADINE] (C - n/a - n/a - [n/a - 5mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a]), [DOPICLONE] (C - n/a - n/a - [n/a - 5mg - n/a]), [ALSOREN 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])	ICSR
EU-EC-1000816367	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Arrhythmia (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Recovered/Resolved -), Death (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown -), Fatigue (n/a - Unknown -), Malaise (n/a - Unknown -), Tachypnoea (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-1000816384	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008165962	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	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 - 40mg - n/a]), [BUDESONIDE, FORMOTEROL, FUMARATE DIHYDRATE, FORMOTEROL, FUMARATE, BUDESONIDE] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [DOLECALFEROL] (C - n/a - n/a - [n/a - 800IU] - n/a), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 40mg - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [TIOTROPIUM, TIOTROPIUM BROMIDE, TIOTROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - 18ug - n/a])	ICSR
EU-EC-10008167199	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008144863	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008144867	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Brain death (n/a - Unknown - Other Medically Important Condition), Brain injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain oedema (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), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (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	ICSR
EU-EC-10008145133	31/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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 -), Fatigue (n/a - Unknown -), Peripheral swelling (n/a - Not Recovered/Not Resolved -), Swelling face (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008145777	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	[ACETYSALICYLIC ACID] (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]), [CLOPIDOGREL] (C - n/a - n/a - [n/a - 75mg - n/a]), [DOLECALFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [DONEPEZIL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 40mg - n/a]), [MEMANTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [METAMIZOLE, METAMIZOLE SODIUM, METAMIZOLE SODIUM MONOHYDRATE] (C - n/a - n/a - [n/a - 500mg - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 50mg - n/a]), [TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 300mg - n/a])	ICSR
EU-EC-10008147073	31/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	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	ICSR
EU-EC-10008147864	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	[PREGABALIN, PREGABALIN 150 MG HARD CAPSULES (PREGABALIN)] (C - n/a - n/a - [n/a - n/a - n/a]), [VEND 200 MG FILM-COATED TABLETS (VORICONAZOLE)] (C - n/a - n/a - [n/a - n/a - n/a]), [ALPRAZOLAM] (C - n/a - n/a - [n/a - n/a - n/a]), [AMODARONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

EU Local Number	EV Gateway Received Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per report)	Patient Sex	Parent Child Report	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)	ICSR Form
EU-EC-10008123171	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMPRI] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMBULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), JANUVA 100 MG FILM-COATED TABLETS [BITAGLIFITIN] (C - n/a - n/a - [n/a - 100mg - n/a]), [ACETYLCHOLINE] (C - n/a - n/a - [n/a - 200mg - n/a]), [COLECALCIFEROL, CALCIUM COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - 1(DF) - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 800IU - 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]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 25mg - n/a]), [NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1(DF) - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [DICYCLODOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 5mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1g - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - 10mg - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-1000812339	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a - n/a])	[CARBAMER, CARBAMER 96] (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 PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008126004	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008126005	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008126071	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(DF) - intramuscular])	Not reported	ICSR
EU-EC-10008126633	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Hypertension (n/a - Unknown - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(DF) - intramuscular])	Not reported	ICSR
EU-EC-10008126219	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Sense of oppression (n/a - Unknown - Results in Death) Blood pressure increased (n/a - Unknown -), Cardiac death (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008092490	28/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Body temperature decreased (n/a - Fatal - Results in Death), Bradycardia (n/a - Fatal - Results in Death), Cold sweat (n/a - Fatal - Results in Death), Cyanosis (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death), Hypoxia (n/a - Fatal - Results in Death), Palor (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]), [FENTANYL] (C - n/a - n/a - [n/a - n/a - n/a]), [MIDAZOLAM] (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])	ICSR
EU-EC-10008092756	26/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Acute myocardial infarction (0d - Fatal - Results in Death), Death (0d - Fatal - Results in Death), Pulmonary oedema (0d - Fatal - Results in Death)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - immunisation - Not applicable - [n/a - 3mL - intramuscular])	[MELPERONE] (C - n/a - Not applicable -), [METOPROLOL] (C - n/a - Not applicable -), [OMEPRAZOLE] (C - n/a - Not applicable -)	ICSR
EU-EC-1000804122	26/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000804505	26/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Diarrhoea (1d - Unknown - Other Medically Important Condition), Malaise (1d - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])	[ACTOS (PIGLITAZONE, PIGLITAZONE HYDROCHLORIDE)] (C - n/a - n/a - [n/a - 15mg - n/a]), [AZOPT (BRINZOLAMIDE)] (C - n/a - n/a - [n/a - n/a - n/a]), [FORTISIP (G) (NOT AVAILABLE)] (C - n/a - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE (PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE)] (C - n/a - n/a - [n/a - 20mg - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - 300mg - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [EZETIMIBE] (C - n/a - n/a - [n/a - 10mg - n/a]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DHYDRATE] (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 - 40mg - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - 7.5mg - n/a])	ICSR
EU-EC-10008095907	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	[EKLON (RIVASTIGMINE)] (C - Demencia Alzheimer's type - n/a - [n/a - n/a - Transdermal]), [MEMANTINE MERZ (MEMANTINE HYDROCHLORIDE)] (C - Demencia Alzheimer's type - n/a - [n/a - n/a - Oral]), [CALCIUM, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [DUTASTERIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10008097019	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008097079	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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])	ICSR
EU-EC-1000809739	26/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a - More in ICSR])	[PARACETAMOL] (C - Pharyngitis - n/a - [n/a - 30(DF) - Oral])	ICSR
EU-EC-10008091233	26/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DF) - intramuscular])	[ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE, LEVOTHYROXINE SODIUM, ANHYDROUS EP] (C - Hypometabolism - n/a - [n/a - n/a - Oral]), [FLUORIDE, SODIUM FLUORIDE] (C - Dental caries - n/a - [n/a - 1(DF) - Dental]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Diuretic therapy - n/a - [n/a - 40mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Gastroesophageal reflux disease - n/a - [n/a - 20mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - Oral]), [PARAFFIN, YELLOW SOFT, LIQUID PARAFFIN] (C - Dry eye - n/a - [n/a - 1(DF) - Subconjunctival]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - [n/a - 750mg - Oral]), [RAMPRI] (C - Hypertension - n/a - [n/a - 5mg - Oral]), [TERBUTALINE SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - 5mg - Respiratory (inhalation)], [TIOTROPUM, OLODATEROL] (C - Chronic obstructive pulmonary disease - n/a - [n/a - 2(DF) - Respiratory (inhalation)])	ICSR
EU-EC-10008067416	25/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pain in extremity (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - intramuscular])	[MELATONIN (MELATONIN)] (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]), [COAL TAR SOLUTION BP, PRECIPITATED SULPHUR BP, SALICYLIC ACID PH. EUR., COAL TAR SOLUTION, SALICYLIC ACID, SULFUR] (C - n/a - n/a - [n/a - n/a - n/a]), [DESOGESTREL] (C - n/a - n/a - [n/a - 75ug - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [RAMPRI] (C - n/a - n/a - [n/a - n/a - n/a]), [SALSALATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000806785	25/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [22d - n/a - intramuscular])	[RILUTEK (RILUZOLE)] (C - Amyotrophic lateral sclerosis - n/a - [n/a - n/a - Oral]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - n/a - Oral]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - n/a - Oral]), [RISPERIDONE] (C - Agitation - n/a - [n/a - n/a - Oral]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Affective disorder - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10008074216	25/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death), Haematoma (n/a - Unknown -), Road traffic accident (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(DF) - 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 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]), [LISINAPRIL, LISINAPRIL DHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [SPRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008053986	24/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DF) - intramuscular])	Not reported	ICSR
EU-EC-10008054068	24/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(DF) - intramuscular])	Not reported	ICSR
EU-EC-10008054752	24/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (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) - intramuscular])	[FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (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]), [LIXIANA (EDOXABAN, EDOXABAN TOSYLATE)] (C - n/a - n/a - [n/a - n/a - n/a]), [CODEINE] (C - Cough - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE] (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]), [PIPAMPERONE, PIPAMPERONE HYDROCHLORIDE] (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 - Constipation - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008055539	24/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Abdominal infection (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), Urinary tract infection (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Cardiomypathy - n/a - [n/a - n/a - n/a]), [SPRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008063209	24/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Chills (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Hypotonia (n/a - Unknown -), Malaise (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-10008063213	24/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Hypophagia (n/a - Not Recovered/Not Resolved -), Hypotonia (n/a - Not Recovered/Not Resolved -), Somnolence (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	ICSR
