

Line Listing Report

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EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Country for Regulatory Purposes	Primary Source Country for Regulatory Purposes	Literature Reference	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		
EU-EC-1000827489	12/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Asthma (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-1000827647	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	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-1000827654	12/04/2021	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])	[BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Hypertension - n/a - [n/a - 1.25mg - Oral - More in ICSR]), [BUPRENORPHINE] (C - Back pain - n/a - [n/a - n/a - Transdermal]), [CALCITONIN (SALMON)] (C - n/a - n/a -), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - Hypertension - n/a - [500d - n/a - Oral]), [PARACETAMOL, PARACETAMOL ASPARTAME] (C - Pain - n/a - [n/a - 1g - Oral]), [QUETIAPINE] (C - n/a - n/a - [n/a - Oral]), [SODIUM FOSFALFATE] (C - n/a - n/a -)	ICSR	
EU-EC-1000827684	12/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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-1000827901	12/04/2021	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 - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-1000827927	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	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-1000827928	12/04/2021	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), 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-1000827966	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	Female	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-1000828020	12/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 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])	Not reported	ICSR	
EU-EC-1000828238	12/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	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-1000828238	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	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-1000828310	12/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	Female	No	Asthma (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-1000828399	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	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), Sepsis (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]), JANUJIA [SITAGLIPTIN, SITAGLIPTIN PHOSPHATE, SITAGLIPTIN PHOSPHATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), TRESIBA [INSULIN DEGLUCIDE] (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-1000829031	09/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Female	No	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-1000829033	09/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	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-1000829064	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	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), Mebisib (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]), [ITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Depressed mood - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-1000829110	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Caused Prolonged Hospitalisation), Immunisation 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-1000829138	09/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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-1000829793	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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 - 1000mg - Oral]), [CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Depression - n/a - [n/a - 10mg - Oral]), [DIGOXIN] (C - Cardiac failure - n/a - [n/a - 250ug - Oral]), [DONEPEZIL HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 10mg - Oral]), [LORAZEPAM] (C - Anxiety, Restlessness - n/a - [1240min - 5mg - Oral]), [MEMANTINE HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 20mg - Oral]), [MORPHINE SULFATE] (C - Dyspnoea, Pain - n/a - [1235min - 25ml - Oral]), [PARACETAMOL] (C - Arthralgia - n/a - [n/a - 500mg - n/a]), [PARACETAMOL] (C - Arthritis - n/a - [n/a - 650mg - Oral]), [AMOXICILIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 100mg - Oral]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 20mg - Oral]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 1800IU] - Oral), [FERROUS SULFATE] (C - n/a - n/a - [n/a - 600mg - Oral]), [FLUTICASON, SALMETEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - n/a - n/a - [n/a - 100mg - Oral]), [NEBIVOLOL] (C - n/a - n/a - [n/a - 2.5mg - Oral]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 80mg - Oral]), [PARACETAMOL] (C - Pain, Pyrexia - n/a - [n/a - 1000mg - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Wheezing - n/a - [n/a - 200ug - Nasal]), [SODIUM HYDROGEN CARBONATE] (C - n/a - n/a - [n/a - 3000mg - Oral]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 75mg - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - 3.75mg - Oral])	ICSR	
EU-EC-1000828133	08/04/2021	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), 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 - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-1000828539	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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-1000828540	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	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-1000828541	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 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-1000828545	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	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-1000828549	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Female	No	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-1000828550	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	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-1000828551	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	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-1000828554	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	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-1000828560	08/04/2021	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 - Intramuscular])	Not reported	ICSR	
EU-EC-1000828963	08/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Elderly	Male	No	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-1000824180	08/04/2021	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 reported	ICSR	
EU-EC-1000824184	08/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Not Specified	No	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-1000824247	08/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 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-1000824357	08/04/2021	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])	ENTRESTO 24 MG/28 MG FILM-COATED TABLETS [VALSARTAN, SACUBITRIL] (C - Cardiomopathy - Not applicable - [n/a - n/a - n/a]), LISIANA 15 MG FILM-COATED TABLETS [EDOXABAN] (C - Atrial fibrillation - Not applicable - [n/a - n/a - n/a]), NOT AVAILABLE (C - Atrial fibrillation, Cardiomopathy - Not applicable - [n/a - n/a - n/a]), [DIGOXIN] (C - Atrial fibrillation - Not applicable - [n/a - n/a - n/a]), [EPLEBRENEM] (C - Cardiomopathy - Not applicable - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - Not applicable - [n/a - n/a - n/a]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYSALICYLIC ACID] (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-1000824374	08/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Blood pressure fluctuation (n/a - Not Recovered/Not Resolved - Caused Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), 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), Muscular weakness (n/a - Unknown - Caused Prolonged Hospitalisation), Pneumonitis (n/a - Not Recovered/Not Resolved - Caused Prolonged Hospitalisation), Pulmonary oedema (n/a - Not Recovered/Not Resolved - Caused Prolonged Hospitalisation), Pulmonary thrombosis (n/a - Unknown - Caused Prolonged Hospitalisation), Pulse abnormal (n/a - Unknown - Caused Prolonged Hospitalisation), Vaccination complication (n/a - Unknown - Caused Prolonged Hospitalisation)	FIRDAPE [AMFAMPRIDINE] (S - Myasthenic syndrome - Unknown - [n/a - 30mg - Oral - More in ICSR]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-1000821633	07/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthma (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 laceration (n/a - Unknown - Caused Prolonged Hospitalisation), Wheezing (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-1000821659	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Male	No	COVID-19 (n/a - Fatal - Results in Death, Life Threatening, Caused Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Life Threatening, Caused Prolonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Fatal - Results in Death, Life Threatening, Caused Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - 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-1000821870	07/04/2021	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 - n/a - n/a - [n/a - 3mL - Intramuscular])	HYDROCORTISONE HYDROCORTISONE, HYDROCORTISONE SODIUM SUCCINATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OLEMASTINE, OLEMASTINE FUMARATE] (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]), [ESCOPRAZOLE MAGNESIUM DIBYDRATE] (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 FUROATE, MOMETASONE FUROATE 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]), [PROPIONAZINE, PROPIONAZINE MALEATE] (C - n/a - n/a - [n/a - 50mg - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - 10mg - n/a])	Not reported	ICSR
EU-EC-1000821923	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Elderly	Male	No	Cerebral ischaemia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - Intramuscular])	JARDANCE 25 MG FILM-COATED TABLETS [EMPAGLIZIN] (C - n/a - n/a - [n/a - 1(Df) - n/a]), VELMETIA 50 MG/1000 MG FILM-COATED TABLETS [METFORMIN HYDROCHLORIDE, SITAGLIPTIN PHOSPHATE MONOHYDRATE] (C - n/a - n/a - [n/a - 2(Df) - 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 Sex (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)	CSR Form
EU-EC-1000821990	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)	COMRNATY [TOZINAMERAN] (S - n/a - n/a - [i/a - n/a - Intramuscular])	[ACETYSALICYLIC ACID] (C - n/a - Dose not changed -), [CYANOCOBALAMIN, THIAMINE DISULFIDE, CYANOCOBALAMIN, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [i/a - 2(D)F - n/a]), [GALICLAZIDE] (C - n/a - n/a - [i/a - 1(D)F - n/a]), [RAMIPRIL] (C - n/a - n/a - [i/a - 1(D)F - n/a]), [SIMVASTATIN] (C - n/a - n/a - [i/a - 1(D)F - n/a]), [TAMOXIFEN] (C - n/a - n/a - [i/a - 1(D)F - n/a]), [ACETYSALICYLIC ACID] (C - n/a - n/a - [i/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [i/a - n/a - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (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]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [i/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [i/a - n/a - n/a]), [SPRIMOCTACTONE] (C - n/a - n/a - [i/a - n/a - n/a])	CSR
EU-EC-1000822085	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - CausedProlonged Hospitalisation), Death (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Dyspnoea (n/a - Unknown - CausedProlonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [i/a - n/a - n/a])	Not reported	CSR
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)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [i/a - 1(D)F - n/a])	NOT AVAILABLE (C - n/a - n/a - [i/a - 1mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [i/a - 1(D)F - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [i/a - 1(D)F - n/a]), [FLUTICASON PROPIONATE, SALMETEROL] (C - n/a - n/a - [i/a - 1(D)F - n/a]), [PRATROPUM BROMIDE] (C - n/a - n/a - [i/a - 1(D)F - n/a]), [TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [i/a - 4mg - n/a])	CSR
EU-EC-1000822181	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 -)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [i/a - 1(D)F - n/a])	NOT AVAILABLE (C - n/a - n/a - [i/a - n/a]), PANTOPRAZOLE 20 MG - GASTRO-RESISTANT TABLET (C - n/a - n/a - [i/a - n/a - n/a])	CSR
EU-EC-1000822054	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 -)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [i/a - 1(D)F - n/a])	NOT AVAILABLE (C - n/a - n/a - [i/a - n/a]), [BARNIDIPINE] (C - n/a - n/a - [i/a - n/a - n/a])	CSR
EU-EC-1000822694	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), Fatigue (n/a - Fatal - Results in Death)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [i/a - 1(D)F - n/a])	XEPLON [PALIPERIDONE PALMATE] (C - n/a - n/a - [i/a - n/a - n/a])	CSR
EU-EC-1000822828	07/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Malaise (n/a - Fatal - Results in Death)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [i/a - 1(D)F - n/a])	NOT AVAILABLE (C - n/a - n/a - [i/a - n/a - n/a])	CSR
EU-EC-1000820591	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)	COMRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [i/a - n/a - Intramuscular])	NOT REPORTED 100 E.M.L. CLOSING VOOR INJECTIE IN FLACON [INSULIN ASPART] (C - n/a - n/a - [i/a - n/a - n/a])	CSR
EU-EC-1000820584	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)	COMRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [i/a - n/a - Intramuscular])	Not reported	CSR
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)	COMRNATY [TOZINAMERAN] (S - Immunisation - n/a - [i/a - n/a - n/a])	Not reported	CSR
EU-EC-1000821064	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)	COMRNATY [TOZINAMERAN] (S - Immunisation - n/a - [i/a - n/a - Intramuscular])	PRADAXA [DABIGATRAN ETEXILATE, DABIGATRAN ETEXILATE MESILATE] (C - Cardiovascular accident prophylaxis - n/a - [i/a - 110mg - Oral]), [BUMETANIDE] (C - Diuretic therapy - n/a - [i/a - 1mg - Oral]), [CYANOCOBALAMIN, HYDROXYCOBALAMIN] (C - Vitamin supplementation - n/a - [i/a - 1mg - Oral]), [FERROUS CHLORIDE TETRAHYDRATE, FERROUS ION] (C - n/a - n/a - [i/a - 9mg - Oral]), [PARACETAMOL, PARACETAMOL ASPARTAME] (C - Pain - n/a - [i/a - 1g - Oral]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [i/a - 1(D)F - Oral]), [QUETIAPINE] (C - Frontotemporal dementia - n/a - [i/a - 50mg - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Dyspnoea - n/a - [i/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 -), [LEVOTHYROIDINE, LEVOTHYROIDINE 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 -), [LITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [i/a - 40mg - n/a]), [LEVOTHYROIDINE, LEVOTHYROIDINE SODIUM] (C - n/a - n/a - [i/a - 05mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [i/a - 05mg - n/a])	CSR
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)	COMRNATY [TOZINAMERAN] (S - Immunisation - n/a - [i/a - n/a - Intramuscular])	NOT AVAILABLE (C - n/a - n/a - [i/a - 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 -), [LEVOTHYROIDINE, LEVOTHYROIDINE 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 -)	CSR
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 Sequelae - CausedProlonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Seizure (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Thalamic infarction (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), White matter lesion (n/a - Recovered/Resolved With Sequelae - CausedProlonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [i/a - n/a - n/a])	[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a -)	CSR
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)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [i/a - n/a - n/a])	Not reported	CSR
EU-EC-1000819369	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Brain ischaemia (n/a - Fatal - Results in Death), 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	CSR
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 - [i/a - n/a - n/a])	Not reported	CSR
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, CausedProlonged Hospitalisation), Death (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), General physical health deterioration (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Hepatic enzyme increased (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Infection (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation)	COMRNATY [TOZINAMERAN] (S - n/a - n/a - [i/a - n/a - n/a])	BRILIQUE [ICAGRELOR] (C - n/a - n/a - [i/a - 90mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [i/a - 80mg - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [i/a - 50mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [i/a - n/a - n/a])	CSR
EU-EC-1000819501	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, CausedProlonged Hospitalisation), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Ptyxia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ATORVASTATIN] (C - Hypercholesterolemia - n/a - [i/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM CARBONATE] (C - Osteopenia - n/a - [i/a - n/a - n/a]), [OMEPRAZOLE] (C - Dyspepsia - n/a - [i/a - n/a - n/a]), [RAMIPRIL] (C - Hypertension - n/a - [i/a - n/a - n/a])	CSR
EU-EC-1000819795	05/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Myelodysplastic syndrome (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	AZACTINE [AZACITIDINE] (C - Myelodysplastic syndrome - n/a - [i/a - n/a - n/a]), [ERYTHRODIETIN] (C - Myelodysplastic syndrome - n/a - [i/a - n/a - n/a]), [OMEPRAZOLE] (C - Dyspepsia - n/a - [i/a - n/a - n/a]), [SOLFENACIN] (C - Hypertonic bladder - n/a - [i/a - n/a - n/a]), [TRANEXAMIC ACID] (C - Thrombocytosis - n/a - [i/a - n/a - n/a])	CSR
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 - [i/a - n/a - n/a])	[VANCOMYCIN, VANCOMYCIN HYDROCHLORIDE] (C - C-reactive protein increased - n/a - [43d - n/a - n/a])	CSR
EU-EC-1000820172	05/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Pulmonary embolism (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Thrombosis (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [i/a - 1(D)F - n/a])	[ACENOCUMAROL] (C - n/a - n/a - [i/a - n/a - n/a])	CSR
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)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [i/a - 3mL - Intramuscular])	[ROSVUASTATIN, ROSUVASTATIN CALCIUM] (C - Dyslipidemia - n/a - [i/a - 1(D)F - Oral])	CSR
EU-EC-1000817643	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)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [i/a - 1(D)F - Intramuscular])	Not reported	CSR
EU-EC-1000817604	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)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [i/a - 1(D)F - Intramuscular])	Not reported	CSR
EU-EC-1000816835	02/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Acute coronary syndrome (1d - Fatal - Results in Death), Death (1d - Fatal - Results in Death)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [i/a - 3mL - Intramuscular])	Not reported	CSR
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)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [i/a - 1(D)F - Intramuscular])	Not reported	CSR
EU-EC-10008170950	02/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [i/a - 1(D)F - Intramuscular])	Not reported	CSR
EU-EC-10008171161	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)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [i/a - 1(D)F - Intramuscular])	Not reported	CSR