EU-EC-10008034911	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008038906	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Circulatory collapse (n/a - Fatal - Results in Death), Death (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 - n/a])	Not reported	ICSR
EU-EC-10008039137	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Condition aggravated (10d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (0d - Fatal - Results in Death), Drug Ineffective (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Irritability (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Malaise (15d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pain (8d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (12d - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008041320	23/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008041983	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-10008042141	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-10008043066	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(DF) - intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ALFUZOSIN HYDROCHLORIDE] (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] (C - n/a - n/a - [n/a - n/a - n/a]), [LIDOCANE, LIDOCANE 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 CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

EU Local Number	EV Gateway Received Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Sex	Patient Report	Parent Child Report	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)	ICSR Form
EU-EC-1000804213	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(D)] - Intramuscular)	[RAMPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000804351	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000804465	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[LEVOTHYROXINE SODIUM] (C - Hypothyroidism - Not applicable - [n/a - 1(D)] - Oral), [RAMPRIL] (C - n/a - n/a - [n/a - n/a - Oral]), [CIRCADIN 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]), [CARBOMER CARBOMER 974P] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (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]), [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]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [DIMEPRAZOLE] (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]), [SODIUM PICOSULFATE, SODIUM PICOSULFATE] (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])	ICSR
EU-EC-1000804562	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Diarhoea (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 - n/a - n/a])	[BISACODYL, DUCUSATE SODIUM, SODIUM PICOSULFATE MONOHYDRATE] (C - Constipation - n/a - [n/a - 10mg - Rectal]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 1(D)] - Oral), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 200(U)] - n/a), [DUCUSATE 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 - Photopig - n/a - [n/a - n/a - Rectal]), [MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - 8(D)] - Oral), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral - More in ICSR]), [SENA 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])	ICSR
EU-EC-1000804805	23/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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), Mucum (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, DUCUSATE SODIUM, SODIUM PICOSULFATE MONOHYDRATE] (C - Constipation - n/a - [n/a - 10mg - Rectal]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 1(D)] - Oral), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 200(U)] - n/a), [DUCUSATE 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 - Photopig - n/a - [n/a - n/a - Rectal]), [MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - 8(D)] - Oral), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral - More in ICSR]), [SENA 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])	ICSR
EU-EC-1000805249	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Disease recurrence (n/a - Unknown - Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000805194	23/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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]), [ACETYSALICYLIC 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]), [RAMPRIL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000802638	22/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (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	ICSR
EU-EC-1000802654	22/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Acute kidney injury (n/a - Unknown - Other Medically Important Condition), 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	ICSR
EU-EC-1000802695	22/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Aphasia (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (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])	Not reported	ICSR
EU-EC-1000802709	22/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000802710	22/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[AZARGA (BRINZOLAMIDE, TIMOLOL, TIMOLOL MALEATE, BRINZOLAMIDE)] (C - n/a - n/a -), [FENTANYL (FENTANYL, FENTANYL CITRATE)] (C - n/a - n/a - [n/a - 25ug - n/a]), [PROLIA (DENOSUMAB)] (C - n/a - n/a - [n/a - 60mg - Subcutaneous]), [BISOPROLOL, BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 2.5mg - Oral]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - Oral]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [FOLIC ACID] (C - n/a - n/a - [n/a - 400ug - n/a]), [LACTULOSE] (C - n/a - n/a -), [LATANOPROST] (C - n/a - n/a -), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 20mg - Oral]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1g - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - 5mg - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - 1mg - Respiratory (inhalation)]), [TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 100mg - Oral]), [ZOLPIDEM, ZOLPIDEM HEMITARTRATE, ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - 5mg - Oral])	ICSR
EU-EC-1000802853	22/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Loss of consciousness (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])	Not reported	ICSR
EU-EC-1000802935	22/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	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), COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dmg ineffective (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - n/a)	[AFIXAS 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])	ICSR
EU-EC-1000802953	22/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Dmg ineffective (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000802028	20/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000799083	19/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-10007991013	19/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Syncope (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[RELVAR ELLIPTA (FLUTICASON FURATE, VILANTEROL)] (C - Chronic obstructive pulmonary disease - n/a - [n/a - 1(D)] - n/a), [ACETYLCYSTEINE, ACETYLCYSTEINE SODIUM] (C - Productive cough - n/a - [n/a - n/a]), [AMIODARONE, AMIODARONE HYDROCHLORIDE] (C - Atrial fibrillation - n/a - [n/a - 200mg - n/a]), [BISACODYL] (C - Constipation - n/a - [n/a - n/a]), [BUMETANIDE] (C - Cardiac failure - n/a - [n/a - 1mg - n/a]), [CETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - 10mg - n/a]), [COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [n/a - 200(U)] - n/a), [CYANOCOBALAMIN, HYDROXYCOBALAMIN] (C - Vitamin B12 deficiency - n/a - [n/a - 1mg - n/a]), [ENOXAPARIN SODIUM] (C - Thrombosis prophylaxis - n/a -), [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [LACTULOSE, LACTULOSE LIQUID] (C - Constipation - n/a - [n/a - n/a - n/a]), [MORPHINE SULFATE, MORPHINE SULFATE PENTAHYDRATE] (C - Osteoarthritis - n/a - [n/a - 10mg - Oral]), [OXAZEPAM] (C - Insomnia - n/a - [n/a - n/a - Oral]), [DICYCLONE HYDROCHLORIDE] (C - Osteoarthritis, Pain - n/a -), [POTASSIUM CITRATE] (C - Hypokalaemia - n/a - [n/a - 660mg - 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 - 1(D)] - n/a), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [n/a - n/a - n/a]), [SPRONOLACTONE] (C - Cardiac failure - n/a - [n/a - 25mg - n/a]), [ZOPICLONE] (C - Insomnia - n/a - [n/a - 7.5mg - n/a])	ICSR
EU-EC-10007992106	19/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007992303	19/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cold sore (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Pain (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]), [NEMANTINE] (C - n/a - n/a - [n/a - 20mg - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 100mg - n/a]), [PROGLITAZONE (PROGLITAZONE)] (C - n/a - Not applicable - [n/a - 30mg - Oral]), [ACETYSALICYLIC ACID] (C - n/a - Not applicable - [n/a - 100mg - Oral]), [ALLOPURINOL] (C - n/a - Not applicable - [n/a - 100mg - Oral]), [AMTRIPYLINE HYDROCHLORIDE] (C - n/a - Not applicable - [n/a - 25mg - Oral]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - Not applicable - [n/a - 5mg - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - n/a - Not applicable - [n/a - n/a - Oral]), [CLONAZEPAM] (C - n/a - Not applicable - [n/a - n/a - Oral]), [DIAZEPAM] (C - n/a - Not applicable - [n/a - 5mg - Oral]), [METFORMIN HYDROCHLORIDE] (C - n/a - Not applicable - [n/a - 500mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - Not applicable - [n/a - 40mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - Not applicable - [n/a - n/a - Oral]), [PARACETAMOL, TRAMADOL, TRAMADOL HYDROCHLORIDE, PARACETAMOL] (C - n/a - Not applicable - [n/a - 1(D)] - Oral), [ZOLPIDEM TARTRATE] (C - n/a - Not applicable - [n/a - 5mg - Oral]), NON SPECIFIED STATINE (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]), [XARELTO 15 MG (RIVAROXABAN)] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008000754	19/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Gastroenteritis (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(D)] - n/a)	[ACETYLSALICYLIC ACID] (C - Atrial fibrillation - Dose not changed - [n/a - 100mg - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE] (C - Hypertension - Dose not changed - [n/a - 10mg - n/a]), [CETIRIZINE DIHYDROCHLORIDE] (C - Prophylaxis - n/a - [n/a - 1(D)] - n/a), [DRY EXTRACT OF GINKGO BILOBA LEAVES (35-67 %), EXTRACTION SOLVENT: ACETONE 60% (M / M), GINKGO BILOBA] (C - n/a - Dose not changed - [n/a - 100mg - n/a]), [PARACETAMOL] (C - Prophylaxis - n/a - [n/a - 3(D)] - n/a), [TRIAZOLAM] (C - Insomnia - n/a -)	ICSR
EU-EC-10007974848	18/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Pain in extremity (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-10007974917	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-10007974480	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (1d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin discoloration (n/a - Unknown - Caused/Prolonged Hospitalisation, 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]), [RAMPRIL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007977917	18/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000799497	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000799802	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-1000799985	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR
EU-EC-10007996749	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007968080	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(D)] - Intramuscular)	Not reported	ICSR

EU Local Number	EV Gateway Received Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Sex	Patient Report	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])	ICSR Form