EU-EC-10008171827	02/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Aerococcus urinae infection (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Hyperthermia (n/a - Fatal - Results in Death), Ptyxia (n/a - Fatal - Results in Death), Urosepsis (n/a - Fatal - Results in Death)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [FOSFOMYCIN] (S - n/a - Unknown - [i/a - n/a - n/a])	Not reported	CSR
EU-EC-1000817488	02/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [i/a - n/a - Intramuscular])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [i/a - n/a - n/a]), [BUDESONIDE, FORMOTEROL, FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - n/a - n/a - [i/a - n/a - n/a]), [MONTELUKAST SODIUM] (C - n/a - n/a - [i/a - 10mg - n/a]), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - n/a - n/a - [i/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [i/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [i/a - n/a - n/a]), [ZOLPIDEM TARTRATE] (C - n/a - n/a - [i/a - 10mg - n/a])	CSR
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)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [i/a - 3mL - Intramuscular])	Not reported	CSR
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)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [i/a - n/a - n/a])	Not reported	CSR
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)	COMRNATY [TOZINAMERAN] (S - n/a - n/a - [i/a - 3mL - Intramuscular])	[AMLODIPINE] (C - n/a - n/a - [i/a - 10mg - n/a]), [ATENOLOL] (C - n/a - n/a - [i/a - 50mg - n/a]), [DESLORATADINE] (C - n/a - n/a - [i/a - 5mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [i/a - 1000mg - n/a]), [ZOPICLONE] (C - n/a - n/a - [i/a - 5mg - n/a])	CSR
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)	COMRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [i/a - 1(D)F - n/a])	ALISKIREN 300MG TABLET (C - n/a - n/a - [i/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [i/a - n/a - n/a])	CSR
EU-EC-10008163884	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)	COMRNATY [TOZINAMERAN] (S - Immunisation - n/a - [i/a - n/a - n/a])	Not reported	CSR
EU-EC-10008165922	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)	COMRNATY [TOZINAMERAN] (S - n/a - n/a - [i/a - n/a - n/a])	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [i/a - 75mg - n/a]), [ALLOPURINOL] (C - n/a - n/a - [i/a - 100mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [i/a - 40mg - n/a]), [BUDESONIDE, FORMOTEROL, FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - n/a - n/a - [i/a - 1(D)F - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [i/a - 800(u) - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [i/a - 40mg - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [i/a - 20mg - n/a]), [TIOTROPIUM, TIOTROPIUM BROMIDE, TIOTROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [i/a - 18ug - n/a])	CSR
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)	COMRNATY [TOZINAMERAN] (S - n/a - n/a - [i/a - n/a - Intramuscular])	Not reported	CSR
EU-EC-10008144683	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 - CausedProlonged Hospitalisation), Tachycardia (n/a - Unknown - CausedProlonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [i/a - n/a - n/a])	Not reported	CSR
EU-EC-10008144687	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)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	CSR

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 (as per report)	Patient 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-10008140731	30/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - n/a)	NOT AVAILABLE (C - n/a - n/a - [n/a - 250mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 40mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 50mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 75mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008142815	30/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Confusional state (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Delusion (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovering/Resolving -), Mobility decreased (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Recovering/Resolving -)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - n/a)	[MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]) NOT AVAILABLE (C - n/a - n/a - [n/a - 12.5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 20mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 5mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008119672	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death), SARS-CoV-2 test negative (n/a - Fatal - Results in Death)	COMRNRATY [TOZINAMERAN] (S - n/a - n/a - [22d - n/a - Intramuscular])	[SODIUM VALPROATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008119962	29/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMRNRATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008120002	29/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Unknown -), Muscle twitching (n/a - Unknown -)	COMRNRATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008120146	29/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Pediatric (n/a - Unknown -), Acute cardiac event (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Electrocardiogram ST segment abnormal (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	MRABEGRON [MRABEGRON] (C - Micturition urgency - n/a - [n/a - n/a - n/a]), OLANZAPINE [OLANZAPINE] (C - Depression - n/a - [n/a - n/a - n/a]), PREGABALIN [PREGABALIN] (C - Depression - n/a - [n/a - n/a - n/a]), [AHONG KONG/481/2014 (H1N1)PDMA-DERIVED STRAIN (A/HONG KONG/481/2014, X-2638), B/BRISBANE/602/2009 LIKE STRAIN (B/BRISBANE/602/2009, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDMA-DERIVED STRAIN USED IN VMC X-181), A/HONG KONG/481/2014 (H1N1)PDMA-DERIVED STRAIN (A/HONG KONG/481/2014, X-2638), B/BRISBANE/602/2009 LIKE STRAIN (B/BRISBANE/602/2009, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDMA-DERIVED STRAIN (A/SINGAPORE/GP1908/2015, V/180), INFLUENZA VACCINE] (C - Immunisation - n/a - [1d - n/a - n/a]), [ACETYSALICYLIC ACID] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [ANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [SMYASTATIN] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - Micturition urgency - n/a - [n/a - n/a - n/a]), [VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008120402	29/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Not Caused Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Caused/Not Caused Prolonged Hospitalisation), Thrombosis (n/a - Unknown - Caused/Not Caused Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008121515	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008121738	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)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008122870	29/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Hypoxaemia (n/a - Fatal - Results in Death), Increased upper airway secretion (n/a - Fatal - Results in Death)	COMRNRATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	ANORO ELLIPTA [UMECLODINIUM BROMIDE, VILANTEROL, UMECLIDINIUM BROMIDE, VILANTEROL, TRIFENATE, UMECLIDINIUM, VILANTEROL] (C - n/a - n/a - [n/a - n/a - n/a]), GALVUS [VILDAGLIPTIN] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DONPEZIL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [DUTASTERIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - n/a - n/a - [n/a - n/a - n/a]), [MEMANTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
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)	COMRNRATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	JANUVA 100 MG FILM-COATED TABLETS [SITAGLIPTIN] (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 - 800UJ - 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]), [DXYCODONE 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-10008123389	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMRNRATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[CARBOMER, CARBOMER 980] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - Oral]), [SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10008125004	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)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	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)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	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)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1]DF - Intramuscular)	Not reported	ICSR
EU-EC-10008126835	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)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1]DF - Intramuscular)	Not reported	ICSR
EU-EC-10008128210	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), 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), Hypoxa (n/a - Fatal - Results in Death), Pallor (n/a - Fatal - Results in Death), Vomiting (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-10008129090	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Elderly	Female	No	Death (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), Hypoxa (n/a - Fatal - Results in Death), Pallor (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMRNRATY [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 - Oral])	ICSR
EU-EC-10008129775	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), Vomiting (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death, Life Threatening), Dyspnoea (n/a - Fatal - Results in Death, Life Threatening), Loss of consciousness (n/a - Fatal - Results in Death, Life Threatening)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 3mL - Intramuscular])	MICARDIS [TELISARTAN] (C - n/a - n/a - [n/a - n/a - Oral]), NOT AVAILABLE (C - n/a - n/a - [n/a - 85mg - Oral]), PREGABALIN [PREGABALIN] (C - n/a - n/a - [n/a - 75mg - Oral]), RANOLAZINE [RANOLAZINE] (C - Cardiac failure - n/a - [n/a - 750mg - Oral]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE] (C - n/a - n/a - [n/a - n/a - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a - [n/a - n/a - Oral]), [LEVOTHYROXINE] (C - n/a - n/a - [n/a - 50ug - Oral]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - Oral]), [SPIRONOLACTONE] (C - Cardiac failure - n/a - [n/a - n/a - Oral]), [TORSEMIDE, TORSEMIDE SODIUM] (C - Cardiac failure - n/a - [n/a - 10mg - Oral]), [MEFENOLIC] (C - n/a - n/a - [n/a - Not applicable -]), [METOPROLOL] (C - n/a - n/a - [n/a - Not applicable -]), [MEPRAZOLE] (C - n/a - n/a - [n/a - Not applicable -])	ICSR
EU-EC-100081292756	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Acute myocardial infarction (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death)	COMRNRATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 3mL - Intramuscular])	[TORSEMIDE, TORSEMIDE SODIUM] (C - Cardiac failure - n/a - [n/a - 10mg - Oral]), [MEFENOLIC] (C - n/a - n/a - [n/a - Not applicable -]), [METOPROLOL] (C - n/a - n/a - [n/a - Not applicable -]), [MEPRAZOLE] (C - n/a - n/a - [n/a - Not applicable -])	ICSR
EU-EC-100081294122	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100081294555	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), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])	ACTOS [PIOGLITAZONE, PIOGLITAZONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 15mg - n/a]), ADZOP [BRINZOLAMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), FORTSP (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 DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SMYASTATIN] (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-100081294574	29/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMRNRATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	EXELON [RIVASTIGMINE] (C - Dementia Alzheimer's type - n/a - [n/a - n/a - Transdermal]), MEMANTINE MERZ [MEMANTINE HYDROCHLORIDE] (C - Dementia Alzheimer's type - n/a - [n/a - n/a - Oral]), [CALCIUM, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - Oral]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - Oral]), [CYANOCOBALAMIN, FOLIC ACID, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [DUTASTERIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-100081295607	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-100081297019	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMRNRATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-100081297079	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)	COMRNRATY [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-1000812979730	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)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a - More in ICSR])	[PARACETAMOL] (C - Phyllysis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000812981233	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1]DF - Intramuscular)	[ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE, LEVOTHYROXINE SODIUM, LEVOTHYROXINE SODIUM ANHYDROUS EPI] (C - Hypometabolism - n/a - [n/a - n/a - Oral]), [FLUCLOXACIL, SODIUM FLUCLOXACIL] (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]), [RAMPRIL] (C - Hypertension - n/a - [n/a - 5mg - Oral]), [TERBUTALINE SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - 5mg - Respiratory (inhalation)], [TROTROPAM, OLODATEROL] (C - Chronic obstructive pulmonary disease - n/a - [n/a - 2]DF - Respiratory (inhalation))	ICSR
EU-EC-1000812987046	29/03/2021	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])	[METATONIN, METATONIN] (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]), [CAL, 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]), [FLUXETINE, FLUXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [RAMPRIL] (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-1000812981198	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 65 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Results in Death), Asteria (n/a - Not Recovered/Not Resolved - Results in Death), Death (n/a - Fatal - Results in Death)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1]DF - Intramuscular)	Not reported	ICSR
EU-EC-1000812987865	29/03/2021	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)	COMRNRATY [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]), [ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR
EU-EC-10008129874216	29/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death)	COMRNRATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1]DF - 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 (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
			Professional	European Economic Area	available	Years			Haematoma (n/a - Unknown -), Road traffic accident (n/a - Fatal - Results in Death)		[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 DIHYDRATE] (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]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [BIVAROXAN, BIVAROXAN] (C - n/a - n/a - [n/a - n/a - n/a]), [SILDENAFIL, SILDENAFIL] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - 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]), [NEBIVOLOL] (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-1000805124	24/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	No	Death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])		ICSR
EU-EC-1000805396	24/03/2021	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 - 1[DF] - Intramuscular])		ICSR
EU-EC-1000804068	24/03/2021	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])		ICSR
EU-EC-1000804752	24/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	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])	[FURSEMIDE] (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 TRINTRATE] (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-1000805539	24/03/2021	Spontaneous	Healthcare Professional	Non-European Economic Area	Not available	More than 85 Years	Not Specified	Male	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])		ICSR
EU-EC-1000809627	24/03/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	18-64 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Respiratory arrest (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Vaccination site pain (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		ICSR
EU-EC-1000805439	24/03/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	65-85 Years	Not Specified	Male	Asthenia (n/a - Unknown - Life Threatening), Death (n/a - Fatal - Results in Death, Life Threatening), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Cardiomypopathy - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000806329	24/03/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	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])		ICSR
EU-EC-1000806323	24/03/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	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 -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		ICSR
EU-EC-1000806343	24/03/2021	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 [IRON] (C - Mineral supplementation - n/a - [n/a - n/a - n/a]), [XAGROD [AMAGRELIDE, AMAGRELIDE 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])	ICSR
EU-EC-10008034911	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])		ICSR
EU-EC-1000803896	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	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])		ICSR
EU-EC-10008039137	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	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), Intubility (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])		ICSR
EU-EC-10008041320	23/03/2021	Spontaneous	Non-Healthcare Professional	Non-European Economic Area	Not available	Not Specified	Not Specified	Male	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])		ICSR
EU-EC-10008041893	23/03/2021	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 - n/a - Intramuscular])		ICSR
EU-EC-10008042141	23/03/2021	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 - Intramuscular])		ICSR
EU-EC-10008043066	23/03/2021	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 - Drug withdrawn - [n/a - 1[DF] - Intramuscular])	[ACETYSALICYLIC 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]), [FURSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LIDOCaine, LIDOCaine 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]), [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-10008043213	23/03/2021	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 - Drug withdrawn - [n/a - 1[DF] - Intramuscular])		ICSR
EU-EC-10008043551	23/03/2021	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])		ICSR
EU-EC-10008044865	23/03/2021	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 - n/a - Intramuscular])	[LEVOTHYROXINE SODIUM] (C - Hypothyroidism - Not applicable - [n/a - 1[DF] - Oral]), [RAMPRIL] (C - n/a - n/a - [n/a - n/a - Oral]), [CICIGON [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]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [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]), [TMOLOL, TMOLOL MALEATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008046582	23/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	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, DUCOSATE SODIUM, SODIUM PICOSULFATE MONOHYDRATE] (C - Constipation - n/a - [n/a - 10mg - Rectal]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 1[DF] - Oral]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 2000[μ] - Oral]), [DUCOSATE SODIUM, SENNOSIDE A/B] (C - Constipation - n/a - [n/a - 500mg - Oral]), [ERYTHROMYCIN] (C - n/a - n/a - [n/a - 5g - Ophthalmic]), [ESTRADIOL] (C - n/a - n/a - [n/a - 5g - Vaginal]), [HALOPERIDOL, HALOPERIDOL DECANOATE] (C - n/a - n/a - [n/a - 25mL - Oral]), [HYDROCORTISONE ACETATE, PERU BALSAM, ZINC OXIDE, BENZYL BENZOATE, BISMUTH OXIDE, BISMUTH SUBGALLATE, HYDROCORTISONE ACETATE, ZINC SULPHATE] (C - Proctalgia - n/a - [n/a - Rectal]), [MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 8[DF] - Oral]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral - More in ICSR]), [SENNA ALEXANDRINA LEAF, CASSIA] (C - n/a - n/a - [n/a - 6.6mg - 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	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])		ICSR
EU-EC-10008051094	23/03/2021	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 -), 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]), [FURSEMIDE] (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-10008026026	22/03/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	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])		ICSR
EU-EC-10008026654	22/03/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	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])		ICSR
EU-EC-10008026955	22/03/2021	Spontaneous	Non-Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	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])		ICSR
EU-EC-10008027099	22/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		ICSR
EU-EC-10008027120	22/03/2021	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 - Immunisation - n/a - [n/a - n/a - Intramuscular])	[AZARGA [BRINZOLAMIDE, TMOLOL, TMOLOL MALEATE, BRINZOLAMIDE]] (C - n/a - n/a -), [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]),	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 (as per report)	Parent 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-1000802593	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)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ZOLPIDEM ZOLPIDEM HEMITARTRATE, ZOLPIDEM TARTRATE (C - n/a - n/a - [n/a - 5mg - Oral])	ICSR
EU-EC-1000802595	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)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	APIXABAN 5MG TABLET (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000802595	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), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000802026	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)	COMRNTATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) (TOZINAMERAN) (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000796983	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)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000799103	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)	COMRNTATY TOZINAMERAN (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	RELVA ELLIPTA (FLUTICASON FURATE, VILANTEROL) (C - Chronic obstructive pulmonary disease - n/a - [n/a - 1(Df) - n/a]), [ACETYLCHOLINE, ACETYLCHOLINE SODIUM] (C - Productive cough - n/a - [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 - 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 - 200IE] - n/a), [ENOXAPARIN SODIUM] (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, Pain - n/a -), [OXAZEPAM] (C - Insomnia - n/a - [n/a - n/a - Oral]), [OXYCODONE 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(Df) - 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]), [SPIRONOLACTONE] (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)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007992903	19/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cold sweat (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Falls (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BUPROPION] (C - n/a - n/a - [n/a - 150g - n/a]), [MEMANTINE] (C - n/a - n/a - [n/a - 30mg - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 100mg - n/a]), [PIGLITAZONE (PIGLITAZONE)] (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]), [AMITRIPTYLINE 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]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - Not applicable - [n/a - 10mg - 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 - 600mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, 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(Df) - 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 - Dose not changed -)	ICSR
EU-EC-1000799512	19/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (n/a - Fatal - Results in Death), Fibromyalgia (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])	[JANAGAN] (C - n/a - n/a - [n/a - 150g - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 100mg - n/a]), [PIGLITAZONE (PIGLITAZONE)] (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]), [AMITRIPTYLINE 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]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - Not applicable - [n/a - 10mg - 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 - 600mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, 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(Df) - 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 - Dose not changed -)	ICSR
EU-EC-10008000575	19/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Nausea (n/a - Unknown -)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	[ACETYSALICYLIC ACID] (C - Anal fistula - 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 - Phylaxis - n/a - [n/a - 1(Df) - 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 - 150mg - n/a]), [PARACETAMOL] (C - Prophylaxis - n/a - [n/a - 3(Df) - n/a]), [TRAZOLAM] (C - Insomnia - n/a -)	ICSR
EU-EC-1000800584	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)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - n/a])	[ACETYSALICYLIC ACID] (C - Anal fistula - 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 - Phylaxis - n/a - [n/a - 1(Df) - 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 - 150mg - n/a]), [PARACETAMOL] (C - Prophylaxis - n/a - [n/a - 3(Df) - n/a]), [TRAZOLAM] (C - Insomnia - n/a -)	ICSR
EU-EC-1000800784	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 -)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - n/a])	[ACETYSALICYLIC ACID] (C - Anal fistula - 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 - Phylaxis - n/a - [n/a - 1(Df) - 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 - 150mg - n/a]), [PARACETAMOL] (C - Prophylaxis - n/a - [n/a - 3(Df) - n/a]), [TRAZOLAM] (C - Insomnia - n/a -)	ICSR
EU-EC-1000797488	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)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - 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)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000797640	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]), [RAMIPRIL] (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)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000795497	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000795822	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)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000795965	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)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007966749	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMRNTATY TOZINAMERAN (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000796920	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), 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)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000796903	17/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMRNTATY TOZINAMERAN (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007968270	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007968467	17/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007969507	17/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Aphasia (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Eating disorder (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Gait inability (n/a - Unknown - Other Medically Important Condition), Hypersomnia (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-10007947204	16/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMRNTATY TOZINAMERAN (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007942979	16/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COMRNTATY TOZINAMERAN (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007948527	16/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Confusion (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Maltise (n/a - Fatal - Results in Death), Personality change (n/a - Fatal - Results in Death)	COMRNTATY CONCENTRATE FOR DISPERSION FOR INJECTION (TOZINAMERAN) (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007931687	15/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	Bitter infected (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Pain (n/a - Unknown -)	COMRNTATY 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	No	Death (n/a - Fatal - Results in Death)	COMRNTATY TOZINAMERAN (S - n/a - n/a - [n/a - n/a - n/a])	[ALENDRONATE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [BUDESONIDE, BUDESONIDE, MICRONISED] (C - n/a - n/a - [n/a - n/a - n/a]), [CALCIUM, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007931821	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMRNTATY TOZINAMERAN (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007931961	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]), COMRNTATY TOZINAMERAN (S - n/a - n/a - [n/a - n/a - n/a])	BETMGA (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]), [FURSEMIDE, FURSEMIDE 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 DIHYDRATE] (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	No	Death (n/a - Fatal - Results in Death)	COMRNTATY 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	No	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), Resuscitation (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007934179	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death), Dyspnoea (1d - Fatal - Results in Death), General physical condition abnormal (1d - Fatal - Results in Death)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007934867	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMRNTATY 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]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1(Df) - n/a])	ICSR
EU-EC-10007934930	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	[CALCIUM POLYSTYRENE SULFONATE] (C - n/a - n/a - [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-10007935935	15/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Loss of consciousness (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMRNTATY TOZINAMERAN (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007901674</													

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 (as per report)	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
												<p>PRIVIGEN (PLAMIN NORMAL IMMUNOGLOBULIN) (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[CLONAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[DIPYRIDAMOL] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[FURSEMIDE, FURSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[LEVOMEPROMAZINE] (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>[MAGNESIUM OXIDE, MAGNESIUM OXIDE, LIGHT] (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>[SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[TRAMADOL, TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])</p>	ICSR
EU-EC-1000708757	12/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	<p>Asthenia (n/a - Unknown -),</p> <p>Chills (n/a - Unknown -),</p> <p>Death (n/a - Fatal - Results in Death),</p> <p>Discomfort (n/a - Unknown -),</p> <p>Dyspnoea (n/a - Unknown -),</p> <p>Fatigue (n/a - Unknown -),</p> <p>Feeling cold (n/a - Unknown -),</p> <p>Hypertidrosis (n/a - Unknown -),</p> <p>Loss of consciousness (n/a - Unknown - Other Medically Important Condition),</p> <p>Malaise (n/a - Unknown -),</p> <p>Respiratory distress (n/a - Unknown - Other Medically Important Condition)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1000709182	12/03/2021	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 - Drug withdrawn - [1d - 1(Df) - intramuscular])	Not reported	ICSR
EU-EC-1000709748	12/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Anger (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Aphasia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling),</p> <p>Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Death (n/a - Fatal - Results in Death, Other Medically Important Condition),</p> <p>Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling),</p> <p>Intracranial aneurysm (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling),</p> <p>Loss of consciousness (n/a - Unknown - Other Medically Important Condition),</p> <p>Mood swings (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling),</p> <p>Pain (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Rash (n/a - Unknown -),</p> <p>Ruptured cerebral aneurysm (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),</p> <p>Stabismus (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling),</p> <p>Subarachnoid haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)</p>	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	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-1000788638	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - 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	No	<p>Death (n/a - Fatal - Results in Death),</p> <p>Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Mental status changes (n/a - Unknown - Caused/Prolonged Hospitalisation)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - intramuscular])	<p>KEPPRA [LEVETIRACETAM] (C - Seizure - n/a - [n/a - 10mL - Oral]),</p> <p>LANTUS [INSULIN GLARGINE] (C - Diabetes mellitus - n/a - [n/a - 10(U) - Subcutaneous]),</p> <p>[ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Hyperlipidaemia - n/a - [n/a - 40mg - Oral]),</p> <p>[CASSIA] (C - Constipation - n/a - [n/a - 17.2mg - Oral]),</p> <p>[COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [n/a - 5000(IU) - Oral]),</p> <p>[LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - n/a - [n/a - 40mg - Oral]),</p> <p>[METFORMIN HYDROCHLORIDE] (C - Diabetes mellitus - n/a - [n/a - 1000mg - Oral]),</p> <p>[METOPROLOL SUCCINATE] (C - Hypertension - n/a - [n/a - 50mg - Oral]),</p> <p>[PARACETAMOL] (C - Body temperature increased, Pain - n/a - [n/a - 325mg - Oral])</p>	ICSR
EU-EC-1000789140	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	<p>Coma (n/a - Fatal - Results in Death),</p> <p>Death (n/a - Fatal - Results in Death),</p> <p>Hypertonia (n/a - Fatal - Results in Death)</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000789190	11/03/2021	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-10007892484	11/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	<p>COVID-19 (n/a - Fatal - Results in Death),</p> <p>Cough (n/a - Fatal - Results in Death),</p> <p>Death (n/a - Fatal - Results in Death),</p> <p>Pyrexia (n/a - Fatal - Results in Death)</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	<p>NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[CARBOMER] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[FURSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[SODIUM HYALURONATE, SODIUM HYALURONATE, CARBOMER 801] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[SODIUM HYALURONATE] (C - n/a - n/a - [n/a - n/a - n/a])</p>	ICSR
EU-EC-1000789339	11/03/2021	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) - n/a])	[GOSERELIN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000789489	11/03/2021	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 - n/a - n/a - [n/a - n/a - n/a])	<p>[ACETYL SALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[XYLOXIDONE 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> <p>[ZOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])</p>	ICSR
EU-EC-10007894972	11/03/2021	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 - 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	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - intramuscular])	Not reported	ICSR
EU-EC-10007895796	11/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	<p>Cough (n/a - Unknown -),</p> <p>Death (n/a - Fatal - Results in Death),</p> <p>Dyspnoea (n/a - Unknown -),</p> <p>Lung infiltration (n/a - Unknown -),</p> <p>Pneumonia (n/a - Unknown - Other Medically Important Condition),</p> <p>Wheezing (n/a - Unknown -)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - intramuscular])	<p>PLAVIX [CLOPIDOGREL, CLOPIDOGREL HYDROGEN SULFATE] (C - Arteriosclerosis - n/a - [n/a - 75mg - Oral]),</p> <p>[ACETYL SALICYLIC ACID] (C - Cardiac disorder - n/a - [n/a - 81mg - Oral]),</p> <p>[AMLODIPINE BESILATE] (C - Hypertension - n/a - [n/a - 5mg - Oral]),</p> <p>[COLECALCIFEROL] (C - Vitamin D deficiency - n/a - [n/a - 1000(IU) - Oral]),</p> <p>[DONEPEZIL HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 15mg - Oral]),</p> <p>[FOLIC ACID] (C - Supplementation therapy - n/a - [n/a - 1mg - Oral]),</p> <p>[FURSEMIDE] (C - Oedema - n/a - [n/a - 20mg - Oral]),</p> <p>[GUAFENESIN] (C - Nasopharyngitis - n/a - [n/a - 30mL - Oral]),</p> <p>[MEMANTINE HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 20mg - Oral]),</p> <p>[METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - 25mg - Oral]),</p> <p>[OMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Gastrooesophageal reflux disease - n/a - [n/a - 40mg - Oral]),</p> <p>[PARACETAMOL] (C - Body temperature increased, Pain - n/a - [n/a - 650mg - Oral]),</p> <p>[POTASSIUM CHLORIDE] (C - Supplementation therapy - n/a - [n/a - 10ug - Oral]),</p> <p>[PRIMIDONE] (C - Epilepsy - n/a - [n/a - 50mg - Oral])</p>	ICSR
EU-EC-10007874237	10/03/2021	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-10007874843	10/03/2021	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])	<p>[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - Drug withdrawn - [n/a - 10mg] - Oral),</p> <p>[LOXAPINE] (C - n/a - Drug withdrawn - [n/a - 15mg] - Oral),</p> <p>[OXAZEPAM] (C - n/a - Drug withdrawn - [n/a - 5mg] - Oral),</p> <p>[PARACETAMOL] (C - n/a - Dose not changed - [n/a - 1(Df) - Oral])</p>	ICSR
EU-EC-10007875182	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) - intramuscular])	Not reported	ICSR
EU-EC-10007876482	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	<p>Death (n/a - Fatal - Results in Death),</p> <p>General physical condition abnormal (n/a - Fatal - Results in Death)</p>	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-10007881044	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	<p>Death (n/a - Fatal - Results in Death),</p> <p>Fatigue (n/a - Fatal - Results in Death),</p> <p>General physical health deterioration (n/a - Fatal - Results in Death),</p> <p>Nausea (n/a - Fatal - Results in Death),</p> <p>Pyrexia (n/a - Fatal - Results in Death)</p>	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - intramuscular])	<p>ELIQUIS [APIXABAN] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[CHLORZOXAZONE] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[DILTIAZEM, DILTIAZEM HYDROBROMIDE, DILTIAZEM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[DIGOXIN] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a])</p>	ICSR