						Years			Face oedema (n/a - Unknown - Results in Death), Hypotension (n/a - Unknown - Results in Death), Oedema peripheral (n/a - Unknown - Results in Death), Pyrexia (n/a - Unknown - Results in Death), Tachycardia (n/a - Unknown - Results in Death)			
EU-EC-1000796803	17/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000796820	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Hypertensive crisis (n/a - Recovering/Resolving - Results in Death, Other Medically Important Condition), Tremor (n/a - Recovering/Resolving - Results in Death, Other Medically Important Condition), Vertigo (n/a - Recovering/Resolving - Results in Death, Other Medically Important Condition), Visual impairment (n/a - Recovering/Resolving - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000796847	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10007947204	16/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10007949279	16/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (1-d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007949527	16/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Confusion (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Personality change (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])	Not reported	ICSR
EU-EC-10007931697	15/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Bleiser infected (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Pain (n/a - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007931817	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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, MIBRONISED] (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])	ICSR
EU-EC-10007931821	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Pneumonia (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	ICSR
EU-EC-10007931861	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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]), COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	BETMIG (MIRABEGRON) (C - n/a - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID, SUCCINIC ACID, IRON, FERROUS (II) GLYCINE SULFATE COMPLEX, FERROUS ION, FERROUS (II) GLYCINE SULFATE COMPLEX, POLYSACCHARIDE IRON COMPLEX] (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]), [ISOSORBIDE 5 MONONITRATE, 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]), [NALOXONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE, NALOXONE, OXYCODONE, OXYCODONE HYDROCHLORIDE, NALOXONE, OXYCODONE HYDROCHLORIDE, NALOXONE HYDROCHLORIDE, OXYCODONE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007932284	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10007932753	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Acute myocardial infarction (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (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	ICSR
EU-EC-10007934179	16/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), Resuscitation (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dyspnoea (10d - Fatal - Results in Death), General physical condition abnormal (10d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007934987	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	ICSR
EU-EC-10007934900	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007901674	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10007901780	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Death (0d - Fatal - Results in Death), Resuscitation (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Death (n/a - 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	ICSR
EU-EC-10007902877	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10007906099	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	AVAMY'S (FLUTICASON FURATE) (C - n/a - n/a - [n/a - n/a - n/a]), BETMIG (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]), [LEVOMEPRAZOLE] (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])	ICSR
EU-EC-10007908757	12/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Asthenia (n/a - Unknown -), Chills (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Discomfort (n/a - Unknown -), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown -), Feeling cold (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown -), Respiratory distress (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007909182	12/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [1d - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007909748	12/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	Anger (n/a - Unknown - Caused/Prolonged Hospitalisation), Aphasia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Intracranial aneurysm (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Mood swings (n/a - Unknown - Caused/Prolonged Hospitalisation), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown -), Ruptured cerebral aneurysm (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Strabismic (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Subarachnoid haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000788371	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-1000788638	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (1-d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000789672	11/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation), Menstrual 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 - 10U] - Subcutaneous), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Hyperlipaemia - 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 - 5000U] - Oral), [LISINAPRIL, LISINAPRIL DHYDRATE] (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])	ICSR
EU-EC-10007891400	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Come (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Hypopyxia (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007892484	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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) (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 DHYDRATE] (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]), [GOSERELIN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007893389	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	Not reported	ICSR
EU-EC-10007894940	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	ICSR
EU-EC-10007894972	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10007894973	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10007895786	11/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	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 - 1000U] - 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 - Gastroesophageal 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 - 10g - Oral]), [PRIMIDONE] (C - Epilepsy - n/a - [n/a - 50mg - Oral])	ICSR
EU-EC-10007874237	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR
EU-EC-10007874843	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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 - 100mg] - Oral), [LOXAPINE] (C - n/a - Drug withdrawn - [n/a - 100mg] - Oral), [OXAZEPAM] (C - n/a - Drug withdrawn - [n/a - 100mg] - Oral), [PARACETAMOL] (C - n/a - Dose not changed - [n/a - 1(Df) - Oral])	ICSR
EU-EC-10007875182	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group (as per report)	Patient Sex	Patient Age	Parent Child Report	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)	ICSR Form
EU-EC-10007876482	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	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	ICSR
EU-EC-10007877723	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a] - n/a)	Not reported	ICSR
EU-EC-10007861944	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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 (APIXIBAN) (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), (DOXIN) (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)	ICSR
EU-EC-1000786300	10/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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 -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a] - n/a)	Not reported	ICSR
EU-EC-1000788337	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Swelling (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Melisae (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 - n/a] - n/a), 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), CARBIDOPA, LEVODOPA, CARBIDOPA MONOHYDRATE (C - n/a - n/a - [n/a - 1(Df) - n/a]), GANFORT 0.3 MGML + 5 MGML (TMOLOL MALATE, BMAPROST) (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, IPATROPIUM BROMIDE MONOHYDRATE) (C - n/a - n/a - [n/a - n/a] - n/a)	ICSR
EU-EC-1000788436	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-1000786220	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 3(Dg) - Intramuscular])	Not reported	ICSR
EU-EC-1000786227	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [n/a - 3(Dg) - Intramuscular])	Not reported	ICSR
EU-EC-10007864731	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	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)	APIXIBAN (APIXIBAN) (C - n/a - n/a - [n/a - n/a] - n/a), LEVETIRACETAM (LEVETIRACETAM) (C - n/a - n/a - [n/a - n/a] - n/a), LUMGAN (BMAPROST) (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), (ALFUDRIN HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a] - n/a), (CARTEOLOL HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a] - n/a), (BERCANDOPHNE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a] - n/a), (MACROGOL 4000) (C - n/a - n/a - [n/a - n/a] - n/a), (PARACETAMOL) (C - n/a - n/a - [n/a - n/a] - n/a)	ICSR
EU-EC-10007866134	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a] - n/a)	Not reported	ICSR
EU-EC-10007868243	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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 -), (SPRONOLACTONE) (C - n/a - n/a -)	ICSR
EU-EC-10007847908	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a] - Intramuscular)	Not reported	ICSR
EU-EC-1000784907	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a] - n/a)	Not reported	ICSR
EU-EC-10007848934	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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	ICSR
EU-EC-10007848163	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a] - Intramuscular)	Not reported	ICSR
EU-EC-10007848421	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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 - n/a]), (PARACETAMOL, PARACETAMOL, ASPARTAME) (C - n/a - n/a - [n/a - n/a] - n/a), (DOPLONE) (C - n/a - n/a - [n/a - n/a] - n/a), EXFOSGE (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])	ICSR
EU-EC-10007849887	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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 (M - Recovered/Resolved -), Vomiting (M - Unknown -)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - Intramuscular)	Not reported	ICSR
EU-EC-10007850196	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a] - n/a)	Not reported	ICSR
EU-EC-10007850200	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	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	ICSR
EU-EC-10007850211	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a] - Intramuscular)	Not reported	ICSR
EU-EC-10007850212	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	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	ICSR
EU-EC-10007850217	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	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	ICSR
EU-EC-10007850219	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	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	ICSR
EU-EC-10007850221	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	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	ICSR