EU-EC-10007882188	10/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	<p>Abdominal discomfort (n/a - Unknown -),</p> <p>Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Constipation (n/a - Unknown -),</p> <p>Cough (n/a - Unknown -),</p> <p>Death (n/a - Fatal - Results in Death),</p> <p>Diarrhoea (n/a - Unknown -),</p> <p>Dysphonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Fatigue (n/a - Not Recovered/Not Resolved -),</p> <p>Hypertidrosis (n/a - Not Recovered/Not Resolved -),</p> <p>Loss of consciousness (n/a - Unknown - Other Medically Important Condition),</p> <p>Myalgia (n/a - Not Recovered/Not Resolved -),</p> <p>Nasopharyngitis (n/a - Not Recovered/Not Resolved -),</p> <p>Nausea (n/a - Unknown -),</p> <p>Pain (n/a - Not Recovered/Not Resolved -),</p> <p>Pyrexia (n/a - Unknown -),</p> <p>Sensation of foreign body (n/a - Unknown -),</p> <p>Vomiting (n/a - Unknown -)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007883000	10/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	<p>Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Haemoglobin decreased (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Lymphoedema (n/a - Unknown -),</p> <p>Oxygen saturation decreased (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Peripheral swelling (n/a - Unknown -),</p> <p>Swelling (n/a - Unknown - Other Medically Important Condition)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007883357	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	<p>Death (n/a - Fatal - Results in Death),</p> <p>Malaise (n/a - Unknown -)</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a])	<p>HYDROXYCOBALAMIN [HYDROXYCOBALAMIN] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>NOT AVAILABLE (C - n/a - n/a - [n/a - 20mg - n/a]),</p> <p>NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[CARBIDOPA, LEVODOPA, LEVODOPA, CARBIDOPA MONOHYDRATE] (C - n/a - n/a - [n/a - 1(Df) - n/a]),</p> <p>[GANFORT 3 MAGM + 5 MGML, [TIMOXOL MALEATE, BIMATOPROST] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[HALOPERIDOL] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[SALBUTAMOL SULFATE, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])</p>	ICSR
EU-EC-10007884396	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-10007882200	09/03/2021	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 - Drug withdrawn - [n/a - 30ug - intramuscular])	Not reported	ICSR
EU-EC-10007882227	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 30ug - intramuscular])	Not reported	ICSR
EU-EC-10007884731	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	<p>Death (n/a - Fatal - Results in Death),</p> <p>Dyspnoea (n/a - Not Recovered/Not Resolved - Results in Death),</p> <p>Feeling hot (n/a - Not Recovered/Not Resolved - Results in Death),</p> <p>Vomiting (n/a - Not Recovered/Not Resolved - Results in Death)</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - intramuscular])	<p>APIXABAN [APIXABAN] (C - n/a - n/a - [n/a - n/a - Oral]),</p> <p>LEVETIRACETAM [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - Oral]),</p> <p>LUMIGAN [BIMATOPROST] (C - n/a - n/a - [n/a - n/a - Ophthalmic]),</p> <p>PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]),</p> <p>[ALFUZOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]),</p> <p>[CARTEOLOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Ophthalmic]),</p> <p>[LERCANIDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]),</p> <p>[MACROGOL 400] (C - n/a - n/a - [n/a - n/a - Oral]),</p> <p>[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral])</p>	ICSR
EU-EC-10007886613	09/03/2021	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 - [n/a - n/a - intramuscular])	Not reported	ICSR
EU-EC-10007886134	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-10007886387	09/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	<p>Circulatory collapse (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition),</p> <p>Death (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DILTIAZEM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), <p>[LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]),</p>	ICSR
EU-EC-10007886243	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (05 - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 3mL - n/a])	<p>[ACETYL SALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - n/a]),</p> <p>[ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a -),</p> <p>[CARVEDILOL] (C - n/a - n/a -),</p> <p>[SPIRONOLACTONE] (C - n/a - n/a -)</p>	ICSR
EU-EC-10007847808	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85	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 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	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-1000784807	08/03/2021	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 - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000784834	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007849163	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007849421	08/03/2021	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 - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - Oral]), [PARACETAMOL, PARACETAMOL, ASPARTAME] (C - n/a - n/a - [n/a - n/a - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - Oral]), EXFORGE [VALSARTAN, AMLODIPINE, VALSARTAN, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), ZYPREXA 10 MG COATED TABLET [OLANZAPINE] (C - n/a - n/a - [n/a - 10mg - n/a]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [QUETIAPINE] (C - n/a - n/a - [n/a - 100mg - n/a])	ICSR
EU-EC-1000784987	08/03/2021	Spontaneous	Healthcare Professional	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), Dyspnoea (n/a - Not Recovered/Not Resolved -), Oedema peripheral (n/a - Not Recovered/Not Resolved -), Pyrexia (3d - Recovered/Resolved -), Vomiting (2d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1DF] - Intramuscular)		ICSR
EU-EC-10007850196	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Not Specified	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007850200	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Arrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Disturbance in attention (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007850211	08/03/2021	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 - Intramuscular])	Not reported	ICSR
EU-EC-10007850212	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007850217	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007850219	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Respiratory distress (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007850221	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Bradycardia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007850222	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), 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	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Female	Arrhythmia (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), 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-10007850236	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Asthma (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-10007850237	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Dehydration (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Gastrointestinal pain (n/a - Unknown -), Nausea (n/a - Unknown -), Oliguria (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007850238	08/03/2021	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 - Intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007850231	08/03/2021	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 - Intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007850235	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Asphyxia (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	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	COVID-19 (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007850244	08/03/2021	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 - Intramuscular])	Not reported	ICSR
EU-EC-10007850245	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Chronic kidney disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10007850255	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007850256	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007850259	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Not Specified	COVID-19 (n/a - Not Recovered/Not Resolved -), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007850261	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Dementia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007850264	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007850719	08/03/2021	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 - Intramuscular])	Not reported	ICSR
EU-EC-10007850721	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007850737	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death), Influenza like illness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10007850739	08/03/2021	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 - Intramuscular])	Not reported	ICSR
EU-EC-10007851156	08/03/2021	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 - 1DF] - n/a)	[RBESARTAN 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]), [DORAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PAMPEFONE] (C - n/a - n/a - [n/a - n/a - n/a]), [BUMETANIDE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE, IPRATROPIUM 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]), JANUVA 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-10007853867	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown -), Muscular weakness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)		ICSR
EU-EC-10007853884	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death), Dizziness (n/a - Unknown -), Injection site pain (n/a - Unknown -), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)		ICSR
EU-EC-10007857293	08/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	Blue toe syndrome (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling cold (n/a - Unknown -), Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial infarction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (n/a - Unknown -), Pneumothorax (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (5d - Recovered/Resolved -), Skin 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-10007892146	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - 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]), 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]), [BIDUAL VALPRICATE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [AZITHROMYCIN, AZITHROMYCIN DIHYDRATE, AZITHROMYCIN HYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PHATROPROM] (C - n/a - n/a - [n/a - n/a - n/a]), [LUSINAPRIL, LUSINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007892948	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - n/a)		ICSR
EU-EC-10007903008	05/03/2021	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 - 1DF] - n/a)		ICSR
EU-EC-10007903365	05/03/2021	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-10007903375	05/03/2021	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 - 3mL - n/a])	[ATORVASTATIN, RIVASTIGMINE] (C - n/a - n/a - [n/a - n/a - n/a]), [BECLOMETHASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETHASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE, BECLOMETHASONE DIPROPIONATE ANHYDROUS] (C - n/a - n/a - [n/a - n/a - n/a]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOMER, CARBOMER 980] (C - n/a - n/a - [n/a - n/a - n/a]), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ESTRIOL] (C - n/a - n/a - [n/a - n/a - n/a]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007906388	05/03/2021	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 - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007908335	05/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown -), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dehydration (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Dizziness (n/a - Unknown -), Immunodeficiency (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Unknown -), Pyrexia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007945011	04/03/2021	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 - 3mL - More in ICSR])	Not reported	ICSR
EU-EC-10007970670	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Abdominal distension (n/a - Unknown -), Cardiomegaly (n/a - Unknown -), Condition aggravated (n/a - Unknown -), Confusion (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Decreased appetite (n/a - Unknown -), Fatigue (n/a - Unknown -), Ocular hyperaemia (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Productive cough (n/a - Unknown -), Sepsis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYSALICYLIC ACID] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXAZOSIN, DOXAZOSIN MESLATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXYCYCLINE, DOXYCYCLINE HYDRATE, 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]), [PHATROPROM 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]), [INCORANOL] (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]), [TAMISULOSIN, TAMISULOSIN 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-10007974522	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	Aspiration (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007977709	03/03/2021	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-10007977739	03/03/2021	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-10007977844	03/03/2021	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 - 3mL - Intramuscular])	[MEMANTINE] (C - n/a - n/a - [n/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 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
			Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Decreased appetite (n/a - Fatal - Results in Death), Dizziness (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death) Death (n/a - Fatal - Results in Death)		[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-10007778163	03/03/2021	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-10007760263	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-10007762217	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 - CausedProlonged 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-10007763305	02/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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-10007764043	02/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cardiovascular 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-10007764414	02/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Abdominal wall haemorrhage (n/a - Not Recovered/Not Resolved - CausedProlonged Hospitalisation), Abdominal wall haemorrhage (n/a - Not Recovered/Not Resolved - CausedProlonged Hospitalisation, Other Medically Important Condition), Acute respiratory failure (n/a - Not Recovered/Not Resolved - CausedProlonged Hospitalisation, Other Medically Important Condition), COVID-19 pneumonia (n/a - Not Recovered/Not Resolved - CausedProlonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Hypotension (n/a - Not Recovered/Not Resolved - CausedProlonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007765505	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-10007765739	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-10007766503	02/03/2021	Spontaneous	Healthcare Professional	Non 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]), [COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOCUSATE] (C - n/a - n/a - [n/a - n/a - n/a]), [INFLUENZA VIRUS] (C - n/a - n/a - [1d - n/a - n/a]), [LAMOTRIGINE] (C - n/a - n/a - [n/a - n/a - n/a]), [ALPRAZOLAM] (C - n/a - n/a - [n/a - 25mg - n/a]), [ENOXAPARIN SODIUM] (C - n/a - n/a - [n/a - 4000(U) - 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]), [VINCOCETINE] (C - n/a - n/a -)	ICSR
EU-EC-10007767324	02/03/2021	Spontaneous	Non 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 - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007769024	02/03/2021		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-10007769530	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-10007770521	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 - [n/a - 1(Df) - Intramuscular])	[KEPPRA] [LEVETIRACETAM] (C - Epilepsy - n/a - [n/a - 2.5mL - n/a]), [TOUJEO SOLOGSTAR] [INSULIN GLARGINE] (C - Diabetes mellitus - n/a - [n/a - 14(U) - 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 - Prophyllaxis 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-10007748840	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-10007748854	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-10007748939	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), Pyelonephritis (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death), SARS-CoV-2 test negative (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[TRAJENTA] [LINAGLIPIN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [ANITRIFAMID COMPOUND, DIMETICONE, DIMETICONE, COLLOIDAL SILICON DIOXIDE, DIMETICONE, SILICA, COLLOIDAL ANHYDROUS, DIMETICONE 100S] (C - Flatulence - n/a - [n/a - n/a - n/a]), [BUPRENORPHINE] (C - Pain - n/a - [n/a - n/a - n/a]), [FURSEMIDE] (C - Swelling - n/a - [n/a - n/a - n/a]), [MACROGOL 400S] (C - Constipation - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - n/a]), [DOPHLONE] (C - Insomnia - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007749029	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-10007749406	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])	[TORSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007751131	01/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Unknown - CausedProlonged Hospitalisation), Abdominal pain (n/a - Unknown - CausedProlonged Hospitalisation), Abdominal pain upper (n/a - Unknown - CausedProlonged Hospitalisation), Acute kidney injury (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Blood pressure decreased (n/a - Unknown - CausedProlonged Hospitalisation), COVID-19 (n/a - Unknown - Other Medically Important Condition), Cardiac arrest (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Unknown - CausedProlonged 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 - CausedProlonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - CausedProlonged Hospitalisation), Pneumonia (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Posturing (n/a - Unknown - CausedProlonged Hospitalisation), Renal failure (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Respiratory distress (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Respiratory failure (n/a - Unknown - CausedProlonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Unknown - CausedProlonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - Move 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-10007755395	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])	[ACETYSALICYLIC 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]), [DOXAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TIOTROPIUM, OLODATROLOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007756891	01/03/2021	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 - Not applicable - [n/a - 3mL - Intramuscular])	[NOVGRAPID] [INSULIN ASPART] (C - n/a - n/a -), [TRESIBA] [INSULIN DEGLUCIDE] (C - n/a - n/a - [n/a - 30(U) - 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]), [FURSEMIDE] (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-10007758591	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])	[ACETYSALICYLIC 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]), [DOXAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TIOTROPIUM, OLODATROLOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007759712	01/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Dehydration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[FLUCONAZOLE] (C - Fungal infection - n/a - [n/a - 100mg - n/a])	ICSR
EU-EC-10007739446	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-10007739812	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-10007740366	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-10007740421	27/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	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-10007740926	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])	[CARBIMAZOLE] (C - n/a - n/a - [n/a - 5mg - n/a]), [NADLOL] (C - n/a - n/a - [n/a - 40mg - n/a]), [DOXAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 500mg - n/a])	ICSR
EU-EC-10007740927	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-10007741627	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-10007742409	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-EC-10007742970	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) 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-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 25 MG FILM-COATED TABLETS] [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007729856	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	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Chills (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Confusional state (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Death (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Fall (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Headache (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Hypoglycaemia (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Hypophagia (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Hypotension (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Hypothermia (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Hypoxia (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Malaise (n/a - Unknown -), Oedema peripheral (n/a - Fatal - Results in Death, CausedProlonged Hospitalisation), Oxygen saturation decreased (n/a - Fatal - Results in Death, CausedProlonged 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]), [TIMOLOL, TIMOLOL MALEATE] (C - n/a - n/a - [n/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 (as per report)	Patient Sex	Parent Child	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-1000772636	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Stimulant (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Somnolence (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation) Death (n/a - Fatal - Results in Death)	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	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYSALICYLIC ACID, ASPIRIN BP] (C - n/a - n/a - [n/a - 75mg - n/a]), [ANHYDROUS LEVOTHYROXINE SODIUM, LEVOTHYROXINE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 20mg - n/a]), [BUMETANIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007719978	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007720021	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Back pain (n/a - Unknown -), Confusional state (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Unknown -), Hypertension (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ELIQUIS (APIXIBAN)] (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-10007720060	25/02/2021	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 - [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	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	Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ELIQUIS (APIXIBAN)] (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]), [METFORMAN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - 500mg - n/a]), [METOPROLOL, METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 100mg - Oral]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - 750mg - Oral]), [RAMIPRIL] (C - Cardiac failure - n/a - [n/a - 5mg - Oral])	ICSR
EU-EC-10007722038	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	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	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-10007722257	25/02/2021	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 - 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	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	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-10007723064	25/02/2021	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 - 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	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	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), Pneumonia (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	Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (1d - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007706729	24/02/2021	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 - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007706926	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	Abdominal pain (n/a - Unknown -), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown -), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Death (1d - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007706991	24/02/2021	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 - 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	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-10007708490	24/02/2021	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 - 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	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	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	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-10007708780	24/02/2021	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])	Not reported	ICSR
EU-EC-10007709425	24/02/2021	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 - 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	Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007709493	24/02/2021	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])	Not reported	ICSR
EU-EC-10007709494	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007711838	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Aortic aneurysm rupture (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3mL - Intramuscular])	[BIMATOROST (BIMATOROST)] (C - n/a - n/a - [n/a - n/a - n/a]), [BUPRENORPHINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a]), [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - 75mg - n/a]), [FELODIPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCORTISONE ACETATE, LIDOCANE, LIDOCANE, HYDROCORTISONE ACETATE PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [MACROGOL 400] (C - n/a - n/a - [n/a - 1[DF] - n/a]), [OMEPRazole] (C - n/a - n/a - [n/a - 20mg - n/a]), [OXycodone HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a])	ICSR
EU-EC-10007711855	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Intramuscular])	[TRIMBOW (BECLOMETASONE DIPROPIONATE, GLYCOPHYRRONIUM BROMIDE, FORMOTEROL FUMARATE DIHYDRATE)] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSTYRENE] (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]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [IPRATROPIUM, IPRATROPIUM BROMIDE, IPRATROPIUM BROMIDE ANHYDROUS, IPRATROPIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000769372	23/02/2021	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 - [1d - n/a - Intramuscular])	[EBIXA (MEANTHEIN 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 DINITRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [OXycodone HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10007693777	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007694613	23/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007697979	23/02/2021	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 - n/a])	Not reported	ICSR
EU-EC-10007697435	23/02/2021	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 - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007699400	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FOLIC ACID] (C - n/a - 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 - n/a - Not applicable - [n/a - n/a - n/a]), [DIONEFER, DIONEFERZ, HYDROCHLORIDE] (C - Demantia Alzheimer's type - n/a - [n/a - 10mg - Oral]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 25mg - Oral])	ICSR
EU-EC-10007693526	22/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007685708	22/02/2021	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 - n/a - n/a])	Not reported	ICSR
EU-EC-10007685843	22/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007687881	22/02/2021	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 - Intramuscular])	Not reported	ICSR
EU-EC-10007689504	22/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	Coma (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Disturbance in attention (n/a - Fatal - Results in Death), Peripheral vascular disorder (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[CLOPIDOGREL (CLOPIDOGREL, CLOPIDOGREL BESILATE)] (C - n/a - n/a - [n/a - n/a - n/a]), [ENTRESTO (VALSARTAN, SACUBITRIL)] (C - n/a - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007677192	20/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-10007677199	20/02/2021	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-10007677877	20/02/2021	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])	Not reported	ICSR
EU-EC-10007679410	20/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	Aspiration (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Epilepsy (n/a - Fatal - Results in Death), Seizure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007683756	19/02/2021	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])	Not reported	ICSR
EU-EC-10007684355	19/02/2021	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 - Not applicable - [n/a - 1[DF] - Intramuscular]), [OXAZEPAM] (S - Anxiety - Not applicable - [n/a - 10mg - Oral])	Not reported	ICSR
EU-EC-10007684883	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	Death (n/a - Fatal - Results in Death, Life Threatening), Rectal haemorrhage (n/a - Unknown - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-10007685048	19/02/2021	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 - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-10007686201	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 23d - n/a - Intramuscular])	[FUROSEMIDE] (C - Cardiac failure - n/a - [10d - n/a - Intravenous (not otherwise specified)])	ICSR
EU-EC-10007687294	19/02/2021	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 - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007687405	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years						

EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference available	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-10007669170	19/02/2021	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-10007669247	19/02/2021	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 - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007669325	19/02/2021	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-10007669361	19/02/2021	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-10007669704	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Heart rate decreased (n/a - Unknown -), Peripheral coldness (n/a - Unknown -), Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - n/a]), [FENTANYL] (S - Pain - Dose not changed - [n/a - 1(Df) - n/a])	EXFORGE 5 MG/80 MG FILM-COATED TABLETS [VALSARTAN, AMLODIPINE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [ALUMINIUM OXIDE, MAGNESIUM HYDROXIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FENTANYL, FENTANYL CITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARAFFIN] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [THAMINE HYDROCHLORIDE, DEXRISPERIDONE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [VASELINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007651711	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Fall (n/a - Unknown - Other Medically Important Condition), General physical health deterioration (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007651931	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007651961	18/02/2021	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-10007655687	18/02/2021	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 - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007637853	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (1d - Fatal - Results in Death), Malaise (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	ABASAGLAR 100 UNTS/MML SOLUTION FOR INJECTION IN A CARTRIDGE [INSULIN GLARGINE] (C - Dementia - n/a - [n/a - 6(U) - Subcutaneous]), [FLUNDINONE] (C - Arrhythmia - n/a - [n/a - n/a - Oral]), [FUROSEMIDE] (C - Cardiac failure - n/a - [n/a - 1(Df) - Oral]), [MACROGOL 4000] (C - Constipation - n/a - [n/a - 1(Df) - Oral]), [OMEPRAZOLE] (C - Gastric ulcer - n/a - [n/a - 1(Df) - Oral]), [PARACETAMOL] (C - Osteoarthritis - n/a - [n/a - 2(Df) - Oral]), [PAROXETINE] (C - Depression - n/a - [n/a - 1(Df) - Oral]), [RISPERIDONE] (C - Dementia - n/a - [n/a - 5mg - Oral]), [ACETYLSALICYLIC ACID] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [BENDROFLUMETHAZIDE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007638370	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	APIXABAN [APIXABAN] (C - n/a - n/a - [n/a - 2.5mg - Oral]), FENTANYL [FENTANYL, FENTANYL CITRATE] (C - n/a - n/a - [n/a - 4mg - Transdermal]), PREGABALIN [PREGABALIN] (C - n/a - n/a - [n/a - 150mg - Oral]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - Oral]), [METAMIZOLE, METAMIZOLE MAGNESIUM, METAMIZOLE SODIUM] (C - n/a - n/a - [n/a - 500mg - n/a]), [RAMPRIL] (C - n/a - n/a - [n/a - 5mg - Oral]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 5mg - Oral])	ICSR
EU-EC-10007639513	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Ileus paralytic (4d - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Microcytic anaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007639530	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Blood pressure decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Body temperature increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Heart rate decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oxygen saturation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1(Df) - n/a])	DULOXETINE [DULOXETINE] (C - n/a - n/a -), ESOMEPRAZOLE [ESOMEPRAZOLE] (C - n/a - n/a -), NEUPRO [PROTIGOTINE] (C - n/a - n/a -), [ACENOCOLAMAROL] (C - n/a - n/a -), [CARVEDILOL] (C - n/a - n/a -), [FLUTICASON PROPRIONATE, SALMETEROL] (C - n/a - n/a -), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a -), [GABAPENTIN] (C - n/a - n/a -), [SPIRONOLACTONE] (C - n/a - n/a -)	ICSR
EU-EC-10007639674	17/02/2021	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 - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007643387	17/02/2021	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-10007643445	17/02/2021	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-10007647256	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Heart rate decreased (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	KEPPRA [LEVETIRACETAM] (C - Epilepsy - n/a - [n/a - 1500mg - Oral]), LANTUS [INSULIN GLARGINE] (C - Diabetes mellitus - n/a - [n/a - 32(U) - Subcutaneous]), LURASIDONE HYDROCHLORIDE [LURASIDONE HYDROCHLORIDE] (C - Schizophrenia - n/a - [n/a - 120mg - Oral]), [ACETYLSALICYLIC ACID] (C - Cardiac disorder - n/a - [n/a - 81mg - Oral]), [ATENLOLOL, ATENLOLOL BPF] (C - Essential hypertension - n/a - [n/a - 25mg - Oral]), [ATORVASTATIN CALCIUM] (C - Hyperlipidaemia - n/a - [n/a - 40mg - Oral]), [FINASTERIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - 5mg - Oral]), [HALOPERIDOL] (C - Schizophrenia - n/a - [n/a - 10mg - Oral]), [HYDROXYMETHYLCELLULOSE, GLYCEROL, MACROGOL 400, POLYVINYL ALCOHOL, PROPYLENE GLYCOL, VASELINE LIQUID PARAFFIN] (C - Dry eye - n/a - [n/a - 469] - Ophthalmic), [LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - 88ug - Oral]), [LITHIUM CARBONATE] (C - Schizophrenia - n/a - [n/a - 900mg - Oral]), [LORAZEPAM] (C - Anxiety, Restlessness - n/a - [n/a - 1mg - Oral]), [LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - 25mg - Oral]), [OMEPRAZOLE] (C - Gastroesophageal reflux disease - n/a - [n/a - 20mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 3000mg - Oral]), [SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - 200mg - Oral]), [TAMSULOSIN HYDROCHLORIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - 8mg - Oral]), [VITAMIN D] (C - Supplementation therapy - n/a - [n/a - 2000(IU) - Oral])	ICSR
EU-EC-10007625788	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Results in Death), Death (n/a - Fatal - Results in Death), Vertigo (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007626286	16/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Vomiting (n/a - Unknown - Results in Death), Agitation (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Neuropsychiatric symptoms (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007626621	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007627114	16/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007627154	16/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COVID-19 pneumonia (6d - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007627333	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Administration site pain (8d - Unknown -), Death (04 - Fatal - Results in Death), Somnolence (8d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	[ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Hypercholesterolemia - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10007630250	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Chronic obstructive pulmonary disease (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pneumonia (n/a - Fatal - Results in Death), Renal failure (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007630544	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Blood glucose decreased (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3mL - Intramuscular])	NOVOPRID [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), TRAJENTA 5 MG FILM-COATED TABLETS [NANALIPITIN] (C - n/a - n/a - [n/a - 5mg - n/a]), [AMLODIPINE] (C - n/a - n/a - [n/a - 5mg - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 40mg - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [CANDESARTAN CILEXTEL] (C - n/a - n/a - [n/a - 8mg - n/a]), [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - 75mg - n/a]), [ECONAZOLE NITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FERROUS SULFATE] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 500mg - n/a]), [PANTOPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007630619	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Cardio-respiratory arrest (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007633814	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007618264	15/02/2021	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 - Intramuscular])	Not reported	ICSR
EU-EC-10007619881	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Intramuscular])	[BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - 25mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 75ug - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 5mg - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOSULFATE, SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - 50mg - n/a])	ICSR