EU-EC-10007850222	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Gait instability (n/a - Not Recovered/Not Resolved -), Quadriceps (n/a - Not Recovered/Not Resolved -)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a] - Intravenous (not otherwise specified))	Not reported	ICSR
EU-EC-10007850224	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Female	No	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	ICSR
EU-EC-10007850228	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Asthensia (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	ICSR
EU-EC-10007850227	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	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	ICSR
EU-EC-10007850228	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a] - Intravenous (not otherwise specified))	Not reported	ICSR
EU-EC-10007850231	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a] - Intravenous (not otherwise specified))	Not reported	ICSR
EU-EC-10007850235	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	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	ICSR
EU-EC-10007850243	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	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	ICSR
EU-EC-10007850244	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a] - Intramuscular)	Not reported	ICSR
EU-EC-10007850245	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	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	ICSR
EU-EC-10007850255	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a] - Intramuscular)	Not reported	ICSR
EU-EC-10007850256	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	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	ICSR
EU-EC-10007850259	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Not Specified	No	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	ICSR
EU-EC-10007850261	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	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	ICSR
EU-EC-10007850264	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a] - Intramuscular)	Not reported	ICSR
EU-EC-10007850719	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a] - Intramuscular)	Not reported	ICSR
EU-EC-10007850721	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a] - Intramuscular)	Not reported	ICSR
EU-EC-10007850737	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	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	ICSR
EU-EC-10007850739	09/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a] - Intramuscular)	Not reported	ICSR
EU-EC-10007851156	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	(RIBESARTAN 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), (PAPAPERONE) (C - n/a - n/a - [n/a - n/a] - n/a), BUNTAISSE (BUNTAISSE) (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 HYDRATE, AZITHROMYCIN HYDRATE) (C - n/a - n/a - [n/a - n/a] - n/a), (SALBUTAMOL SULFATE, IPATROPIUM BROMIDE MONOHYDRATE) (C - n/a - n/a - [n/a - n/a] - 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)	ICSR
EU-EC-10007853987	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	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])	Not reported	ICSR
EU-EC-10007853984	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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])	Not reported	ICSR
EU-EC-10007857293	09/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Elderly	Male	No	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 (M - Recovered/Resolved -), Skin discoloration (n/a - Unknown -), Tremor (n/a - Unknown -)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-100078602148	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	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)	ICSR
EU-EC-100078602948	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	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), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a] - n/a)	ICSR
EU-EC-100078603008	05/03/												

EU Local Number	EV Gateway Received Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patent Age Group (as per report)	Patent Age Group (as per report)	Patent Sex	Parent Child Report	Reaction List PT (Duration 7 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)	ICSR Form
												DRIED FERROUS SULFATE, FERROUS SULFATE (C - n/a - n/a - [n/a - n/a - n/a]). [ESTROL] (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-1000780388	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])		ICSR
EU-EC-1000780853	05/03/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	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	ICSR
EU-EC-1000778450	04/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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	ICSR
EU-EC-1000774522	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	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	ICSR
EU-EC-1000777739	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000777739	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000777844	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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])	ICSR
EU-EC-1000778163	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000778253	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000778217	02/03/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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	ICSR
EU-EC-1000778434	02/03/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	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	ICSR
EU-EC-1000778444	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Abdominal wall haematomas (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	ICSR
EU-EC-1000778595	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000778579	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000778563	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	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]), [COLCALSIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXUSATE] (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]), [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 -)	ICSR
EU-EC-1000778924	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000778939	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000779051	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 1(Df) - Intramuscular])	KEPPRA (LEVETIRACETAM) (C - Epilepsy - n/a - [n/a - 2.5mL - n/a]), TOLUENO 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]), [GLYCOPYRROLIUM BROMIDE, GLYCOPYRROLIUM 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])	ICSR
EU-EC-1000774884	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	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	ICSR
EU-EC-1000774854	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	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	ICSR
EU-EC-1000774839	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	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), 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]), [ANTHRAQUINONE, DIMETICONE, DIMETICONE COLLOIDAL SILICON DIOXIDE, DIMETICONE, SILICA, COLLOIDAL ANHYDROUS SILICA, COLLOIDAL ANHYDROUS DIMETICONE 1000] (C - Flatulence - n/a - [n/a - n/a - n/a]), [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 - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - n/a]), [ZOPICLONE] (C - Insomnia - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000774929	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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	ICSR
EU-EC-1000774906	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	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])	ICSR
EU-EC-1000775131	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Unknown - 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), Posturing (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory distress (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation)	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])	ICSR
EU-EC-1000775335	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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])	ICSR
EU-EC-1000775689	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (0d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	[FLOTROPIDUM, OLGATEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [NOVORAPID] (INSULIN ASPART) (C - n/a - n/a -), [TREBSIA (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])	ICSR
EU-EC-1000775851	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown -), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000773944	27/02/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000773912	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000774036	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000774028	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000774092	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000774162	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	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	ICSR
EU-EC-1000774249	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Literature Reference	Patient Age Group (per report)	Patient Sex	Patient Group (per report)	Parent Child Report	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)	ICSR Form	
EU-EC-10007742670	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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	ICSR
EU-EC-10007729795	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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])	ICSR
EU-EC-10007729956	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	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])	ICSR
EU-EC-10007730003	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Chills (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation), Confusional state (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation), Fall (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation), Headache (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation), Hypoglycaemia (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation), Hypohydia (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation), Hypotension (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation), Hypothermia (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation), Hypoxia (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation), Malaise (n/a - Unknown -), Oedema peripheral (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation), Oxygen saturation decreased (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation), Skin ulcer (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation), Somnolence (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation), Tachypnoea (n/a - Fatal - Results in Death, Caused/Protracted 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]), ACETYSALICYLIC 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]), TACROLIMOL, MALEATE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007732636	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Unresponsive to stimuli (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007737139	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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]), ESICLALOPRAM, ESICLALOPRAM OXALATE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007719978	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007720021	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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])	ELIGIUS (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)])	ICSR