EU-EC-10007620170	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Lixidry (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007622335	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	No	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007622579	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Blood pressure immeasurable (n/a - Recovered/Resolved - Other Medically Important Condition), Breath sounds (n/a - Unknown -), Checking (n/a - Unknown -), Death (n/a - Fatal - Results in Death), Fatigue (n/a - Recovered/Resolved -), Oxygen saturation immeasurable (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1(Df) - n/a])	[LORATADINE] (C - Drug hypersensitivity - n/a - [n/a - 10mg - n/a])	ICSR
EU-EC-10007611817	14/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - Cough - n/a - [n/a - 100mg - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Cough - n/a - [n/a - n/a - Respiratory (Inhalation)])	ICSR
EU-EC-10007607987	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Subless (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007600007	13/02/2021	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 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	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-1000706020	13/02/2021	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-1000706029	13/02/2021	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-10007589120	12/02/2021	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 - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-10007589407	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Arrhythmia (n/a - Unknown - Results in Death), Cardiomyopathy (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-10007594197	12/02/2021	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 - Drug withdrawn - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-10007594275	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), 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-10007594349	12/02/2021	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 - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-10007596345	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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-10007597273	12/02/2021	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 - Intramuscular])	Not reported	ICSR	
EU-EC-10007597682	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (Sd - Fatal - Results in Death), General physical health deterioration (Sd - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10007598076	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Dyspnoea (n/a - Fatal - Results in Death), Gaze palsy (n/a - Fatal - Results in Death), Opisthotonus (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	EXELON (RIVASTIGMINE) (C - Dementia Alzheimer's type - n/a - [n/a - n/a - Oral]), MELATONIN (MELATONIN) (C - Sleep disorder - n/a - [n/a - n/a - Oral]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - Oral]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Hypertension - n/a - [n/a - n/a - Oral]), [COLECALCIFEROL, CALCIUM COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - Oral]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM] (C - Gastrointestinal disorder [prophylaxis] - n/a - [n/a - n/a - Oral]), [ISOSORBIDE 5 MONONITRATE, ISOSORBIDE MONONITRATE] (C - Hypertension - n/a - [n/a - n/a - Oral]), [MEMANTINE] (C - Dementia Alzheimer's type - n/a - [n/a - n/a - Oral]), [MIRTAZAPINE] (C - Insomnia - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral]), [RISPERIDONE] (C - Behaviour disorder - n/a - [n/a - n/a - Oral]), [WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BPI] (C - Atrial fibrillation - n/a - [n/a - n/a - Oral]), [FLUCONAZOLE] (C - Fungal infection - n/a - [n/a - 100mg - Oral])	ICSR	
EU-EC-10007598366	12/02/2021	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 - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10007598800	11/02/2021	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])	COMPROVEL 150 MG/12.5 MG TABLETS [HYDROCHLOROTHIAZIDE, IRBESARTAN] (C - n/a - Dose not changed - [n/a - 1(Df) - Oral]), [MANSERIN 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]), [VENAFAXINE, VENAFAXINE HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - 75mg - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - 1(Df) - Oral])	ICSR	
EU-EC-10007598922	11/02/2021	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 - Not applicable - [n/a - 1(Df) - Intramuscular]), KEPPRA 500 MG FILM-COATED TABLETS [LEVITRACETAM] (S - Product used for unknown indication - Dose not changed - [n/a - 1(Df) - Oral]), [ACETYL SALICYLIC ACID, D,L-LYSINE ACETYL SALICYLATE] (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 SESQUIHYDRATE] (S - Product used for unknown indication - Dose not changed - [n/a - 1(Df) - Oral]), [POTASSIUM CHLORIDE, POTASSIUM CHLORIDE, ETHYLCELLULOSE MICROENCAPSULATED 80-90%] (S - Product used for unknown indication - Dose not changed - [n/a - 1(Df) - Oral]), [THIAPRIDE, THIAPRIDE] (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])	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007598271	11/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	Asthenia (6d - Fatal - Results in Death), Chills (6d - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Malaise (6d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10007598269	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Not Specified	No	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-10007598261	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	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-10007598472	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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-10007598761	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (Sd - 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]), [MEVASTATIN, MEVASTATIN CALCIUM, 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]), [TIOTROPUM, TIOTROPUM BROMIDE, TIOTROPUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-10007599174	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	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-10007599238	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Lip oedema (n/a - Recovering/Resolving - Results in Death), Pyrexia (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ALPRAZOLAM] (C - n/a - n/a - [n/a - 125mg - Oral]), [LEVOTHYRONINE SODIUM] (C - n/a - n/a - [n/a - 25ug - Oral])	ICSR	
EU-EC-10007599255	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Coronavirus infection (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Recovering/Resolving - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-10007599361	10/02/2021	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])	[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]), [LUMIGAN] [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 SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [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)], [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - Oral]), [THEOPHYLLINE, THEOPHYLLINE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [TIOTROPUM, TIOTROPUM BROMIDE, TIOTROPUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)], [WARFARIN, WARFARIN SODIUM, WARFARIN SODIUM BPI] (C - n/a - n/a - [n/a - n/a - Oral]), [ZOPICLONE] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR	
EU-EC-10007599399	10/02/2021	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 - [1d - n/a - Intramuscular])	[AMICLOARONE 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 -), [ESOMEPRAZOLE] (C - n/a - Unknown -), [WARFARIN SODIUM] (C - n/a - Unknown -)	ICSR	
EU-EC-10007599415	10/02/2021	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 - Immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10007599438	10/02/2021	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 - 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-10007599509	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Acute kidney injury (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Hesitancy (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-10007599645	10/02/2021	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 -), Hypotonia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1(Df) - n/a])	XARELTO 15 MG [RIVAROXABAN] (C - Atrial fibrillation - n/a - [n/a - 1(Df) - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 1(Df) - n/a])	ICSR	
EU-EC-10007599724	10/02/2021	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 - 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])	ICSR	
EU-EC-10007599726	10/02/2021	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 - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-10007599730	10/02/2021	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 - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-100075997313	10/02/2021	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 - COVID-19 immunisation - Unknown - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-100075997326	10/02/2021	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 - COVID-19 immunisation - Unknown - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-100075997327	10/02/2021	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 - Unknown - [n/a - 1(Df) - Intramuscular])	BETMIGL [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]), [FLUCRIDE, SODIUM FLUCRIDE] (C - Dental disorder prophylaxis - n/a - [n/a - n/a - Dental]), [FUROSEMIDE] (C - Diuretic therapy - n/a - [n/a - 40mg - Oral]), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Heart rate irregular - n/a - [n/a - 50mg - Oral]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - Gastroesophageal reflux disease - n/a - [n/a - 40mg - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - Oral]), [POTASSIUM CHLORIDE] (C - Mineral supplementation - n/a - [n/a - 750mg - Oral]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - 1(Df) - Oral]), [VITAMIN D, CALCIUM] (C - Mineral supplementation - n/a - [n/a - n/a - Oral])	ICSR	
EU-EC-100075997331	10/02/2021	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 - Unknown - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR	
EU-EC-100075997332	10/02/2021	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 - Unknown - [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	Patient 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-10007557616	09/02/2021	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-10007558333	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1] [DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007558601	09/02/2021	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)	XARELTO [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007558678	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1] [DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007558699	09/02/2021	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-10007559165	09/02/2021	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 - 3mL - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Intramuscular])	BUPRENORPHINE [BUPRENORPHINE] (C - n/a - n/a - [n/a - n/a - n/a]), MIDAZOLAM [MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), (ACETYL)SALICYLIC ACID (C - n/a - n/a - [n/a - n/a - n/a]), (CLOMETHAZOLE, CLOMETHAZOLE EDISILATE) (C - n/a - n/a - [n/a - n/a - n/a]), (DRIED FERROUS SULFATE, FERROUS SULFATE) (C - n/a - n/a - [n/a - n/a - n/a]), (FOLIC ACID) (C - n/a - n/a - [n/a - n/a - n/a]), (FUROSEMIDE, FUROSEMIDE SODIUM) (C - n/a - n/a - [n/a - n/a - n/a]), (GLYCEROL) (C - n/a - n/a - [n/a - n/a - n/a]), (GLYCOPYRRONIUM BROMIDE, GLYCOPYRRONIUM BROMIDE, NEOSTIGMINE METHYLSULFATE) (C - n/a - n/a - [n/a - n/a - n/a]), (HALOPERIDOL, HALOPERIDOL DECANOATE) (C - n/a - n/a - [n/a - n/a - n/a]), (MEMANTINE) (C - n/a - n/a - [n/a - n/a - n/a]), (METHENAMINE HIPPURATE) (C - n/a - n/a - [n/a - n/a - n/a]), (METOPROLOL, METOPROLOL TARTRATE) (C - n/a - n/a - [n/a - n/a - n/a]), (MIRTAZAPINE) (C - n/a - n/a - [n/a - n/a - n/a]), (MORPHINE, MORPHINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - n/a - n/a - [n/a - n/a - n/a]), (ZOPICLONE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007560067	09/02/2021	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 - n/a - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007560068	09/02/2021	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 - n/a - n/a - [n/a - n/a - Intramuscular])	(LACTULOSE) (C - n/a - n/a - [n/a - n/a - n/a]), (RSFENIDOLINE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007561109	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Asthenia (3d - Fatal - Results in Death, Other Medically Important Condition), Death (0d - Fatal - Results in Death), Fall (3d - Fatal - Results in Death, Other Medically Important Condition), Restlessness (1d - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007562986	09/02/2021	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 - Immunisation - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007563601	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	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 - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007563602	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death), Hypertensive crisis (n/a - Fatal - Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007563606	09/02/2021	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), (NOT AVAILABLE) (S - Insus - Dose not changed - [n/a - 1000mg - n/a]), (NOT AVAILABLE) (S - Insus, Pneumonia - Dose increased - [n/a - 1] [DF] - n/a), (NOT AVAILABLE) (S - Palliative care - Dose not changed - [n/a - 10mg - n/a])	Not reported	ICSR
EU-EC-10007563604	09/02/2021	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)	NOT AVAILABLE (C - n/a - n/a - [n/a - 10mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1] [DF] - n/a), NOT AVAILABLE (C - n/a - n/a - [n/a - 45mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 500mg - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 7.5mg - n/a]), (CARBODOPA, LEVODOPA, LEVODOPA, CARBODOPA MONOHYDRATE) (C - n/a - n/a - [n/a - 1] [DF] - n/a), (CARBOMER) (C - n/a - n/a - [n/a - 1] [DF] - n/a), (ETHANAMINE HYDROCHLORIDE, DEXTANAMINE, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 1] [DF] - n/a), (EUSLON [PRIVASTATINE]) (C - n/a - n/a - [n/a - n/a - n/a]), (ATORVASTATIN) (C - n/a - n/a - [n/a - n/a - n/a]), (CARBOMER) (C - n/a - n/a - [n/a - 5mL - n/a]), (CASSIA, SENNA PODS) (C - n/a - n/a - [n/a - n/a - n/a]), (FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (FUROSEMIDE, FUROSEMIDE, ANHYDROUS AMILORIDE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (FUROSEMIDE) (C - n/a - n/a -), (HALOPERIDOL, HALOPERIDOL BP) (C - n/a - n/a - [n/a - n/a - n/a]), (HALOPERIDOL) (C - n/a - n/a - [n/a - n/a - n/a]), (LACTULOSE) (C - n/a - n/a -), (LANSOPRAZOLE) (C - n/a - n/a - [n/a - n/a - n/a]), (MEMANTINE) (C - n/a - n/a - [n/a - n/a - n/a]), (PARAFFIN) (C - n/a - n/a -), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - n/a - n/a -), (SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350) (C - n/a - n/a - [n/a - n/a - n/a]), (SOLFENACIN SUCCINATE) (C - n/a - n/a - [n/a - n/a - n/a]), (TRAZODONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (TRAZODONE, TRAZODONE HYDROCHLORIDE) (C - n/a - n/a -), (VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007564720	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cyanosis (n/a - Recovered/Resolved -), Death (n/a - Fatal - Results in Death), Depressed level of consciousness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - n/a])	(ITHAMINE HYDROCHLORIDE, DEXTANAMINE, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - 1] [DF] - n/a), (EUSLON [PRIVASTATINE]) (C - n/a - n/a - [n/a - n/a - n/a]), (ATORVASTATIN) (C - n/a - n/a - [n/a - n/a - n/a]), (CARBOMER) (C - n/a - n/a - [n/a - 5mL - n/a]), (CASSIA, SENNA PODS) (C - n/a - n/a - [n/a - n/a - n/a]), (FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (FUROSEMIDE, FUROSEMIDE, ANHYDROUS AMILORIDE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (FUROSEMIDE) (C - n/a - n/a -), (HALOPERIDOL, HALOPERIDOL BP) (C - n/a - n/a - [n/a - n/a - n/a]), (HALOPERIDOL) (C - n/a - n/a - [n/a - n/a - n/a]), (LACTULOSE) (C - n/a - n/a -), (LANSOPRAZOLE) (C - n/a - n/a - [n/a - n/a - n/a]), (MEMANTINE) (C - n/a - n/a - [n/a - n/a - n/a]), (PARAFFIN) (C - n/a - n/a -), (SALBUTAMOL, SALBUTAMOL SULFATE) (C - n/a - n/a -), (SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350) (C - n/a - n/a - [n/a - n/a - n/a]), (SOLFENACIN SUCCINATE) (C - n/a - n/a - [n/a - n/a - n/a]), (TRAZODONE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (TRAZODONE, TRAZODONE HYDROCHLORIDE) (C - n/a - n/a -), (VENLAFAXINE, VENLAFAXINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007564861	09/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Asthenia (n/a - Unknown -), Cerebral haemorrhage (0d - Fatal - Results in Death, Other Medically Important Condition), Death (0d - Fatal - Results in Death, Other Medically Important Condition), Fatigue (n/a - Unknown -), Malaise (n/a - Unknown -), Myalgia (n/a - Unknown -)	COMIRNATY COVID-19 mRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 3mL - Intramuscular])	(ASCORBIC ACID) (C - n/a - n/a - [n/a - n/a - n/a]), (ZINC) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007561142	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Arrhythmia (n/a - Fatal - Results in Death), COVID-19 (n/a - Fatal - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Drug ineffective (n/a - Fatal - Results in Death, Other Medically Important Condition), Pneumonia (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	(ASCORBIC ACID) (C - n/a - n/a - [n/a - n/a - n/a]), (ZINC) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007564988	07/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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 [NLSLN GLARGINE] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), SITAGLIPTIN [SITAGLIPTIN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), (ACETYL)SALICYLIC ACID (C - Angina pectoris - n/a - [n/a - n/a - n/a]), (ATORVASTATIN) (C - Angina pectoris - n/a - [n/a - n/a - n/a]), (BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE) (C - Angina pectoris - n/a - [n/a - n/a - n/a]), (FLEOPIPINE) (C - Hypertension - n/a - [n/a - n/a - n/a]), (GLYCERYL TRINITRATE) (C - Angina pectoris - n/a - [n/a - n/a - n/a]), (LEVOTHYROXINE, LEVOTHYROXINE SODIUM) (C - Hypothyroidism - n/a - [n/a - n/a - n/a]), (PARACETAMOL) (C - Osteoarthritis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007522943	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Headache (n/a - Not Recovered/Not Resolved - Results in Death), Vomiting (n/a - Not Recovered/Not Resolved - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1] [DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007523214	05/02/2021	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 - Drug withdrawn - [n/a - 1] [DF] - Intramuscular)	XARELTO [RIVAROXABAN] (C - Artrial fibrillation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007524454	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1] [DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007526658	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac failure (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007527303	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Vaccination site pain (n/a - Unknown - Other Medically Important Condition) Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007527590	05/02/2021	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 - n/a - n/a - [n/a - n/a - n/a])	(BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE) (C - n/a - n/a - [n/a - 2] [DF] - n/a), (COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE) (C - n/a - n/a - [n/a - 1] [DF] - n/a), (CYANOCOBALAMIN) (C - n/a - n/a - [n/a - 1mg - n/a]), (ESCITALOPRAM, ESCITALOPRAM OXALATE) (C - n/a - n/a - [n/a - 10mg - n/a]), (FOLIC ACID) (C - n/a - n/a - [n/a - 1mg - n/a]), (LOSARTAN, LOSARTAN POTASSIUM) (C - n/a - n/a - [n/a - 50mg - n/a]), (SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350) (C - n/a - n/a - [n/a - 1] [DF] - n/a)	ICSR
EU-EC-10007528461	05/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007530163	05/02/2021	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 - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007534113	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	CELLCEPT [MYCOPHENOLATE MOFETIL] (C - Renal transplant - n/a - [n/a - 2g - n/a]), CICLOSPORIN [CICLOSPORIN] (C - Renal transplant - n/a - [n/a - 75mg - n/a]), NOT AVAILABLE (C - Aorta coarctation repair - n/a - [n/a - n/a - n/a]), VALSARTAN, SACUBITRIL [VALSARTAN, SACUBITRIL] (C - Hypertension - n/a - [n/a - n/a - n/a]), (BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE) (C - Hypertension - n/a - [n/a - 5mg - n/a]), (METHYLPREDNISOLONE, METHYLPREDNISOLONE SODIUM SUCCINATE) (C - Renal transplant - n/a - [n/a - 2mg - n/a]), (TORASEMIDE) (C - Cardiac failure - n/a - [n/a - 10mg - n/a])	ICSR
EU-EC-10007534203	05/02/2021	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])	Not reported	ICSR
EU-EC-10007515738	04/02/2021	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 - Not applicable - [n/a - 1] [DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007515751	04/02/2021	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] - Intramuscular)	Not reported	ICSR
EU-EC-10007515914	04/02/2021	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 - Not applicable - [n/a - 1] [DF] - Intramuscular)	ABILIFY 10 MG TABLETS [ARIPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), (BISOPROLOL HEMIFUMARATE) (C - n/a - n/a - [n/a - n/a - n/a]), (HYDROXYCHLOROQUINE SULFATE) (C - n/a - n/a - [n/a - n/a - n/a]), (NICARDIPINE HYDROCHLORIDE) (C - n/a - n/a - [n/a - n/a - n/a]), (RAMPRIL) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007516030	04/02/2021	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 - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007516334	04/02/2021	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-10007516465	04/02/2021	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 - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007518287	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Pleuritis (n/a - Fatal - Results in Death), Respiratory distress (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007519820	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Acute myocardial infarction (0d - Fatal - Results in Death), Death (0d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 3mL - Intramuscular])	(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 -), (TRIMETAZIDINE DIHYDROCHLORIDE) (C - n/a - n/a -)	ICSR
EU-EC-10007502904	03/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	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-10007505560	03/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Anxiety (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	(LEVOTHYROXINE SODIUM) (C - n/a - n/a - [n/a - n/a - n/a]), (LORAZEPAM) (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007507351	03/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Cardiac failure (3d - 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 Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Sex (as per report)	Patient Status	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-1000750687	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Hypertension (3d - Fatal - Results in Death) Death (1d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000748003	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), 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-1000748164	02/02/2021	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-1000748257	02/02/2021	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 - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-1000748762	02/02/2021	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 - Intramuscular])	TRESIBA [INSULIN DEGLUDEC] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYL SALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE, LISINAPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL, CODEINE PHOSPHATE HEMHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000749032	02/02/2021	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 - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000749033	02/02/2021	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 - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007490618	02/02/2021	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 - [1d - n/a - Intramuscular])	[BUPRENORPHINE] (C - Pan - n/a - [n/a - 1(Df) - Cutaneous]), [CARBOMER, CARBOMER 980] (C - Dry eye - n/a - [n/a - 3(dsp) - Ophthalmic]), [LACTULOSE] (C - Constipation - n/a - [n/a - 40mL - Oral]), [PARACETAMOL] (C - Pan - n/a - [n/a - 3g - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Restlessness - n/a - [n/a - 25mg - Oral]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [n/a - 20(Df) - Oral]), [VITAMIN D] (C - n/a - n/a - [n/a - 40ug - n/a]), [LISINAPRIL] (C - n/a - n/a - [n/a - 5mg - Oral]), [METAZOLE SODIUM] (C - Analgesic therapy, Antiinflammatory therapy - n/a - [2d - 20(dsp) - Oral]), [METOCLOPRAMIDE HYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE MONOHYDRATE] (C - n/a - n/a - [1d - 20(dsp) - Oral]), [OXYCODONE HYDROCHLORIDE, NALOXONE HYDROCHLORIDE DIHYDRATE] (C - Analgesic therapy, Antiinflammatory therapy - n/a - [1d - 1(Df) - Oral]), [PARACETAMOL] (C - Analgesic therapy, Antiinflammatory therapy - n/a - [n/a - 500mg - Oral]), [QUETIAPINE] (C - Agitation - n/a - [2d - 25mg - Oral - More in ICSR]), [SULFAMETHOXAZOLE, TRIMETHOPRIM] (C - Antibiotic therapy - n/a - [n/a - 2(Df) - Oral]), [TAMBUSOLON HYDROCHLORIDE] (C - n/a - n/a - [n/a - 4mg - Oral]), [TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20(dsp) - Oral - More in ICSR]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-1000749076	02/02/2021	Spontaneous	Healthcare Professional	Non 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 - [1d - n/a - Intramuscular])	[BUPRENORPHINE] (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]), [DOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRALENTA 1 MG FILM-COATED TABLETS (RANGLUPTIN)] (C - n/a - n/a - [n/a - 5mg - n/a]), [BENSERAZIDE HYDROCHLORIDE, LEVODOPA, BENSERAZIDE, LEVODOPA] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CANOCANE HYDROCHLORIDE, PREDNISOLONE CAPROATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 800(U) - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [FERROUS SULFATE] (C - n/a - n/a - [n/a - 100mg - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 1mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - n/a]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTULOSE, LACTULOSE, LIQUID] (C - n/a - n/a - [n/a - n/a - n/a]), [MAGNESIUM CITRATE, MAGNESIUM LACTATE] (C - n/a - n/a - [n/a - 120mg - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [PROPYLENE GLYCOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOSULFATE, SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TOTROPOLIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007493759	02/02/2021	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 - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007494159	02/02/2021	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-10007494357	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Loss of consciousness (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007494983	02/02/2021	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 - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-1000749569	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Fatigue (n/a - Fatal - Results in Death) Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[CLOMETHAZOLE, CLOMETHAZOLE EDISILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOPICLONE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRALENTA 1 MG FILM-COATED TABLETS (RANGLUPTIN)] (C - n/a - n/a - [n/a - 5mg - n/a]), [BENSERAZIDE HYDROCHLORIDE, LEVODOPA, BENSERAZIDE, LEVODOPA] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 2.5mg - n/a]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CANOCANE HYDROCHLORIDE, PREDNISOLONE CAPROATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - 1(Df) - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - 800(U) - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [FERROUS SULFATE] (C - n/a - n/a - [n/a - 100mg - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 1mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - n/a]), [GLYCERYL TRINITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTULOSE, LACTULOSE, LIQUID] (C - n/a - n/a - [n/a - n/a - n/a]), [MAGNESIUM CITRATE, MAGNESIUM LACTATE] (C - n/a - n/a - [n/a - 120mg - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [PROPYLENE GLYCOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOSULFATE, SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TOTROPOLIUM BROMIDE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007499124	02/02/2021	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 - Immunisation - n/a - [n/a - 3mL - Intramuscular])	[RAMPRIL] (C - Left ventricular hypertrophy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007478374	01/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Adult	Male	No	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])	Not reported	ICSR
EU-EC-1000747939	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Pain in extremity (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007479649	01/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown -), Anal haemorrhage (n/a - Unknown -), Back pain (n/a - Recovered/Resolved -), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), Coma (n/a - Unknown - Other Medically Important Condition), Death (n/a - Fatal - Results in Death), General physical health deterioration (n/a - Unknown - Other Medically Important Condition), Heart rate decreased (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown -), Oxygen saturation decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition), Tachypnoea (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	[ACETYL SALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - Oral]), [HYDROXYCARBAMIDE] (C - Myeloproliferative neoplasm - n/a - [n/a - 1500mg - Oral]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [TORASEMIDE SODIUM] (C - n/a - n/a - [n/a - 100mg - Oral])	ICSR
EU-EC-10007480165	01/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), General physical condition abnormal (23d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007480253	01/02/2021	Spontaneous	Non 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-10007482017	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	[COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - Supplementation therapy - n/a - [n/a - n/a - Oral]), [MEMANTINE HYDROCHLORIDE] (C - Dementia Alzheimer's type - n/a - [n/a - n/a - Oral]), [OXAZEPAM] (C - Relaxation therapy, Sleep disorder - n/a - [n/a - n/a - Oral]), [MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ANTIPYRAMID, COMPOUND, DIMETICONE, DIMETICONE, COLLOIDAL SILICON DIOXIDE, DIMETICONE, SILICA, COLLOIDAL ANHYDROUS, SILICA, COLLOIDAL ANHYDROUS, DIMETICONE 1000] (C - n/a - n/a - [n/a - n/a - n/a]), [EPINEPHRINE BITARTRATE, LIDOCANE HYDROCHLORIDE, LIDOCANE, LIDOCANE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASON PROPRIONATE, FORMOTEROL FUMARATE DIHYDRATE, FLUTICASON PROPRIONATE, FORMOTEROL FUMARATE DIHYDRATE PHEUR] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCOPYRROLIUM BROMIDE, GLYCOPYRROLIUM BROMIDE, NEOSTIGMINE METHYLSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [HALOPERIDOL, HALOPERIDOL, DECANOATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MOMETASON FURATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOSULFATE, SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007486506	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Hypertensive emergency (n/a - Recovered/Resolved - Other Medically Important Condition), Pain (1d - Unknown - Other Medically Important Condition), Rales (1d - Unknown -), Somnolence (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1(Df) - n/a])	Not reported	ICSR
EU-EC-10007487006	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Productive cough (n/a - Fatal - Results in Death), Wheezing (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	[AZOPT (BRIZOLAMIDE)] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYL SALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - n/a]), [CITALOPRAM] (C - n/a - n/a - [n/a - 10mg - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [FENTANYL, FENTANYL CITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 1mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - n/a - n/a - [n/a - 100mg - n/a]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 50mg - n/a]), [MIDAZOLAM, MIDAZOLAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE, MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXYCODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [UREA] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007477308	31/01/2021	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 - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007473305	30/01/2021	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 - Drug withdrawn - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007473313	30/01/2021	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 - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007474006	30/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (23d - Fatal - Results in Death), Pyrexia (23d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [23d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007474085	30/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (5d - Fatal - Results in Death), General physical health deterioration (5d - Fatal - Results in Death), Influenza like illness (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007461769	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007461911	29/01/2021	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) - Intramuscular])	Not reported	ICSR
EU-EC-10007461984	29/01/2021	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 - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular])	Not reported	ICSR
EU-EC-10007463054	29/01/2021	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 - n/a])	Not reported	ICSR
EU-EC-10007463995	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not Specified	No	Body temperature increased (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), Malaise (n/a - Fatal - Results in Death), Tremor (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007465137	29/01/2021	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 - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007465136	29/01/2021	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 - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007467137	29/01/2021	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 - [n/a - 3mL - Intramuscular])	[KETOCONAZOLE [KETOCONAZOLE]] (C - n/a - n/a - [n/a - n/a - n/a]), [PROLIA [DENOSUMAB]] (C - n/a - n/a - [n/a - n/a - n/a]), [RESOLOR [PRILICAFIPRI]] (C - n/a - n/a - [n/a - n/a - n/a]), [BENSERAZIDE HYDROCHLORIDE, LEVODOPA, BENSERAZIDE, LEVODOPA] (C - n/a - n/a - [n/a - n/a - n/a]), [BUPRENORPHINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBIDOPA, LEVODOPA] (C - n/a - n/a - [n/a - n/a - n/a]), [CLOZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - n/a - n/a])	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 (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
												[DOCUSATE SODIUM, SORBITOL (E409)] (C - n/a - n/a - [n/a - n/a - n/a]), [ECONAZOLE ECONAZOLE NITRATE, ECONAZOLE NITRATE, ZINC OXIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIDODORINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [POTASSIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PROPYLENE GLYCOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CHLORHEXIDINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CTALOPRAM] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTULOSE, LACTULOSE LIQUID] (C - n/a - n/a - [n/a - 20mL - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 50ug - n/a]), [MEMANTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - n/a]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - 25mg - n/a]), [SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL (E402), SODIUM LAURYL SULFOACETATE, SODIUM CITRATE DIPHOSPHATE] (C - n/a - n/a - [n/a - n/a - Rectal]), [SODIUM FLUORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TMOLOL, PLOLCARPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [TMOLOL] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10007467491	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])		ICSR
EU-EC-10007470767	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Death (01 - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007471240	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1[DF] - n/a])	Not reported	ICSR
EU-EC-10007451396	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-10007452321	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007452962	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007456651	28/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (74 - Fatal - Results in Death, Other Medically Important Condition), Influenza like illness (74 - Fatal - Results in Death, Other Medically Important Condition)	COMRNNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10007458677	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	FIASP [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), TRESIBA [INSULIN DEGLUDEC] (C - n/a - n/a - [n/a - n/a - n/a]), [ATENOLOL, ATENOLOL BP] (C - n/a - n/a - [n/a - n/a - n/a]), [DONEPEZIL] (C - n/a - n/a - [n/a - n/a - n/a]), [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LOPERAMIDE HYDROCHLORIDE, LOPERAMIDE OXIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMINE, PYRIDOXINE HYDROCHLORIDE, VITAMIN B] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007440963	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-10007440968	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - Intramuscular])	[AMOCICILIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 200mg - Oral]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - 1.25mg - Oral]), [FLUNDIONE] (C - n/a - n/a - [n/a - Oral]), [FLUTICASONO PROPIONATE, SALMETEROL, FLUTICASONO PROPIONATE, SALMETEROL XINAFOATE] (C - n/a - n/a - [n/a - n/a - Respiratory (inhalation)]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - Oral]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [MORPHINE SULFATE] (C - n/a - n/a - [n/a - n/a - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - n/a - Oral]), [STERCULIA, STERCULIA GUM, STERCULIA URENS ROXB. GUM] (C - n/a - n/a - [n/a - n/a - Rectal]), [ALPRAZOLAM] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [STERCULIA, STERCULIA GUM, STERCULIA URENS ROXB. GUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LIXIANA, EDOXABAN, EDOXABAN TOSYLATE] (C - n/a - n/a - Dose not changed - [n/a - 30mg - n/a]), [COLECALCIFEROL] (C - n/a - n/a -), [FOLIC ACID] (C - n/a - n/a - Dose not changed -), [FUROSEMIDE] (C - n/a - n/a - Dose not changed - [n/a - 20mg - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - Dose not changed - [n/a - 50mg - n/a]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - n/a - n/a - Dose not changed - [n/a - 12mg - n/a]), [CLOPIDOGREL, CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - Dose not changed - [n/a - 75mg - n/a]), [LORAZEPAM] (C - n/a - n/a - Dose not changed - [n/a - 2.5mg - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - Dose not changed - [n/a - 50mg - n/a]), [CANDESARTAN CILEXETIL] (C - n/a - n/a - Dose not changed - [n/a - 8mg - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - Dose not changed - [n/a - 12.5mg - n/a]), FENTANYL, FENTANYL CITRATE] (C - n/a - n/a - [n/a - n/a - Unknown]), PANTOPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUHYDRATE] (C - n/a - n/a - [n/a - n/a - Unknown]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - Unknown]), [CALCIUM CITRATE, MAIZE STARCH, STEARIC ACID, TALC, CALCIUM CITRATE] (C - n/a - n/a - [n/a - n/a - Unknown]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - Unknown]), [ENOXAPARIN SODIUM] (C - n/a - n/a - [n/a - n/a - Unknown]), [FOLIC ACID, DRIED FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - Unknown]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - Unknown]), [ROSUVASTATIN CALCIUM] (C - n/a - n/a - [n/a - n/a - Unknown]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - n/a - Unknown])	ICSR