EU-EC-10007720090	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007720134	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007721191	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	ELIGIUS (APIXABAN) (C - Cardiac failure - n/a - [n/a - 2.5mg - Oral]), ACETYSALICYLIC 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]), RAMPRELL (C - Cardiac failure - n/a - [n/a - 5mg - Oral])	ICSR
EU-EC-10007722038	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Hypertension (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007722134	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007722207	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007722492	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007723042	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007723054	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	ACETYSALICYLIC 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])	ICSR
EU-EC-10007723172	25/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (0d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007706343	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	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	ICSR
EU-EC-10007706344	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Protracted Hospitalisation), Multiple organ dysfunction syndrome (1d - Fatal - Results in Death, Life Threatening, Caused/Protracted Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007706729	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007706938	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	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	ICSR
EU-EC-10007706971	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007707211	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007708430	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007708562	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007708715	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007708779	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007708780	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007709425	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007709427	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Caused/Protracted Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007709493	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007709494	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007711838	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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]), FLOPIDIPINE (C - n/a - n/a - [n/a - n/a - n/a]), FLOPIDIPINE (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]), PIANTOPRAZOLE, PIANTOPRAZOLE SODIUM SESQUHYDRATE (C - n/a - n/a - [n/a - n/a - n/a]), PARACETAMOL (C - n/a - n/a - [n/a - 1000mg - n/a])	ICSR
EU-EC-10007711855	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	TRIMBOV (BECLOMETHASONE DIPROPIONATE, GLYCOPYRRONIUM BROMIDE, FORMOTEROL FUMARATE DIHYDRATE) (C - n/a - n/a - [n/a - n/a - n/a]), ACETYSALICYLIC ACID (C - n/a - n/a - [n/a - 200mg - n/a]), ACETYSALICYLIC 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]), CYNOCOBALAMIN (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])	ICSR
EU-EC-10007709372	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - Intramuscular])	EBIXA (MILNATEIN 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]), SOSORBIDE DINTRATE (C - n/a - n/a - [n/a - n/a - n/a]), OXYCODONE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10007709377	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007709413	23/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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	ICSR
EU-EC-10007709379	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007709745	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007709940	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	FOUIC 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]), 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])	ICSR
EU-EC-10007709922	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	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])	Not reported	ICSR
EU-EC-10007709350	22/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	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	ICSR
EU-EC-10007708578	22/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007708584	22/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007708781	22/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	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	ICSR
EU-EC-10007708954	22/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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]), FUROSEMIDE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007707102	20/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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	ICSR
EU-EC-10007707199	20/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-100077													

EU Local Number	EV Gateway Received Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Sex	Patient Report	Reaction List PT (Duration 7 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)	ICSR Form	
			Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	Breath sounds (n/a - Unknown -), Choking (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Falgue (n/a - Recovered/Resolved -), Oxygen saturation immeasurable (n/a - Recovered/Resolved - Other Medically Important Condition), Pain (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)				
EU-EC-1000781817	14/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (1d - Fatal - Results in Death), 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)])	ICSR	
EU-EC-1000780789	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Subitus (n/a - Unknown - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-1000780807	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR	
EU-EC-1000780820	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR	
EU-EC-1000780829	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR	
EU-EC-1000788120	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR	
EU-EC-1000788407	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR	
EU-EC-1000789419	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR	
EU-EC-1000789425	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR	
EU-EC-1000789439	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR	
EU-EC-1000789635	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR	
EU-EC-1000789723	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR	
EU-EC-1000789762	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR	
EU-EC-1000789870	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Gaze palsy (n/a - Fatal - Results in Death), Ophthalmotus (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [1d - n/a - Intramuscular])	EKELON (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 TRHYDRATE, ESOMEPRAZOLE SODIUM] (C - Gastrointestinal disorder prophylaxis - n/a - [n/a - n/a - Oral]), [ESOSORBIDE S MONONTRATE, ESOSORBIDE MONONTRATE] (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 - Bipolar disorder - n/a - [n/a - n/a - Oral]), [WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BP] (C - Arterial fibrillation - n/a - [n/a - n/a - Oral]), [COAPROVEL 150 MG/125 MG TABLETS (HYDROCHLOROTHIAZIDE, RISERSARTAN)] (C - n/a - Does not changed - [n/a - 1(Df) - Oral]), [MANERBIN 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 - [1(Df) - Oral])	ICSR	
EU-EC-1000789850	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR	
EU-EC-1000789822	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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]), [ACETYSALICYLIC ACID, D,L-LYSINE ACETYSALICYLATE] (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]), [OXAZEPAM] (S - Product used for unknown indication - Dose not changed - [n/a - 1(Df) - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUHYDRATE] (S - Product used for unknown indication - Dose not changed - [n/a - 1(Df) - Oral]), [POTASSIUM CHLORIDE, POTASSIUM CHLORIDE, ETHYLCELLULOSE MICROENCAPSULATED 80.00%) (S - Product used for unknown indication - Dose not changed - [n/a - 1(Df) - Oral]), [TIAPRIDE HYDROCHLORIDE] (S - Product used for unknown indication - Dose not changed - [n/a - 145mg - Oral]), [ZOPICLONE] (S - Product used for unknown indication - Dose not changed - [n/a - 1(Df) - Oral])	KEPPRA 500 MG FILM-COATED TABLETS (LEVETIRACETAM) (S - Product used for unknown indication - Dose not changed - [n/a - 1(Df) - Oral]), [ACETYSALICYLIC ACID, D,L-LYSINE ACETYSALICYLATE] (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]), [OXAZEPAM] (S - Product used for unknown indication - Dose not changed - [n/a - 1(Df) - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUHYDRATE] (S - Product used for unknown indication - Dose not changed - [n/a - 1(Df) - Oral]), [POTASSIUM CHLORIDE, POTASSIUM CHLORIDE, ETHYLCELLULOSE MICROENCAPSULATED 80.00%) (S - Product used for unknown indication - Dose not changed - [n/a - 1(Df) - Oral]), [TIAPRIDE HYDROCHLORIDE] (S - Product used for unknown indication - Dose not changed - [n/a - 145mg - Oral]), [ZOPICLONE] (S - Product used for unknown indication - Dose not changed - [n/a - 1(Df) - Oral])	Not reported	ICSR
EU-EC-1000788271	11/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	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])		ICSR	
EU-EC-1000788269	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR	
EU-EC-1000788296	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Asthenia (24h - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-1000788342	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	General physical condition abnormal (24h - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR	
EU-EC-1000788576	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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]), [TIOTROPOLIUM, TIOTROPOLIUM BROMIDE, TIOTROPOLIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000788514	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	ICSR	
EU-EC-1000788528	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Lip oedema (n/a - Recovering/Resolving - 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]), [LEVOHYDROXINE SODIUM] (C - n/a - n/a - [n/a - 25ug - Oral])	ICSR	
EU-EC-1000788525	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Pyrexia (n/a - Unknown - Results in Death), Concomitant 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	ICSR	
EU-EC-1000788831	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	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]), [LUMGAN (BIMATOPROST)] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [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]), [FLUTICASON PROPRIONATE, SALMETEROL, FLUTICASON PROPRIONATE, 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 SESQUHYDRATE] (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]), [RAMPRIL] (C - n/a - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)], [SMVASTATIN] (C - n/a - n/a - [n/a - n/a - Oral]), [THEOPHYLLINE, THEOPHYLLINE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [TIOTROPOLIUM, TIOTROPOLIUM BROMIDE, TIOTROPOLIUM 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]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR	
EU-EC-1000788839	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [1d - n/a - Intramuscular])		ICSR	
EU-EC-1000787319	10/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	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	ICSR	
EU-EC-1000787310	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	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 -), [AMODARONE 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 -)	ICSR	
EU-EC-1000787415	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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	ICSR	
EU-EC-1000787468	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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 (APIXIBAN)] (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])	ICSR	
EU-EC-1000787503	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Heat 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	ICSR	
EU-EC-1000787664	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	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 - [1d - n/a - 1(Df) - n/a])	XARELTO 15 MG (RIVAROXABAN) (C - Arterial 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])	ICSR	
EU-EC-10007877294	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	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])	Not reported	ICSR
EU-EC-10007877300	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-10007877313	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Unknown - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-10007877326	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Elderly	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Unknown - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-10007877327	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Unknown - [n/a - 1(Df) - Intramuscular])	[BETMIG (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]),	ICSR	

EU Local Number	EV Gateway Received Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Sex (as per report)	Parent Child Report	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)	ICSR Form	
											METOPROLOL SUCCINATE, METOPROLOL TARTRATE (C - Heart rate irregular - n/a - [i/a - 50mg - Oral]), PANTOPRAZOLE, PANTOPRAZOLE SODIUM (C - Gastroesophageal reflux disease - n/a - [i/a - 40mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [i/a - 1000mg - Oral]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - [i/a - 750mg - Oral]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [i/a - 1] [DF] - Oral), [VITAMIN D, CALCIUM] (C - Mineral supplementation - n/a - [i/a - n/a - Oral])		ICSR
EU-EC-1000757321	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Unknown - [i/a - 1] [DF] - Intramuscular)		ICSR	
EU-EC-1000757332	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Unknown - [i/a - 1] [DF] - Intramuscular)		ICSR	
EU-EC-1000757618	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - n/a])		ICSR	
EU-EC-1000755633	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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 - [i/a - 1] [DF] - Intramuscular)		ICSR	
EU-EC-1000755861	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - 1] [DF] - Intramuscular)	XARELTO (RIVAROXABAN) (C - n/a - n/a - [i/a - n/a - n/a])	ICSR	
EU-EC-1000755899	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - 1] [DF] - Intramuscular)		ICSR	
EU-EC-10007559165	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - 3mL - Intramuscular]), COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [i/a - 3mL - Intramuscular])	BUPRENORPHINE (BUPRENORPHINE) (C - n/a - n/a - [i/a - n/a - n/a]), MIDAZOLAM (MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE) (C - n/a - n/a - [i/a - n/a - n/a]), (ACETYL SALICYLIC ACID) (C - n/a - n/a - [i/a - n/a - n/a]), (CLOMETHAZOLE, CLOMETHAZOLE EDISILATE) (C - n/a - n/a - [i/a - n/a - n/a]), (DRIED FERROUS SULFATE, FERROUS SULFATE) (C - n/a - n/a - [i/a - n/a - n/a]), (FOLIC ACID) (C - n/a - n/a - [i/a - n/a - n/a]), (FUROSEMIDE, FUROSEMIDE SODIUM) (C - n/a - n/a - [i/a - n/a - n/a]), (GLYCEROL) (C - n/a - n/a - [i/a - n/a - n/a]), (GLYCOPYRROLONIUM BROMIDE, GLYCOPYRROLONIUM BROMIDE, NEOSTIGMINE METHYLSALFATE) (C - n/a - n/a - [i/a - n/a - n/a]), (HALOPERIDOL, HALOPERIDOL DECANOATE) (C - n/a - n/a - [i/a - n/a - n/a]), (MEMANTINE) (C - n/a - n/a - [i/a - n/a - n/a]), (METHANAMINE HIPPURATE) (C - n/a - n/a - [i/a - n/a - n/a]), (METOPROLOL, METOPROLOL TARTRATE) (C - n/a - n/a - [i/a - n/a - n/a]), (MIRTAZAPINE) (C - n/a - n/a - [i/a - n/a - n/a]), (MORPHINE, MORPHINE HYDROCHLORIDE) (C - n/a - n/a - [i/a - n/a - n/a]), (PARACETAMOL) (C - n/a - n/a - [i/a - n/a - n/a]), (ZOPICLONE) (C - n/a - n/a - [i/a - n/a - n/a])	ICSR	
EU-EC-1000756067	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [i/a - 3mL - Intramuscular])		ICSR	
EU-EC-1000756098	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [i/a - n/a - Intramuscular])	[LACTULOSE] (C - n/a - n/a - [i/a - n/a - n/a]), [RUFENONE] (C - n/a - n/a - [i/a - n/a - n/a])	ICSR	
EU-EC-10007561109	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Asthma (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 - [i/a - n/a - n/a])		ICSR	
EU-EC-1000754298	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [i/a - 3mL - Intramuscular])		ICSR	
EU-EC-1000754364	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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), Fibrotic infection (4d - Fatal - Results in Death, Life Threatening), Rhonchi (4d - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - Intramuscular])		ICSR	
EU-EC-1000754360	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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 - [i/a - n/a - Intramuscular])		ICSR	
EU-EC-1000754396	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - 1] [DF] - n/a), [NOT AVAILABLE] (S - Ilius - Dose not changed - [i/a - 1000mg - n/a]), [NOT AVAILABLE] (S - Ilius, Pneumonia - Dose increased - [i/a - 1] [DF] - n/a), [NOT AVAILABLE] (S - Palliative care - Dose not changed - [i/a - 10mg - n/a])		ICSR	
EU-EC-1000754384	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - 1] [DF] - n/a)	NOT AVAILABLE (C - n/a - n/a - [i/a - 10mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [i/a - 1] [DF] - n/a), NOT AVAILABLE (C - n/a - n/a - [i/a - 45mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [i/a - 500mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [i/a - 7.5mg - n/a]), [CARBIDOPA, LEVODOPA, LEVODOPA CARBIDOPA MONOHYDRATE] (C - n/a - n/a - [i/a - 1] [DF] - n/a), [CARBOMER] (C - n/a - n/a - [i/a - 1] [DF] - n/a), [THIAMINE HYDROCHLORIDE, DEXPANHENOL, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [i/a - 1] [DF] - n/a)	ICSR	
EU-EC-10007547320	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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 - [i/a - 3mL - n/a])	EXELON (RIVASTIGMINE) (C - n/a - n/a - [i/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [i/a - n/a - n/a]), [CARBOMER] (C - n/a - n/a - [i/a - 6mL - n/a]), [CASSIA, SENNA PODS] (C - n/a - n/a - [i/a - n/a - n/a]), [FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - n/a - n/a - [i/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE, ANHYDROUS AMLODIPINE HYDROCHLORIDE] (C - n/a - n/a - [i/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a -), [HALOPERIDOL, HALOPERIDOL BPI] (C - n/a - n/a - [i/a - n/a - n/a]), [HALOPERIDOL] (C - n/a - n/a - [i/a - n/a - n/a]), [LACTULOSE] (C - n/a - n/a -), [LANOPRAZOLE] (C - n/a - n/a - [i/a - n/a - n/a]), [MEMANTINE] (C - n/a - n/a - [i/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 - [i/a - n/a - n/a]), [SULFENACIN SUCCINATE] (C - n/a - n/a - [i/a - n/a - n/a]), [TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - [i/a - n/a - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - n/a - n/a -), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [i/a - n/a - n/a])	ICSR	
EU-EC-10007548481	08/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Asthma (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 - [i/a - 3mL - Intramuscular])	PANTOPRAZOLE - GASTRO-RESISTANT TABLET (C - n/a - n/a - [i/a - n/a - Oral]), [AMLODIPINE, AMLODIPINE BESILATE] (C - Hypertension - Not applicable - [i/a - n/a - Oral]), [PARACETAMOL, CAFFEINE, COCAINE PHOSPHATE] (C - Rheumatoid arthritis - Not applicable - [i/a - n/a - Oral]), [PREDNISOLONE] (C - Rheumatoid arthritis - Not applicable - [i/a - n/a - Oral])	ICSR	
EU-EC-10007551142	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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 - [i/a - n/a - n/a]), [ZINC] (C - n/a - n/a - [i/a - n/a - n/a])	ICSR	
EU-EC-1000754988	07/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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 - [i/a - n/a - n/a]), SITAGLIPTIN (SITAGLIPTIN) (C - Diabetes mellitus - n/a - [i/a - n/a - n/a]), (ACETYL SALICYLIC ACID) (C - Angina pectoris - n/a - [i/a - n/a - n/a]), [ATORVASTATIN] (C - Angina pectoris - n/a - [i/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Angina pectoris - n/a - [i/a - n/a - n/a]), [FELODIPINE] (C - Hypertension - n/a - [i/a - n/a - n/a]), [GLYCERYL TRINITRATE] (C - Angina pectoris - n/a - [i/a - n/a - n/a]), [LEVOHYDROXINE, LEVOHYDROXINE SODIUM] (C - Hypothyroidism - n/a - [i/a - n/a - n/a]), [PARACETAMOL] (C - Osteoarthritis - n/a - [i/a - n/a - n/a])	ICSR	
EU-EC-10007522843	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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 - [1d - n/a] - Intramuscular)		ICSR	
EU-EC-10007524454	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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 - [i/a - 1] [DF] - Intramuscular)		ICSR	
EU-EC-1000752668	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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 - [i/a - n/a - Intramuscular])		ICSR	
EU-EC-10007527303	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [i/a - n/a - Intramuscular])		ICSR	
EU-EC-10007527590	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [i/a - n/a - n/a])	BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE (C - n/a - n/a - [i/a - 2] [DF] - n/a), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [i/a - 1] [DF] - n/a), [CYANOCOBALAMIN] (C - n/a - n/a - [i/a - 1mg - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [i/a - 10mg - n/a]), [FOLIC ACID] (C - n/a - n/a - [i/a - 1mg - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [i/a - 50mg - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [i/a - 1] [DF] - n/a)	ICSR	
EU-EC-10007528481	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Asthma (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])		ICSR	
EU-EC-10007530163	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - n/a])		ICSR	
EU-EC-10007534113	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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 - [i/a - n/a - n/a])	CELLEPT (MYCOPHENOLATE MOFETIL) (C - Renal transplant - n/a - [i/a - 2g - n/a]), CICLOSPORIN (CICLOSPORIN) (C - Renal transplant - n/a - [i/a - 75mg - n/a]), NOT AVAILABLE (C - Aorta coarctation repair - n/a - [i/a - n/a - n/a]), VALSARTAN, SACUBITRIL (VALSARTAN, SACUBITRIL) (C - Hypertension - n/a - [i/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Hypertension - n/a - [i/a - 5mg - n/a]), [METHYLPREDNISOLONE, METHYLPREDNISOLONE SODIUM SUCCINATE] (C - Renal transplant - n/a - [i/a - 2mg - n/a]), [TORASEMIDE] (C - Cardiac failure - n/a - [i/a - 10mg - n/a])	ICSR	
EU-EC-10007534293	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - n/a - n/a])		ICSR	
EU-EC-10007519738	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - 1] [DF] - Intramuscular)		ICSR	
EU-EC-10007515751	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - 1] [DF] - Intramuscular)		ICSR	
EU-EC-10007519194	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - 1] [DF] - Intramuscular)	ABILIFY 10 MG TABLETS (ARIPRAZOLE) (C - n/a - n/a - [i/a - n/a - n/a]), [BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [i/a - n/a - n/a]), [HYDROXYCHLOROQUINE SULFATE] (C - n/a - n/a - [i/a - n/a - n/a]), [NICARDIPINE HYDROCHLORIDE] (C - n/a - n/a - [i/a - n/a - n/a]), [RAMPRIL] (C - n/a - n/a - [i/a - n/a - n/a])	ICSR	
EU-EC-10007516030	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - n/a])		ICSR	
EU-EC-10007516334	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - 1] [DF] - Intramuscular)		ICSR	
EU-EC-10007516485	04/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - Intramuscular])		ICSR	
EU-EC-10007518287	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - Intramuscular])		ICSR	
EU-EC-10007519820	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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 - [i/a - 3mL - Intramuscular])	(ACETYL SALICYLIC 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 -), [TIMAZEPINE DIHYDROCHLORIDE] (C - n/a - n/a -)	ICSR	
EU-EC-10007502904	03/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - n/a - n/a])		ICSR	
EU-EC-10007505560	03/02/2021	Non Healthcare	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	Anxiety (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 - [i/a - n/a - n/a]),	ICSR		

EU Local Number	EV Gateway Record Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Sex (as per report)	Parent Child Report	Reaction List PT (Duration 7 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)	ICSR Form
											<p>FUROSEMIDE, FUROSEMIDE SODIUM (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[LACTULOSE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>MICRONNE HYDROCHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>PARACETAMOL (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>POTASSIUM CHLORIDE (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>PROPYLENE GLYCOL (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>SODIUM PICOSULFATE (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[CHLORHEXIDINE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[DILTALPRAM] (C - n/a - n/a - [n/a - 10mg - n/a]).</p> <p>[LACTULOSE, LIQUID] (C - n/a - n/a - [n/a - 20mL - n/a]).</p> <p>[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 50ug - n/a]).</p> <p>MEMANTINE HYDROCHLORIDE (C - n/a - n/a - [n/a - 20mg - n/a]).</p> <p>[OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[RISPERIDONE] (C - n/a - n/a - [n/a - 25mg - n/a]).</p> <p>[SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL (E402), SODIUM LAURYL SULFOACETATE, SODIUM CITRATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - Rectal]).</p> <p>[SODIUM FLUORIDE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[TIMOLOL, PLOCARPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Ophthalmic]).</p> <p>[TIMOLOL] (C - n/a - n/a - [n/a - n/a - n/a]).</p>	ICSR
EU-EC-10007467481	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007470767	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Death (05 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])		ICSR
EU-EC-10007471240	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007451396	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007452321	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007452952	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007456951	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (74 - Fatal - Results in Death, Other Medically Important Condition), Influenza like illness (74 - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Propylthiouracil - n/a - [n/a - n/a - Unknown])		ICSR
EU-EC-10007458677	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	<p>FIASP (INSULIN ASPART) (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>TRESIBA (INSULIN DEGLUDEC) (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[ATENOLOL, ATENOLOL BP] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[DONEPEZIL] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[LOPERAMIDE HYDROCHLORIDE, LOPERAMIDE OXIDE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[THIAMINE, PYRIDOXINE HYDROCHLORIDE, VITAMIN B] (C - n/a - n/a - [n/a - n/a - n/a]).</p>	ICSR
EU-EC-10007440863	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007440868	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	<p>[AMIODARONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 200mg - Oral]).</p> <p>[BISOPROLOL, FUMARATE] (C - n/a - n/a - [n/a - 1.25mg - Oral]).</p> <p>[FLUNDISON] (C - n/a - n/a - [n/a - n/a - Oral]).</p> <p>[FLUTICASON PROPIONATE, SALMETEROL, FLUTICASON PROPIONATE, SALMETEROL XINAFOATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)]).</p> <p>[FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - Oral]).</p> <p>[LATANOPROST] (C - n/a - n/a - [n/a - n/a - Ophthalmic]).</p> <p>[MORPHINE SULFATE] (C - n/a - n/a - [n/a - n/a - Oral]).</p> <p>[OXAZEPAM] (C - n/a - n/a - [n/a - n/a - Oral]).</p>	ICSR
EU-EC-10007441212	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Increased bronchial secretion (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular]), [PENTANYL] (S - Pain - Dose not changed - [n/a - 0.12mg - Transdermal])	<p>[ALPRAZOLAM] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]).</p>	ICSR
EU-EC-10007444683	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	<p>[STERILIA, STERILIA GUM, STERILIA URENS ROXB, GUM] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[LIXIANA, LIXIANA, EDOXABAN, EDOXABAN TOPOLATE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[COLCALCIFEROL] (C - n/a - n/a - n/a).</p> <p>[FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[ZOLPIDEM, ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[CLOPIDOGREL, CLOPIDOGREL, CLOPIDOGREL, BESILATE] (C - n/a - n/a - [n/a - 75mg - n/a]).</p>	ICSR
EU-EC-10007444684	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	<p>[LORAZEPAM] (C - n/a - n/a - [n/a - 2.5mg - n/a]).</p> <p>[TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 50mg - n/a]).</p>	ICSR
EU-EC-10007444685	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (05 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	<p>[QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - 12.5mg - n/a]).</p> <p>FENTANYL, FENTANYL, FENTANYL CITRATE (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>PANTOPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE (C - n/a - n/a - [n/a - n/a - Unknown]).</p> <p>[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - Unknown]).</p> <p>[CALCIUM CITRATE, MAIZE STARCH, STEARIC ACID, TALC, CALCIUM CITRATE] (C - n/a - n/a - [n/a - n/a - Unknown]).</p> <p>[COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - Unknown]).</p> <p>[ENOXAPARIN SODIUM] (C - n/a - n/a - [n/a - n/a - Unknown]).</p> <p>[FOLIC ACID, DRIED FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - Unknown]).</p> <p>[FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - Unknown]).</p> <p>[ROSUVASITIN, CALCIUM] (C - n/a - n/a - [n/a - n/a - Unknown]).</p> <p>[SPRONOLACTONE] (C - n/a - n/a - [n/a - n/a - Unknown]).</p>	ICSR
EU-EC-10007445203	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007445211	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Subcutaneous])		ICSR
EU-EC-10007445410	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (54 - Fatal - Results in Death), General physical condition abnormal (54 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])		ICSR
EU-EC-10007446819	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007446863	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	<p>[ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[RAMPRIL] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]).</p>	ICSR
EU-EC-10007446873	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007446887	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	<p>[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[FINASTERIDE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[OXYCODONE, OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]).</p>	ICSR
EU-EC-10007431088	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (14 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - Intramuscular])	<p>JANUVA 100 MG FILM-COATED TABLETS [BITAGLIPITIN] (C - n/a - n/a - [n/a - n/a - Oral]).</p> <p>MMPARA 30 MG FILM-COATED TABLETS [CINACLET, CINACLET HYDROCHLORIDE] (C - n/a - n/a - [n/a - 30mg - Oral]).</p> <p>[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]).</p> <p>[ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a - [n/a - 20mg - Oral]).</p> <p>[BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral]).</p> <p>[DEAMETHASONE SODIUM PHOSPHATE] (C - n/a - n/a - [n/a - 6mg - Oral]).</p> <p>[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 - 559g - Oral]).</p> <p>[ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 5mg - Oral]).</p> <p>[OXAZEPAM] (C - n/a - n/a - [n/a - n/a - Oral]).</p> <p>[PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]).</p> <p>[TRIZAPARIN, TRIZAPARIN SODIUM] (C - Atrial fibrillation - n/a - [n/a - 7mL - Subcutaneous])</p>	ICSR
EU-EC-10007431167	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007431177	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007431178	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - Intramuscular])		ICSR
EU-EC-10007431600	26/01/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	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])	<p>[BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]).</p> <p>[LOPERAMIDE, LOPERAMIDE HYDROCHLORIDE] (C - Diarrhoea - n/a - [n/a - n/a - n/a]).</p> <p>[OMEPRAZOLE] (C - Reflux gastritis - n/a - [n/a - n/a - n/a]).</p> <p>[SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]).</p>	ICSR
EU-EC-10007431613	26/01/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	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])	<p>RIVASTIGMINE [RIVASTIGMINE, RIVASTIGMINE HYDROGEN TARTRATE] (C - Parkinson's disease - n/a - [n/a - n/a - n/a])</p>	ICSR
EU-EC-10007433053	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007433980	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	<p>[DORZOLAMIDE, TIMOLOL] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 25ug - n/a]).</p> <p>[PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a]).</p> <p>[SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[UREA] (C - n/a - n/a - [n/a - n/a - n/a]).</p>	ICSR
EU-EC-10007436275	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (05 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		ICSR
EU-EC-10007424270	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Agitation (04 - Fatal - Results in Death), Death (05 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - n/a])		ICSR
EU-EC-10007423215	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007423313	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007423721	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Elderly	Not Specified	Male	Death (04 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])		ICSR
EU-EC-10007423825	25/01/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	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])		ICSR
EU-EC-10007427948	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	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])	<p>ADENURIC 80 MG FILM-COATED TABLETS [FEBUXOSTAT] (C - n/a - n/a - [n/a - 1[DF] - n/a]).</p> <p>NOT AVAILABLE (C - n/a - n/a - [n/a - 1[DF] - n/a]).</p> <p>NOVOMIX 30 PENFILL [INSULIN ASPART, INSULIN ASPART, INSULIN ASPART PROTAMINE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[AMLODIPINE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - 5[DF] - n/a]).</p> <p>[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]).</p> <p>[CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 1[DF] - n/a]).</p> <p>[CLOPIDOGREL] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[D-LIMONENE] (C - n/a - n/a - [n/a - n/a - n/a]).</p> <p>[HYDROCHLOROTHIAZIDE, CANDESARTAN CILEXETIL] (C - n/a - n/a - [n/a - 1[DF] - n/a]).</p>	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Country for Regulatory Purposes	Primary Source Country for Regulatory Purposes	Literature Reference	Patent Age Group (as per report)	Patent Age Group (as per report)	Patent Sex	Parent Child Report	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)	ICSR Form
												HYDROXYZINE HYDROCHLORIDE, HYDROXYZINE HYDROCHLORIDE (C - n/a - n/a - [i/a - 1(Df)] - n/a), HYDROXYZINE (C - n/a - n/a - [i/a - 1(Df)] - n/a), LIQUID PARAFIN (C - n/a - n/a - [i/a - n/a - n/a]), MELALEUCA ALTERNIFOLIA OIL (C - n/a - n/a - [i/a - n/a - n/a]), METHYLPREDNISOLONE, METHYLPREDNISOLONE ACETATE, METHYLPREDNISOLONE SODIUM HEMISUCCINATE (C - Ecema - n/a - [i/a - 5(Df)] - n/a), PANTOPRAZOLE, PANTOPRAZOLE SODIUM (C - n/a - n/a - [i/a - 1(Df)] - n/a), SOYA BEAN OIL REFINED PLEUR., SOYA OIL, SOYA BEAN OIL REFINED (C - n/a - n/a - [i/a - n/a - n/a]), VASELINE (C - n/a - n/a - [i/a - n/a - n/a])	
EU-EC-1000740306	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), No adverse event (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - Intramuscular])		ICSR
EU-EC-1000740304	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000740318	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000740346	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - Intramuscular])	NOT AVAILABLE (C - n/a - n/a - [i/a - n/a - n/a]), RIVAROXABAN (RIVAROXABAN) (C - n/a - n/a - [i/a - n/a - n/a]), SITAGLIPTIN (SITAGLIPTIN) (C - n/a - n/a - [i/a - n/a - n/a]), DIGITOXIN (C - n/a - n/a - [i/a - n/a - n/a]), FOLIC ACID (C - n/a - n/a - [i/a - n/a - n/a]), LORAZEPAM (C - n/a - n/a - [i/a - n/a - n/a]), METAMIZOLE, METAMIZOLE MAGNESIUM, METAMIZOLE SODIUM (C - n/a - n/a - [i/a - n/a - n/a]), METOPROLOL, METOPROLOL TARTRATE (C - n/a - n/a - [i/a - n/a - n/a]), MIRTAZAPINE (C - n/a - n/a - [i/a - n/a - n/a]), TORASEMIDE (C - n/a - n/a - [i/a - n/a - n/a])	ICSR
EU-EC-1000740362	22/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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	ICSR
EU-EC-1000740374	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not Specified	No	Death (05 - Fatal - Results in Death), Decreased appetite (04 - Fatal - Results in Death), Diet refusal (04 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000740421	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - 1(Df)] - Intramuscular)	Not reported	ICSR
EU-EC-1000740426	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Drug withdrawn - [i/a - 1(Df)] - Intramuscular)	Not reported	ICSR
EU-EC-1000740454	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (04 - Fatal - Results in Death), Nausea (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000741012	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (05 - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - 1(Df)] - Intramuscular)	Not reported	ICSR
EU-EC-1000741058	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [i/a - n/a - Intramuscular])	[BUPRENORPHINE] (C - Pain - n/a - [i/a - 1(Df)] - Cutaneous), [CARBOMER, CARBOMER 980] (C - Dry eye - n/a - [i/a - n/a - Ophthalmic]), [LACTULOSE] (C - Constipation - n/a - [i/a - 20mL - Oral]), [PARACETAMOL] (C - Pain - n/a - [i/a - 1g - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Restlessness - n/a - [i/a - 25mg - Oral]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [i/a - 20(Df)] - Oral), [VITAMIN D] (C - n/a - n/a - [i/a - 40ug - n/a])	ICSR
EU-EC-1000741142	22/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [i/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000741143	22/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	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 - [i/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000741143	22/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (03 - Unknown - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [i/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000738048	20/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Axialgia (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	ICSR
EU-EC-1000738958	20/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007374218	19/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000737596	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000737624	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [i/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007376516	19/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Hypertension (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 - [i/a - n/a - n/a]), MELATONIN (MELATONIN) (C - n/a - n/a - [i/a - n/a - n/a]), [ACETYL SALICYLIC ACID] (C - n/a - n/a - [i/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [i/a - n/a - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [i/a - n/a - n/a]), [CASSIA] (C - n/a - n/a - [i/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [i/a - n/a - n/a]), [DIMETICONE] (C - n/a - n/a - [i/a - n/a - n/a]), [DOCUSATE SODIUM] (C - n/a - n/a - [i/a - n/a - n/a]), [DOXYCYCLINE HYCLATE] (C - n/a - n/a - [i/a - n/a - n/a]), [SODIUM BICARBONATE] (C - n/a - n/a - [i/a - n/a - n/a]), [MACROGOL 3350] (C - n/a - n/a - [i/a - n/a - n/a]), [PARACETAMOL, CODEINE PHOSPHATE] (C - n/a - n/a - [i/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [i/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [i/a - n/a - n/a]), [TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [i/a - n/a - n/a]), [TRAMACETIN] (C - n/a - n/a - [i/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [i/a - 40mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [i/a - 20mg - n/a]), [LEVOTHYRAXINE, LEVOTHYRAXINE SODIUM] (C - n/a - n/a - [i/a - 75ug - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [i/a - 100mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [i/a - 5mg - n/a]), [RAMPREL] (C - n/a - n/a - [i/a - n/a - n/a]), [WARFARIN SODIUM] (C - n/a - n/a - [i/a - n/a - n/a])	ICSR
EU-EC-10007364887	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007367303	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - n/a - [i/a - 30ug - Intramuscular])	AERUS 5 MG FILM-COATED TABLET (DESORATADINE) (C - n/a - n/a - [i/a - 5mg - n/a]), ARANE SP 30 MICROGRAMS SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE (DARBEPOETIN ALFA) (C - n/a - n/a - [i/a - 1(Df)] - n/a), [ACETYLCYSTEINE] (C - n/a - n/a - [i/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - n/a - [i/a - 100mg - n/a]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [i/a - n/a - n/a]), [CARBOMER] (C - n/a - n/a - [i/a - n/a - n/a]), [DILTIAZEM SODIUM] (C - n/a - n/a - [i/a - 1(Df)] - n/a), [FINASTERIDE] (C - n/a - n/a - [i/a - 5mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [i/a - 250mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [i/a - n/a - n/a]), [GLYCEROL] (C - n/a - n/a - [i/a - n/a - n/a]), [GLYCERYL TRINITRATE, GLYCERYL TRINITRATE SOLUTION 10 %] (C - n/a - n/a - [i/a - n/a - n/a]), [GLYCOPYRROLONIUM BROMIDE] (C - n/a - n/a - [i/a - 1mL - n/a]), [HALOPERIDOL] (C - n/a - n/a - [i/a - n/a - n/a]), [HYDROXYMETHYLCELLULOSE] (C - n/a - n/a - [i/a - n/a - n/a]), [LATANOPROST] (C - n/a - n/a - [i/a - n/a - n/a]), [MIDAZOLAM HYDROCHLORIDE] (C - n/a - n/a - [i/a - n/a - n/a]), [MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [i/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [i/a - 10mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [i/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [i/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 - [i/a - n/a - n/a]), [SODIUM PICOSULFATE, SODIUM PICOSULFATE] (C - n/a - n/a - [i/a - n/a - n/a]), [SODIUM POLYSTYRENE SULPHONATE] (C - n/a - n/a - [i/a - n/a - n/a])	ICSR
EU-EC-1000736293	17/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [i/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - n/a -), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a -), [HYDROCHLOROTHIAZIDE, LISINAPRIL, HYDROCHLOROTHIAZIDE, LISINAPRIL ANHYDRUS, LISINAPRIL DIHYDRATE, HYDROCHLOROTHIAZIDE] (C - n/a - n/a -), [LEVOTHYRAXINE, LEVOTHYRAXINE SODIUM] (C - n/a - n/a -), [PARACETAMOL, CODEINE PHOSPHATE HEMIHYDRATE] (C - n/a - n/a -), [ZOPICLONE] (C - n/a - n/a -)	ICSR
EU-EC-1000736292	11/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [i/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007367481	15/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	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 - [i/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007361020	15/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - 1(Df)] - Intramuscular)	Not reported	ICSR
EU-EC-10007346524	14/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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	ICSR
EU-EC-10007346083	13/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007347342	13/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [i/a - 1(Df)] - Intramuscular)	ELIQUIS (APIXIBAN) (C - Thrombosis prophylaxis - n/a - [i/a - 5mg - Oral]), [ATORVASTATIN] (C - Cardiovascular event prophylaxis - n/a - [i/a - 80mg - Oral]), [DONEPEZIL HYDROCHLORIDE] (C - Dementia - n/a - [i/a - 10mg - Oral]), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Heart rate irregular - n/a - [i/a - 25mg - Oral]), [RISPERIDONE] (C - Aggression - n/a - [i/a - 25mg - Oral]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [i/a - 50mg - Oral]), [TAMUSLOSIN HYDROCHLORIDE] (C - Dysuria - n/a - [i/a - 4mg - Oral])	ICSR
EU-EC-1000733363	12/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY (TOZINAMERAN) (S - Prophylaxis - n/a - [i/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000733335	12/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	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 - [i/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000733936	12/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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	ICSR
EU-EC-10007318464	08/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [i/a - n/a - Intramuscular])	[CARVEDILOL] (C - n/a - n/a - [i/a - 25mg - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [i/a - 20mg - n/a]), [COLECALCIFEROL, CALCIUM COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [i/a - 1(Df)] - n/a), [FUROSEMIDE] (C - n/a - n/a - [i/a - n/a - n/a]), [LEVOTHYRAXINE, LEVOTHYRAXINE SODIUM] (C - n/a - n/a - [i/a - 100ug - n/a]), [PARACETAMOL] (C - n/a - n/a - [i/a - 1000mg - n/a]), [UREA] (C - n/a - n/a - [i/a - n/a - n/a]), [WARFARIN SODIUM] (C - n/a - n/a - [i/a - n/a - n/a])	ICSR
EU-EC-10007313051	07/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death)	COMIRNATY (TOZINAMERAN) (S - Immunisation - n/a - [i/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007307981	06/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	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 - [i/a - n/a - n/a])	BETMIG (BIRABEGRON) (C - n/a - Not applicable - [i/a - n/a - n/a]), NOT AVAILABLE (C - n/a - Not applicable - [i/a - n/a - n/a]), NOT AVAILABLE (C - n/a - Not applicable - [i/a - n/a - n/a])	ICSR

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per report)	Patient Sex	Patient Child Report	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])	ICSR Form
												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]), [COLCALCIFEROL, CYANOCOBALAMIN, EROGICALCIFEROL, RETINOL ACETATE, EROGICALCIFEROL, 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 HEMHYDRATE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [FDIC 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, QUIETAPINE 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	06/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Adult	Male	No	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	ICSR
EU-EC-10007298416	05/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007291936	04/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Male	No	Death (D - Fatal - Results in Death, Other Medically Important Condition), Influenza like illness (D - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007292008	04/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	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	ICSR
EU-EC-10007293100	04/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	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	ICSR