EU-EC-10007441212	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Increased bronchial secretion (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular]), [FENTANYL] (S - Pain - Dose not changed - [n/a - 0.12mg - Transdermal])		ICSR
EU-EC-10007444663	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMRNNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1[DF] - n/a])		ICSR
EU-EC-10007444664	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening), Fatigue (n/a - Fatal - Results in Death, Life Threatening), Somnolence (n/a - Fatal - Results in Death, Life Threatening)	COMRNNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1[DF] - n/a])		ICSR
EU-EC-10007444862	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Death (n/a - Fatal - Results in Death, Life Threatening)	COMRNNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1[DF] - n/a])		ICSR
EU-EC-10007444951	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (01 - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])		ICSR
EU-EC-10007445203	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [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	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 3mL - Subcutaneous])	Not reported	ICSR
EU-EC-10007445410	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Death (01 - Fatal - Results in Death), General physical condition abnormal (01 - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007446819	27/01/2021	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 - Recovered/Resolved -)	COMRNNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007446863	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3mL - Intramuscular])		ICSR
EU-EC-10007446873	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [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	No	Death (n/a - Fatal - Results in Death), Fatigue (n/a - Fatal - Results in Death), Productive cough (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FNASTERIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [DIXYDOLONE, 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])	ICSR
EU-EC-10007431098	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (11 - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - Intramuscular])	JANUVA 100 MG FILM-COATED TABLETS [SITAGLIPTIN] (C - n/a - n/a - [n/a - n/a - Oral]), MIMPARA 30 MG FILM-COATED TABLETS [SINACALCET, ONACALCET HYDROCHLORIDE] (C - n/a - n/a - [n/a - 30mg - Oral]), [AMOXICILIN SODIUM, CLAVULANIC ACID, AMOXICILIN TRHYDRATE, CLAVULANIC ACID, AMOXICILIN TRHYDRATE, POTASSIUM CLAVULANATE, AMOXICILIN, CLAVULANIC ACID, AMOXICILIN, POTASSIUM CLAVULANATE] (C - n/a - n/a - [n/a - 1g - Oral]), [ATORVASTATIN, ATORVASTATIN CALCIUM] (C - n/a - n/a - [n/a - 20mg - Oral]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [DEXAMETHASONE SODIUM PHOSPHATE] (C - n/a - n/a - [n/a - 6mg - Oral]), [SODIUM PHOSPHATE, ANHYDROUS, CALCIUM MAGNESIUM GLYCEROPHOSPHATE, PHOSPHORIC ACID CONCENTRATED, DISODIUM PHOSPHATE, ANHYDROUS, MAGNESIUM GLYCEROPHOSPHATE, PHOSPHORIC ACID CONCENTRATED, CALCIUM BISDIHYDROGENPHOSPHATE MONOHYDRATE, DISODIUM PHOSPHATE, MAGNESIUM GLYCEROPHOSPHATE, PHOSPHORIC ACID CONCENTRATED, CALCIUM BISDIHYDROGENPHOSPHATE, MONOHYDRATE] (C - n/a - n/a - [n/a - 5000 - Oral]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 5mg - Oral]), [OXAZEPAM] (C - n/a - n/a - [n/a - 10mg - Oral]), [PANTOPRAZOLE SODIUM SESQUHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral]), [TINZAPARIN, TINZAPARIN SODIUM] (C - Atrial fibrillation - n/a - [n/a - 7mL - Subcutaneous])	ICSR
EU-EC-10007431167	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [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	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-10007431178	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death), Pyrexia (n/a - Not Recovered/Not Resolved - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - Intramuscular])	Not reported	ICSR
EU-EC-10007431600	26/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	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])	[BECLOMETHASONE DIPROPIONATE, FORMOTEROL FUMARATE, BECLOMETHASONE DIPROPIONATE, FORMOTEROL FUMARATE DIHYDRATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [LOPERAMIDE, LOPERAMIDE HYDROCHLORIDE] (C - Diarrhoea - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Reflux gastritis - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007431613	26/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Drug ineffective (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[RIVASTIGMINE, RIVASTIGMINE, RIVASTIGMINE HYDROGEN TARTRATE] (C - Parkinson's disease - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007433063	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	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)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007433980	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])		ICSR
EU-EC-10007422315	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (01 - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007422470	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Agitation (2d - Fatal - Results in Death), Death (01 - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1[DF] - n/a])	Not reported	ICSR
EU-EC-10007423215	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death), Circulatory collapse (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007423213	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Death (01 - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007423221	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Male	No	Death (01 - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007423266	25/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Asthma (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)	COMRNNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007427048	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death)	COMRNNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1[DF] - n/a])	ADENURIC 80 MG FILM-COATED TABLETS [PEBUXOSTATIN] (C - n/a - n/a - [n/a - 1[DF] - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - 1[DF] - 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 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	
											NOVOMIX 30 PENFILL [INSULIN ASPART, INSULIN ASPART, INSULIN ASPART PROTAMINE] (C - n/a - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - 50DF - n/a]), [BETAMETHASONE DIPHOSPHATE, GENTAMICIN, BETAMETHASONE DIPHOSPHATE, GENTAMICIN SULFATE, GENTAMICIN SULFATE, BETAMETHASONE DIPHOSPHATE (PH. EUR.), GENTAMICIN, BETAMETHASONE] (C - n/a - n/a - [n/a - n/a - n/a]), [CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 1DF] - n/a), [CLOPIDOGREL] (C - n/a - n/a - [n/a - 1DF] - n/a), [D-LIMONENE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE, CANDESARTAN CILEXETIL] (C - n/a - n/a - [n/a - 1DF] - n/a), [HYDROXYZINE DIHYDROCHLORIDE, HYDROXYZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1DF] - n/a), [HYDROMELLOSE] (C - n/a - n/a - [n/a - 155g] - n/a), [LIQUID PARAFFIN] (C - n/a - n/a - [n/a - n/a - n/a]), [MELALEUCA ALTERNIFOLIA OIL] (C - n/a - n/a - [n/a - n/a - n/a]), [METHYLPREDNISOLONE, METHYLPREDNISOLONE ACETATE, METHYLPREDNISOLONE SODIUM HEMISUCCLATE] (C - Ecema - n/a - [n/a - 50DF] - n/a), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 1DF] - n/a), [SOYA BEAN OIL REFINED PH.EUR., SOYA OIL, SOYA-BEAN OIL REFINED] (C - n/a - n/a - [n/a - n/a - n/a]), [VASSALINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
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 - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000740308	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 - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000740313	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 - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1000740342	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 - [n/a - n/a - Intramuscular])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), RIBAROXABAN [RIBAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), SITAGLIPTIN [SITAGLIPTIN] (C - n/a - n/a - [n/a - n/a - n/a]), [DIGITOXIN] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [LORAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [METAMIZOLE, METAMIZOLE MAGNESIUM, METAMIZOLE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [TORASEMIDE] (C - n/a - n/a - [n/a - n/a - n/a])	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 -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007403754	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Not Specified	No	Death (n/a - Fatal - Results in Death), Malaise (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007404231	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 - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007404276	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 - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007404543	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), Nausea (n/a - Unknown - Results in Death, Caused/Not Resolved)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007410192	22/01/2021	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 - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007410538	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 - [n/a - n/a - Intramuscular])	[BUPRENORPHINE] (C - Pain - n/a - [n/a - 1DF] - Cutaneous), [CARBOMER, CARBOMER 980] (C - Dry eye - n/a - [n/a - n/a - Ophthalmic]), [LACTULOSE] (C - Constipation - n/a - [n/a - 20mL - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1g - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - Restlessness - n/a - [n/a - 25mg - Oral]), [SODIUM PICOSULFATE] (C - Constipation - n/a - [n/a - 20DF] - Oral), [VITAMIN D] (C - n/a - n/a - [n/a - 40ug - n/a])	ICSR
EU-EC-10007411429	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/Not Resolved)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007411430	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/Not Resolved)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007411431	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/Not Resolved)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007380408	20/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Asystole (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-10007389528	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 - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007375096	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 - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007376224	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 - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007376516	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Death (1d - Fatal - Results in Death), Hypotension (n/a - Fatal - Results in Death), Livedo reticularis (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Peripheral oedema (n/a - Fatal - Results in Death), Respiratory rate increased (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Subcutaneous])	BUMETANIDE [BUMETANIDE] (C - n/a - n/a - [n/a - n/a - n/a]), MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CASSIA] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCERFOL] (C - n/a - n/a - [n/a - n/a - n/a]), [DIMETICONE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOCUSATE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXYCYCLINE HYCLATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM BICARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL, CODEINE PHOSPHATE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [TRAMADOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRICETIN] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - 40mg - n/a]), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a - [n/a - 20mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 75ug - n/a]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 100mg - n/a]), [XAZEPAM] (C - n/a - n/a - [n/a - 5mg - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007378976	19/01/2021	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 - Intramuscular])	[AERIS 5 MG FILM-COATED TABLET [DESLOXATADINE] (C - n/a - n/a - [n/a - 5mg - n/a]), ARANESP 30 MICROGRAMS SOLUTION FOR INJECTION IN A PRE-FILLED SYRINGE [DARBEPOETIN ALFA] (C - n/a - n/a - [n/a - 1DF] - n/a), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - 100mg - n/a]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOMER] (C - n/a - n/a - [n/a - n/a - n/a]), [DILTIAZEM SODIUM] (C - n/a - n/a - [n/a - 1DF] - n/a), [FINASTERIDE] (C - n/a - n/a - [n/a - 5mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 250mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCERYL TRINITRATE, GLYCERYL TRINITRATE SOLUTION 10 %] (C - n/a - n/a - [n/a - n/a - n/a]), [GLYCOPHYRRIUM BROMIDE] (C - n/a - n/a - [n/a - 1mL - n/a]), [HALOPERIDOL] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROMELLOSE] (C - n/a - n/a - [n/a - n/a - n/a]), [LATANOPROST] (C - n/a - n/a - [n/a - n/a - n/a]), [MIDAZOLAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MORPHINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 10mg - n/a]), [XAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PICOSULFATE, SODIUM PICOSULFATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM PANTOTHENATE, SODIUM PANTOTHENATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TRESIBA [INSULIN DEGLIBEC] (C - n/a - n/a - n/a)], [ACETYLSALICYLIC ACID] (C - n/a - n/a -), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a -), [HYDROCHLOROTHIAZIDE, LISINAPRIL, HYDROCHLOROTHIAZIDE, LISINAPRIL ANHYDROUS, LISINAPRIL DIHYDRATE, HYDROCHLOROTHIAZIDE] (C - n/a - n/a -), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a -), [PARACETAMOL, CODEINE PHOSPHATE HEMHYDRATE] (C - n/a - n/a -), [ZOPICLONE] (C - n/a - n/a -)	ICSR
EU-EC-10007362992	17/01/2021							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 - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007357481	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)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/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	Vomiting (n/a - Unknown - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1DF] - Intramuscular)	Not reported	ICSR
EU-EC-10007346524	14/01/2021	Spontaneous	Non Healthcare Professional	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-10007346983	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 - [n/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 - [n/a - 1DF] - Intramuscular)	ELIQUIS [APIXIBAN] (C - Thrombosis prophylaxis - n/a - [n/a - 5mg - Oral]), [ATORVASTATIN] (C - Cardiovascular event prophylaxis - n/a - [n/a - 80mg - Oral]), [DONEPEZIL HYDROCHLORIDE] (C - Dementia - n/a - [n/a - 10mg - Oral]), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - Heart rate irregular - n/a - [n/a - 25mg - Oral]), [RISPERIDONE] (C - Aggression - n/a - [n/a - 25mg - Oral]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - 50mg - Oral]), [TAMSULOSIN HYDROCHLORIDE] (C - Dysuria - n/a - [n/a - 4mg - Oral])	ICSR
EU-EC-1000733563	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 - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007335395	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/Not Resolved), Circulatory collapse (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Resolved), Death (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Resolved), Resuscitation (n/a - Fatal - Results in Death, Life Threatening, Caused/Not Resolved)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007338366	12/01/2021	Spontaneous	Healthcare Professional	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)	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	Vomiting (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])	[CARVEDILOL] (C - n/a - n/a - [n/a - 25mg - n/a]), [GTALOPRAM, GTALOPRAM HYDROBROMIDE, GTALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - 20mg - 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 Sex (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
												[COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - 1000] - n/a), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a] - n/a), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 100ug - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - 1000mg - n/a]), [UREA] (C - n/a - n/a - [n/a - n/a] - n/a), [WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-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 [TOZNAMERAN] (S - Immunisation - n/a - [n/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 [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	BETMIGA [MIRABEGRON] (C - n/a - Not applicable - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - Not applicable - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [CIPROFLOXACIN, CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [COLECALCIFEROL, CYANOCOBALAMIN, ERGOCALCIFEROL, RETINOL ACETATE, ERGOCALCIFEROL, TOCOPHERYL ACETATE] (C - n/a - Unknown -), [CYNOCOBALAMIN] (C - n/a - Not applicable - [n/a - n/a - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [ESTRADIOL, ESTRADIOL HEMIHYDRATE] (C - n/a - Not applicable -), [FOLIC ACID] (C - n/a - Not applicable - [n/a - n/a - n/a]), [LACTOBACILLUS ACIDOPHILUS, BIFIDOBACTERIUM SPP.] (C - n/a - Not applicable -), [NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - n/a - Not applicable -), [OXAZEPAM] (C - n/a - Not applicable - [n/a - n/a - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - Not applicable - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - Not applicable -)	
EU-EC-10007308259	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 [TOZNAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007298416	05/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZNAMERAN] (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 85 Years	Elderly	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Influenza like illness (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZNAMERAN] (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 [TOZNAMERAN] (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 [TOZNAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR