

Line Listing Report

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EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	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-10007728929	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chest discomfort (1d - Recovered/Resolved -), Chest pain (1d - Recovered/Resolved -), Cranial nerve paralysis (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007729157	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (1d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007730376	26/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved - Disabling), Dry eye (n/a - Unknown -), Dysphagia (n/a - Recovering/Resolving -), Eye pain (n/a - Unknown -), Facial paralysis (n/a - Recovering/Resolving - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Feeling abnormal (n/a - Not Recovered/Not Resolved - Disabling), Hyperhidrosis (n/a - Recovered/Resolved -), Hypertension (n/a - Unknown -), Lymph node pain (n/a - Unknown -), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Disabling), Malaise (n/a - Unknown -), Pain (n/a - Recovering/Resolving - Disabling), Pyrexia (n/a - Not Recovered/Not Resolved - Disabling), Visual impairment (n/a - Recovering/Resolving -), Vocal cord disorder (n/a - Not Recovered/Not Resolved - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007732288	26/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovered/Resolved -), Neuralgia (n/a - Not Recovered/Not Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Occipital neuralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved -), Vision blurred (n/a - Not Recovered/Not Resolved -)			
EU-EC-10007732360	26/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Mobility decreased (n/a - Unknown - Disabling), Muscle rupture (n/a - Unknown - Disabling), Off label use (n/a - Unknown -), Pain (n/a - Unknown - Disabling), Pain in extremity (n/a - Not Recovered/Not Resolved - Disabling), Paresis (n/a - Not Recovered/Not Resolved - Disabling), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007732406	26/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (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-10007732474	26/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [GABAPENTIN] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINOPRIL, LISINOPRIL DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007732494	26/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Hypoaesthesia oral (n/a - Recovering/Resolving -), Paraesthesia oral (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007733264	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - n/a - Unknown -)	ICSR
EU-EC-10007734753	26/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Depressed level of consciousness (20min - Recovered/Resolved - Other Medically Important Condition), Facial paresis (20min - Recovered/Resolved - Other Medically Important Condition), Feeling abnormal (20min - Recovered/Resolved - Other Medically Important Condition), Paraparesis (20min - Recovered/Resolved - Other Medically Important Condition), Paresis (20min - Recovered/Resolved - Other Medically Important Condition), Presyncope (0d - Recovered/Resolved - Other Medically Important Condition), Vomiting (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007736487	26/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Hypoaesthesia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Hypoaesthesia oral (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[TERBUTALINE SULFATE, TERBUTALINE SULFATE PH. EUR.] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR

										Disabling, Other Medically Important Condition), Lacrimation increased (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)			
EU-EC-10007718305	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Circulatory collapse (n/a - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (1d - Recovered/Resolved - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Paraesthesia (1d - Recovered/Resolved -), Poor quality product administered (n/a - Unknown - Other Medically Important Condition), Presyncope (n/a - Unknown - Other Medically Important Condition), Product temperature excursion issue (n/a - Unknown - Other Medically Important Condition), Seizure (26d - Recovered/Resolved - Other Medically Important Condition), Somatic symptom disorder (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Recovered/Resolved - Other Medically Important Condition), Vertigo (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007718817	25/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Drug hypersensitivity (8d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (8d - Recovered/Resolved - Other Medically Important Condition), Feeling cold (n/a - Recovered/Resolved - Other Medically Important Condition), Myalgia (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination site pruritus (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination site rash (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007718837	25/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Diarrhoea (1d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (1d - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Migraine (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Arthralgia - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a]), [GLYCEROL, DOCONEXENT, ICOSAPENT, ALPHA-TOCOPHEROL (PH. EUR.)] (C - Flatulence - n/a - [n/a - n/a - n/a])	ICSR

EU-EC-10007723747	25/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	[n/a - n/a - n/a] TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007723756	25/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cerebrovascular accident (n/a - Unknown - Disabling), Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007723783	25/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [BENDROFLUAZIDE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007723790	25/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Male	No	Facial paralysis (21d - Recovered/Resolved - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007724056	25/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Swelling face (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007725665	25/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	3-11 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Off label use (n/a - Unknown -), Product administered to patient of inappropriate age (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007725916	25/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown -), Pain (n/a - Unknown -), Paraesthesia (n/a - Unknown -), Sensitive skin (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007726455	25/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007726894	25/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Burning sensation (n/a - Recovering/Resolving - Other Medically Important Condition), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling abnormal (n/a - Unknown - Other Medically Important Condition), Hypoesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (n/a -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ALPRAZOLAM] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Recovering/Resolving - Other Medically Important Condition), Vision blurred (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10007703272	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[AMLODIPINE] (C - Hypertension - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007704300	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (1d - Recovered/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007705276	24/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (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-10007707698	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Diplopia (n/a - Recovering/Resolving - Disabling), Disease recurrence (n/a - Unknown - Disabling, Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Disabling), Nausea (n/a - Recovering/Resolving - Disabling), Vith nerve paralysis (n/a - Unknown - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ACETYSALICYLIC ACID] (C - III-defined disorder - n/a - [n/a - 1{DF} - n/a])	ICSR
EU-EC-10007709814	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Facial paralysis (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-10007710832	24/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Drooling (n/a - Unknown - Other Medically Important Condition), Eye disorder (n/a - Unknown - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza (n/a - Unknown - Other Medically Important Condition), Lacrimation increased (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown -), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Product use issue (n/a - Unknown -), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	HUMALOG [INSULIN LISPRO] (C - Type 1 diabetes mellitus - n/a - [n/a - n/a - n/a]), MYCOPHENOLATE MOFETIL [MYCOPHENOLATE MOFETIL] (C - Renal transplant - n/a - [n/a - 1000mg - n/a]), [INSULIN HUMAN ISOPHANE] (C - Type 1 diabetes mellitus - n/a - [n/a - n/a - n/a]), [TACROLIMUS] (C - Renal transplant - n/a - [n/a - 10mg - n/a])	ICSR
EU-EC-10007710925	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovered/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007711242	24/02/2021	Spontaneous	Non Healthcare	Non European	Not available	18-64 Years	Not Specified	Female	No	Eyelid ptosis (0d - Recovered/Resolving - Other	TOZINAMERAN [TOZINAMERAN]	[CLOBETASONE BUTYRATE] (C - Lichen planus - n/a - [n/a - n/a -	ICSR

			Professional	Economic Area						Medically Important Condition), Facial paralysis (0d - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Miosis (0d - Recovered/Resolved - Other Medically Important Condition), Mydriasis (0d - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving -)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	n/a)), [CODEINE PHOSPHATE BP, PARACETAMOL PH. EUR., PARACETAMOL, CODEINE PHOSPHATE] (C - Arthralgia - n/a - [n/a - n/a - n/a])	
EU-EC-10007712404	24/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID] (C - Anticoagulant therapy - n/a - [n/a - n/a - n/a]), [ATORVASTATIN CALCIUM] (C - Blood cholesterol increased - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Cardiac disorder - n/a - [n/a - n/a - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 20mg - n/a])	ICSR
EU-EC-10007713028	24/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Erythema (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling hot (n/a - Not Recovered/Not Resolved -), Red ear syndrome (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007713615	24/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Deafness (n/a - Unknown - Other Medically Important Condition), IIIrd nerve paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007713868	24/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Diplopia (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), VIth nerve paralysis (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - Polycythaemia - n/a - [n/a - n/a - Oral]), [ALFUZOSIN HYDROCHLORIDE] (C - Benign prostatic hyperplasia - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10007715094	24/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Paresis (5d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007692604	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[ASCORBIC ACID, FOLIC ACID, DRIED FERROUS SULFATE] (C - Anaemia - n/a - [n/a - 105mg - Oral])	ICSR
EU-EC-10007693581	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling), Swelling face (n/a - Not Recovered/Not Resolved - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007693591	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling face (n/a - Unknown - Other Medically Important Condition), Tinnitus (n/a - Not Recovered/Not Resolved - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ALENDRONATE SODIUM, ALENDRONIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ANHYDROUS METHYLDOPA, METHYLDOPA] (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]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

EU-EC-10007694574	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paresis (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-10007694711	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Transient ischaemic attack (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-10007695528	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paralysis (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-10007695545	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paralysis (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-10007697154	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007698021	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (1d - Recovering/Resolving - Other Medically Important Condition), Hypoaesthesia (1d - Recovered/Resolved -), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007698061	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Asthenia (24h - Recovered/Resolved -), Blood pressure increased (24h - Recovered/Resolved -), Chest pain (24h - Recovered/Resolved -), Decreased appetite (24h - Recovered/Resolved -), Dyspnoea (24h - Recovered/Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (24h - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007698476	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ALPHATOCOPHEROL ACETATE, LUTEIN] (C - n/a - n/a - [n/a - n/a - n/a]), [CELECOXIB] (C - n/a - n/a - [n/a - n/a - n/a]), [ESTRADIOL] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL SUCCINATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007698506	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Hypoaesthesia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007699200	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR

EU-EC-10007699887	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Clonic convulsion (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Dysgeusia (n/a - Recovered/Resolved - Disabling), Pyrexia (n/a - Recovered/Resolved - Disabling), Seizure (n/a - Unknown - Disabling, Other Medically Important Condition), Sleep paralysis (n/a - Recovered/Resolved With Sequelae - Disabling), Tongue biting (n/a - Unknown - Disabling)	n/a - Intramuscular) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	UMECLIDINIUM BROMIDE [UMECLIDINIUM BROMIDE] (C - Asthma-chronic obstructive pulmonary disease overlap syndrome - n/a - [n/a - n/a - n/a]), [INFLUENZA VIRUS] (C - n/a - n/a - [1d - n/a - n/a]), [MIRTAZAPINE] (C - Depressed mood - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma-chronic obstructive pulmonary disease overlap syndrome - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007701254	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Peripheral paralysis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007701371	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007701388	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10007701548	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Hypertension (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-10007701551	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Ear pain (n/a - Unknown -), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007702339	23/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE] (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]), [METOPROLOL, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007702378	23/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC-10007702475	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007680992	22/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Diplopia (n/a - Unknown -), Dry mouth (n/a - Unknown -), Dysarthria (n/a - Unknown -), Eye oedema (n/a - Unknown -), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Lacrimation increased (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR

EU-EC-10007681111	22/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Dysphagia (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Hypoaesthesia (n/a - Unknown -), Lack of spontaneous speech (n/a - Unknown -), Paraesthesia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007681135	22/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oedema (n/a - Recovered/Resolved - Other Medically Important Condition), Oedema peripheral (n/a - Unknown - Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown - Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other Medically Important Condition), Paraesthesia oral (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BACILLUS CALMETTE-GUERIN VACCINE] (C - n/a - n/a - [1d - n/a - n/a]), [INFLUENZA VIRUS] (C - n/a - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10007681960	22/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Chills (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Transient ischaemic attack (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	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]), [EZETIMIBE] (C - n/a - n/a - [n/a - n/a - n/a]), [MOMETASONE] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007683929	22/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007684440	22/02/2021	Spontaneous	Non Healthcare	European Economic	Not available	More than 85	Not Specified	Female	No	Cerebrovascular accident (n/a - Not Recovered/Not Resolved)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

			Professional	Area		Years				- Disabling), Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling)	(S - n/a - n/a - [n/a - n/a - n/a])		
EU-EC-10007686195	22/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Hypoesthesia (n/a - Not Recovered/Not Resolved -), Lymph node pain (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007686352	22/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007689860	22/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (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-10007690817	22/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Disorientation (n/a - Unknown - Other Medically Important Condition), Facial paralysis (2d - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Feeling abnormal (2d - Recovered/Resolved With Sequelae - Other Medically Important Condition), Headache (1d - Recovered/Resolved - Other Medically Important Condition), Presyncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a]), [NITROFURANTOIN] (C - Antibiotic prophylaxis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007691623	22/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007691632	22/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (1d - Recovered/Resolved -), Paresis (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR])	Not reported	ICSR
EU-EC-10007680088	21/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007676528	20/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Anaesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Cranial nerve paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007677010	20/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

											immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC-10007677015	20/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007677049	20/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (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-10007677185	20/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Aphthous ulcer (n/a - Recovered/Resolved -), Facial paralysis (n/a - Recovering/Resolving -), Myalgia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007678494	20/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007661727	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	No	Facial paralysis (n/a - Unknown -), Injection site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007661871	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Bone pain (1d - Recovered/Resolved -), Facial paralysis (1d - Recovered/Resolved -), Feeling cold (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Hyperpyrexia (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Puncture site pain (1d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007662548	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Unknown -), Paraesthesia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Dose not changed - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007662879	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown -), Injection site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007662946	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cerebral haemorrhage (5d - Fatal - Results in Death), Facial paralysis (5d - Fatal - Results in Death), Monoplegia (5d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007663856	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Facial paralysis (8d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007663874	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007663919	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebellar stroke (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007664223	19/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Myalgia (n/a - Recovering/Resolving -), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10007664374	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007664813	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovered/Resolving - Other Medically Important Condition), Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007664846	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007665392	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007665715	19/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Dysgeusia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Neck pain (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Speech disorder (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-10007667472	19/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Choluria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Deficiency of bile secretion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hyperbilirubinaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Jaundice (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										<p>Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),</p> <p>Sensitive skin (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),</p> <p>Transaminases increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),</p> <p>Vaccination site pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)</p>			
EU-EC-10007667489	19/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Body temperature decreased (n/a - Not Recovered/Not Resolved -),</p> <p>Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Headache (n/a - Not Recovered/Not Resolved -),</p> <p>Odynophagia (n/a - Not Recovered/Not Resolved -),</p> <p>Pain (n/a - Not Recovered/Not Resolved -),</p> <p>Paraesthesia (n/a - Not Recovered/Not Resolved -),</p> <p>Pruritus (n/a - Not Recovered/Not Resolved -),</p> <p>Sensitive skin (n/a - Not Recovered/Not Resolved -),</p> <p>Vaccination site pain (n/a - Not Recovered/Not Resolved -)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007669824	19/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Dry mouth (n/a - Unknown - Other Medically Important Condition),</p> <p>Ear pain (n/a - Unknown - Other Medically Important Condition),</p> <p>Eye disorder (n/a - Unknown - Other Medically Important Condition),</p> <p>Facial pain (n/a - Unknown - Other Medically Important Condition),</p> <p>Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Hypoaesthesia oral (n/a - Unknown - Other Medically Important Condition),</p> <p>Paraesthesia oral (n/a - Unknown - Other Medically Important Condition)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	<p>ESOMEPRAZOLE [ESOMEPRAZOLE] (C - Gastritis - n/a - [n/a - n/a - n/a]),</p> <p>[CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Depressed mood - n/a - [n/a - n/a - n/a]),</p> <p>[DIHYDROCODEINE TARTRATE, PARACETAMOL, PARACETAMOL BP, DIHYDROCODEINE TARTRATE BP, PARACETAMOL, DIHYDROCODEINE TARTRATE BP] (C - Pain - n/a - [n/a - n/a - n/a]),</p> <p>[PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a])</p>	ICSR
EU-EC-10007669825	19/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Arthralgia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),</p> <p>Chills (n/a - Unknown - Disabling, Other Medically Important Condition),</p> <p>Decreased appetite (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),</p> <p>Facial paralysis (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition),</p> <p>Facial spasm (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition),</p> <p>Feeling abnormal (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),</p> <p>Heart rate increased (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),</p> <p>Hyperhidrosis (n/a - Recovering/Resolving -)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Disabling, Other Medically Important Condition), Malaise (n/a - Unknown - Disabling, Other Medically Important Condition), Nausea (1h - Recovered/Resolved - Disabling, Other Medically Important Condition), Pruritus (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Respiration abnormal (n/a - Unknown - Disabling, Other Medically Important Condition), Vaccination site pain (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Vaccination site swelling (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)			
EU-EC-10007669919	19/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved -), Inflammation (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -), Oedema (n/a - Recovered/Resolved -), Pain (n/a - Recovered/Resolved -), Sensitive skin (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007671835	19/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Diaphragmatic paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Phrenic nerve injury (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	BONE UP [ASCORBIC ACID, COLECALCIFEROL, COPPER GLUCONATE, CYANOCOBALAMIN, DURAPATITE, FOLIC ACID, GLUCOSAMINE HYDROCHLORIDE, MAGNESIUM OXIDE, MANGANESE SULFATE, PHYTOMENADIONE, SODIUM BORATE DECAHYDRATE, ZINC AMINO ACID CHELATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CLONAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007672024	19/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007672274	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Neuralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	COSENTYX [SECUKINUMAB] (C - n/a - n/a -)	ICSR
EU-EC-10007672849	19/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007673403	19/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Facial paralysis (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

										Condition), Herpes simplex (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Scar (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10007673708	19/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (10d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007674553	19/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007648927	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cranial nerve paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007648938	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007649088	18/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Hot flush (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007650224	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -), Paresis (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007650320	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Blister (n/a - Recovering/Resolving - Other Medically Important Condition), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10007650889	18/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [BACILLUS CALMETTE-GUERIN VACCINE] (S - n/a - Not applicable - [n/a - n/a - n/a])	ESOMEPRAZOLE [ESOMEPRAZOLE] (C - Gastroesophageal reflux disease - n/a - [n/a - n/a - n/a]), [BECLOMETASONE DIPROPIONATE] (C - Asthma-chronic obstructive pulmonary disease overlap syndrome - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a]), [MOMETASONE] (C - Sinusitis - n/a - [n/a - n/a - n/a]), [PARACETAMOL, CODEINE PHOSPHATE] (C - Sinus pain - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007650893	18/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007653768	18/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007655127	18/02/2021	Spontaneous	Healthcare Professional	European Economic	Not available	65-85 Years	Elderly	Female	No	Facial paralysis (1wk - Unknown -),	COMIRNATY [TOZINAMERAN]	TOLURA [TELMISARTAN] (C - n/a - n/a - [n/a - 40mg - n/a]),	ICSR

				Area						Headache (1wk - Unknown -), Injection site pain (1wk - Unknown -)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	TRIMBOW [BECLOMETASONE DIPROPIONATE, GLYCOPYRRONIUM BROMIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - 100mg - n/a]), [ALLOPURINOL] (C - n/a - n/a - [n/a - 100mg - n/a]), [AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [BIOFLAVONOIDS, DIOSMIN, HESPERIDIN, MICRONISED PURIFIED FLAVONOIC FRACTION] (C - n/a - n/a - [n/a - 500mg - n/a]), [BROMAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUVASTATIN SODIUM] (C - n/a - n/a - [n/a - 80mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 40mg - n/a]), [IBUPROFEN, IBUPROFEN BP, IBUPROFEN LYSINE, IBUPROFEN, CODEINE PHOSPHATE HEMIHYDRATE] (C - n/a - n/a - [n/a - 400mg - n/a]), [TOPRIDIDE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 50mg - n/a]), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - 100mg - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 40mg - n/a])	
EU-EC-10007656207	18/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Disturbance in attention (5d - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Hallucination (n/a - Unknown - Other Medically Important Condition), Hypoaesthesia (n/a - Recovering/Resolving -), Memory impairment (5d - Recovering/Resolving -), Visual impairment (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ATORVASTATIN] (C - Blood cholesterol increased - n/a - [n/a - n/a - n/a]), [EZETIMIBE] (C - Blood cholesterol increased - n/a - [n/a - n/a - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007657739	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Facial paralysis (10d - Recovered/Resolved - Other Medically Important Condition), Paraesthesia (10d - Recovered/Resolved -), Vision blurred (10d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	HUMALOG [INSULIN LISPRO] (C - n/a - n/a - [n/a - n/a - n/a]), TOUJEO [INSULIN GLARGINE] (C - n/a - n/a - [n/a - n/a - n/a]), [BISOPROLOL FUMARATE, BISOPROLOL HEMI-FUMARATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [CLARITHROMYCIN, OMEPRAZOLE, OMEPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 40mg - Oral]), [HYDROCHLOROTHIAZIDE, RAMIPRIL] (C - n/a - n/a - [n/a - 1{DF} - n/a])	ICSR
EU-EC-10007657893	18/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Dysarthria (n/a - Unknown - Other Medically Important Condition), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Myasthenia gravis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	METHOTREXATE [METHOTREXATE] (C - Myasthenia gravis - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - Myasthenia gravis - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE, OMEPRAZOLE MAGNESIUM, OMEPRAZOLE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [PYRIDOSTIGMINE] (C - Myasthenia gravis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007658062	18/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	18/02/2021	Spontaneous	Healthcare	Non	Not	18-64	Not	Female	No	Facial paralysis (n/a - Not	TOZINAMERAN	BUPRENORPHINE	ICSR

10007658250			Professional	European Economic Area	available	Years	Specified			Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BUPRENORPHINE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10007658343	18/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007658415	18/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Eye irritation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Lacrimation increased (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007659612	18/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Periorbital swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	OLANZAPINE [OLANZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [PROMETHAZINE, PROMETHAZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007659664	18/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Eyelid function disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Pain (n/a - Unknown -), Pain in jaw (n/a - Unknown -), Visual impairment (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007659845	18/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Eyelid disorder (n/a - Unknown -), Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Unknown -), Malaise (n/a - Unknown -), Neck pain (n/a - Unknown -), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	AMBEREN [AMMONIUM SUCCINATE, CALCIUM SUCCINATE, GLUTAMATE SODIUM, GLYCINE, MAGNESIUM SUCCINATE, TOCOPHERYL ACETATE, ZINC DIFUMARATE HYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), MELATONIN [MELATONIN] (C - Sleep disorder - n/a - [n/a - 10mg - n/a]), [COLLAGEN] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTOBACILLUS ACIDOPHILUS, BIFIDOBACTERIUM LONGUM, LACTOBACILLUS RHAMNOSUS] (C - n/a - n/a - [n/a - n/a - n/a]), [LORATADINE] (C - Hypersensitivity - n/a - [n/a - n/a - n/a]), [TURMERIC] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007637844	17/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007638047	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -), Eye disorder (n/a - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Speech disorder (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[BISOPROLOL FUMARATE] (C - Hypertension - n/a - [n/a - 5mg - Oral]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Hypercholesterolaemia - n/a - [n/a - n/a - Oral]), [VALSARTAN] (C - Hypertension - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10007638211	17/02/2021	Spontaneous	Healthcare Professional	European Economic	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

				Area						Other Medically Important Condition)	(S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])		
EU-EC-10007638950	17/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Unknown -), Neck pain (n/a - Unknown -), Neuralgia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	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-10007639570	17/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Corneal reflex decreased (n/a - Unknown -), Drooling (n/a - Unknown -), Dysgeusia (n/a - Not Recovered/Not Resolved -), Eyelid ptosis (n/a - Not Recovered/Not Resolved -), Facial asymmetry (n/a - Unknown -), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Facial paresis (n/a - Recovering/Resolving -), Joint range of motion decreased (n/a - Unknown -), Swelling face (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ALLOPURINOL] (C - Gout - n/a - [n/a - n/a - n/a]), [ATENOLOL, ATENOLOL BP] (C - Tachycardia - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINOPRIL, LISINOPRIL DIHYDRATE] (C - Hypertension - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007639572	17/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (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-10007640410	17/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007642200	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paresis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nervous system disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007644126	17/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving -), Lymph node pain (n/a - Recovering/Resolving -), Lymphadenopathy (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	IRON [IRON] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID, ASPIRIN BP] (C - n/a - n/a - [n/a - 85mg - n/a]), [ALPHATOCOPHEROL ACETATE, LUTEIN] (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-10007644744	17/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	[BRIMONIDINE] (C - Cataract, Glaucoma - n/a - [n/a - 2{drp} - Ophthalmic]),	ICSR

				Area						Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Fall (n/a - Unknown -)	immunisation - Not applicable - [n/a - n/a]	[ENALAPRIL, ENALAPRIL MALEATE] (C - Hypertension - n/a - [n/a - 10mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Thyroid disorder - n/a - [n/a - 100ug - n/a])	
EU-EC-10007644976	17/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Giant cell arteritis (n/a - Unknown - Other Medically Important Condition), Sinusitis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007644986	17/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown -), Chills (n/a - Not Recovered/Not Resolved -), Disorientation (n/a - Unknown -), Disturbance in attention (n/a - Unknown -), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (0d - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling of body temperature change (n/a - Unknown -), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Insomnia (n/a - Unknown -), Malaise (n/a - Unknown -), Migraine (n/a - Unknown -), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CARBOCISTEINE] (C - Asthma - n/a - [n/a - n/a - n/a]), [FLUTICASONE PROPIONATE, FORMOTEROL FUMARATE DIHYDRATE, FLUTICASONE PROPIONATE, FORMOTEROL FUMARATE DIHYDRATE PH.EUR.] (C - Asthma - n/a - [n/a - n/a - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - n/a - n/a]), [TIOTROPIUM, TIOTROPIUM BROMIDE, TIOTROPIUM BROMIDE MONOHYDRATE] (C - Empyema - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007646201	17/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007646301	17/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (1wk - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007646953	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Foaming at mouth (n/a - Unknown - Caused/Prolonged Hospitalisation), Myoclonus (n/a - Unknown - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Vertigo (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC-10007647807	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007648053	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Dose not changed - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007648311	17/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - Other Medically Important Condition), Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition), Paresis (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	[VERAPAMIL, VERAPAMIL HYDROCHLORIDE] (C - n/a - n/a - [n/a - 120mg - Oral])	ICSR
EU-EC-10007623731	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (1d - Recovered/Resolved -), Vision blurred (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007623899	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (7d - Recovered/Resolved -), Vaccination site movement impairment (7d - Recovered/Resolved -), Vaccination site paraesthesia (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007624458	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (21d - Recovered/Resolved -), Lymphadenopathy (21d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007624624	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Asthenia (34d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (34d - Recovered/Resolved - Other Medically Important Condition), Injection site pain (34d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007624985	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-	16/02/2021	Spontaneous	Healthcare	European	Not	18-64	Not	Female	No	Eczema (12d -	COMIRNATY	Not reported	ICSR

10007625401			Professional	Economic Area	available	Years	Specified			Recovered/Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC-10007625402	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007626206	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007626330	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Diplopia (n/a - Unknown - Disabling), Headache (n/a - Unknown - Disabling), Nausea (n/a - Unknown - Disabling), Vith nerve paralysis (n/a - Not Recovered/Not Resolved - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007627047	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007630609	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (3d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	[NAPROXEN, NAPROXEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007631558	16/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Hypotonia (3h - Recovered/Resolved - Other Medically Important Condition), Sensory loss (3h - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (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]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007631598	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID, BETA-CAROTENE, BIOTIN, CALCIUM PANTOTHENATE, COLECALCIFEROL, CYANOCOBALAMIN, FOLIC ACID, NICOTINAMIDE, THIAMINE NITRATE, POTASSIUM CHLORIDE, ZINC OXIDE, CHROMIC CHLORIDE, CUPRIC OXIDE, FERROUS FUMARATE, MAGNESIUM OXIDE, MANGANESE SULFATE, POTASSIUM IODIDE, PYRIDOXINE HYDROCHLORIDE, SODIUM MOLYBDATE, CALCIUM HYDROGEN PHOSPHATE, SODIUM SELENATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLESTYRAMINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CYCLOBENZAPRINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [GLIMEPIRIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR

												[PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [SUCRALFATE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10007633897	16/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Oropharyngeal pain (3h - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	IVABRADINE [IVABRADINE, IVABRADINE HYDROCHLORIDE] (C - Myocardial infarction - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - Myocardial infarction - n/a - [n/a - n/a - n/a]), [ATORVASTATIN, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (C - Myocardial infarction - n/a - [n/a - n/a - n/a]), [BETAMETHASONE, BETAMETHASONE DIHYDROGEN PHOSPHATE (PH. EUR), BETAMETHASONE SODIUM PHOSPHATE, BETAMETHASONE SODIUM PHOSPHATE BP, BETAMETHASONE SODIUM PHOSPHATE PH. EUR, BETAMETHASONE SODIUM PHOSPHATE, FRAMYCETIN SULFATE, BETAMETHASONE SODIUM PHOSPHATE, NEOMYCIN SULFATE, NEOMYCIN SULFATE, BETAMETHASONE] (C - Nasal polyps - n/a - [n/a - n/a - n/a]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - Asthma - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Chronic obstructive pulmonary disease - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007635030	16/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007635680	16/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Diplopia (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (7d - Recovered/Resolved -), IVth nerve paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Arthritis - n/a - [n/a - n/a - n/a]), LEFLUNOMIDE [LEFLUNOMIDE] (C - Arthritis - n/a - [n/a - n/a - Oral]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Gastric disorder - n/a - [n/a - n/a - Oral]), [EZETIMIBE] (C - Blood cholesterol increased - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - Oral]), [SULFASALAZINE] (C - Arthritis - n/a - [n/a - n/a - Oral]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Sleep disorder - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007613608	15/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007613655	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	No	Facial paralysis (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-	15/02/2021	Spontaneous	Non	European	Not	18-64	Not	Male	No	Facial paralysis (n/a -	COMIRNATY	Not reported	ICSR

10007613721			Healthcare Professional	Economic Area	available	Years	Specified			Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC-10007613970	15/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Burning sensation (n/a - Unknown -), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved -), Myofascial pain syndrome (n/a - Not Recovered/Not Resolved -), Paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vision blurred (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[A/BRISBANE/59/2007 (H1N1)-LIKE STRAIN, A/BRISBANE/10/2007 (H3N2)-LIKE STRAIN, B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009 (H1N1) V REASS. X - 179 A, A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, NIB-104), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/NANCHANG 933/95 (H3N2), A/BAYERN/7/95 (H1N1) - LIKE STRAIN (A/JOHANNESBURG/82/96), B/BEIJING/184/93-LIKE STRAIN (B/HARBIN/7/94), A/NEW CALEDONIA/20/99 (H1N1) - LIKE STRAIN (A/NEW CALEDONIA/20/99 REASS. IVR-116), A/CALIFORNIA/7/2004 (H3N2) - LIKE STRAIN (A/NEW YORK/55/2004 REASS. NYMC X-157), B/SHANGHAI/361/2002 - LIKE STRAIN (B/JIANGSU/10/2003), A/NEW CALEDONIA/20/99 (H1N1) - LIKE STRAIN (A/NEW CALEDONIA/20/99 REASS. IVR-116), A/MOSCOW/10/99 (H3N2) - LIKE STRAIN (A/PANAMA/2007/99 REASS. RESVIR-17), B/SICHUAN/379/99-LIKE STRAIN (B/JOHANNESBURG/5/99), A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187), A/CALIFORNIA/7/2009 (H1N1)-DERIVED STRAIN USED NYMC X-181, B/BRISBANE/60/2008, A/SWITZERLAND/9715293/2013 (H3N2)-LIKE STRAIN (A/SWITZERLAND/9715293/2013, NIB-88), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/TEXAS/50/2012, INFLUENZA VIRUS INACTIVATED SURFACE ANTIGEN STRAIN B, A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009 (H1N1), A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187), B/BRISBANE/60/2008-LIKE VIRUS, A/CALIFORNIA/7/2009 (H1N1)V-LIKE VIRUS, A/PERTH/16/2009 (H3N2) - LIKE STRAIN (A/VICTORIA/210/2009 REASS. NYMC X-187),	ICSR

												B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/BRISBANE/02/2018 (H1N1)PDM09-LIKE VIRUS (A/BRISBANE/02/2018, IVR-190), A/KANSAS/14/2017 (H3N2)-LIKE VIRUS (A/KANSAS/14/2017, NYMC X-327), B/MASSACHUSETTS/2/2012 - DERIVED STRAIN USED (NYMC BX-51B), A/TEXAS/50/2012 (H3N2) - DERIVED STRAIN USED (NYMC X-223A), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), B/MASSACHUSETTS/2/2012 - DERIVED STRAIN USED (NYMC BX-51B), A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/TEXAS/50/2012, A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), INFLUENZA VIRUS INACTIVATED SURFACE ANTIGEN STRAIN A (H1N1), INFLUENZA VIRUS INACTIVATED SURFACE ANTIGEN STRAIN A (H3N2), INFLUENZA VIRUS INACTIVATED SURFACE ANTIGEN STRAIN B] (C - Immunisation - n/a - [1d - n/a - n/a])	
EU-EC-10007614854	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Ear pain (n/a - Unknown -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Unknown -), Lagophthalmos (n/a - Not Recovered/Not Resolved -), Neck pain (n/a - Unknown -), Vaccination site joint pain (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007614973	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Speech disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Tongue spasm (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007616265	15/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Eye pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), IIIrd nerve paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10007617237	15/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Dysphonia (n/a - Unknown -), Eye oedema (n/a - Unknown -), Eye swelling (n/a - Unknown -), Eyelid oedema (n/a - Unknown -), Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007620043	15/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovered/Resolved -), Hypoaesthesia (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Dysmenorrhoea - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007620581	15/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	CLOPIDOGREL [CLOPIDOGREL, CLOPIDOGREL BESILATE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR

											applicable - [1d - 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]), [EPLERENONE] (C - n/a - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10007620594	15/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007622974	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007623003	15/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Decreased nasolabial fold (n/a - Recovering/Resolving - Other Medically Important Condition), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]), [LITHIUM] (S - Bipolar disorder - Drug withdrawn - [n/a - 100mg - n/a])	Not reported	ICSR
EU-EC-10007612497	14/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007612512	14/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007612618	14/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BECLOMETASONE DIPROPIONATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a]), [TERBUTALINE SULFATE, TERBUTALINE SULFATE PH. EUR.] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007612669	14/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (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-10007606704	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (1d - Recovered/Resolved -), Lip oedema (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	[RAMIPRIL] (C - n/a - n/a - [n/a - n/a - n/a]), [TIBOLONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007607768	13/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Balance disorder (n/a - Not Recovered/Not Resolved - Disabling), Facial pain (9d - Recovered/Resolved - Disabling), Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling), Visual impairment (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007611050	13/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Arthralgia (n/a - Recovering/Resolving -), Balance disorder (n/a - Unknown -), Chills (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - Dose not changed - [n/a - 10mg - n/a]), [TIOGUANINE] (C - n/a - Dose not changed - [n/a - 20mg - n/a])	ICSR

										<p>Diplopia (n/a - Recovered/Resolved -),</p> <p>Disturbance in attention (n/a - Unknown -),</p> <p>Dizziness (n/a - Unknown -),</p> <p>Dysarthria (n/a - Recovered/Resolved -),</p> <p>Facial paralysis (n/a - Recovered/Resolved -),</p> <p>Fatigue (n/a - Recovering/Resolving -),</p> <p>Flushing (n/a - Unknown -),</p> <p>Headache (n/a - Recovering/Resolving -),</p> <p>Hemianaesthesia (n/a - Unknown -),</p> <p>Malaise (n/a - Recovering/Resolving -),</p> <p>Muscular weakness (n/a - Recovered/Resolved -),</p> <p>Myalgia (n/a - Recovering/Resolving -),</p> <p>Nausea (n/a - Recovered/Resolved -),</p> <p>Nystagmus (n/a - Recovering/Resolving -),</p> <p>Pupillary disorder (n/a - Recovering/Resolving -),</p> <p>Torticollis (n/a - Recovering/Resolving -),</p> <p>Vertigo (n/a - Unknown -)</p>			
EU-EC-10007589567	12/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Facial paralysis (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),</p> <p>Fatigue (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),</p> <p>Pain in jaw (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),</p> <p>Pyrexia (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition),</p> <p>Salivary hypersecretion (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007589782	12/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	<p>Facial paralysis (39d - Recovering/Resolving - Other Medically Important Condition),</p> <p>Facial paresis (n/a - Unknown - Other Medically Important Condition),</p> <p>Inflammation (n/a - Unknown - Other Medically Important Condition),</p> <p>Joint swelling (39d - Recovered/Resolved -)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007590688	12/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Facial paralysis (n/a - Unknown - Other Medically Important Condition),</p> <p>Facial paresis (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-10007590698	12/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007590919	12/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	<p>TRIMBOW [BECLOMETASONE DIPROPIONATE, GLYCOPYRRONIUM BROMIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[CITALOPRAM, CITALOPRAM</p>	ICSR

											HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (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]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])		
EU-EC-10007590922	12/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Eye pain (n/a - Unknown - Disabling), Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Unknown - Disabling), Headache (n/a - Unknown - Disabling), Lethargy (n/a - Unknown - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a])	[FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - Sinusitis - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007594565	12/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Unknown -), Malaise (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007594797	12/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Disorganised speech (n/a - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving -), Muscular weakness (n/a - Recovering/Resolving -), Unresponsive to stimuli (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ASCORBIC ACID, BIOTIN, CALCIUM PANTOTHENATE, COLECALCIFEROL, CYANOCOBALAMIN, NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, ZINC, CALCIUM, COPPER, IRON, MAGNESIUM, MANGANESE, PYRIDOXINE HYDROCHLORIDE, RETINOL, ALPHATOCOPHEROL ACETATE, MOLYBDENUM, ASCORBIC ACID, BIOTIN, CALCIUM PANTOTHENATE, COLECALCIFEROL, FOLIC ACID, NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, ZINC, VITAMIN B6, CALCIUM, COPPER, IRON, MAGNESIUM, MANGANESE, PHOSPHORUS, RETINOL, MOLYBDENUM, DL-ALPHA TOCOPHEROL ACETATE, VITAMIN B12, ASCORBIC ACID, BIOTIN, COLECALCIFEROL, FOLIC ACID, NICOTINAMIDE, PHYTOMENADIONE, RIBOFLAVIN, THIAMINE, PHOSPHOROUS ACID, ZINC, VITAMIN B6, CALCIUM, CHROMIUM, COPPER, IODINE, IRON, MAGNESIUM, MANGANESE, PANTOTHENIC ACID, SELENIUM, RETINOL, ALPHA-TOCOPHEROL, MOLYBDENUM, FLUORINE, VITAMIN B12, ASCORBIC ACID, BIOTIN, COLECALCIFEROL, FOLIC ACID, NICOTINAMIDE, RIBOFLAVIN, THIAMINE, ZINC, VITAMIN B6, CALCIUM, COPPER, IRON, MAGNESIUM, MANGANESE, PANTOTHENIC ACID, PHOSPHORUS, RETINOL, ALPHA-TOCOPHEROL, MOLYBDENUM, VITAMIN B12, POTASSIUM ASCORBATE] (C - n/a - n/a - [n/a - 1{DF} - n/a])	ICSR
EU-EC-10007595601	12/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Axillary pain (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown -), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Speech disorder (n/a - Unknown - Other Medically Important Condition), Thirst (n/a - Unknown - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

EU-EC-10007599289	12/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Ear pain (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[INSULIN, INSULIN HUMAN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007603248	12/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) [GABAPENTIN] (C - n/a - n/a - [n/a - 600mg - n/a]), [PRAZOSIN] (C - n/a - n/a - [n/a - 1mg - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-10007573383	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	ETANERCEPT [ETANERCEPT] (C - Psoriatic arthropathy - n/a - [n/a - n/a - Subcutaneous]), METHOTREXATE [METHOTREXATE] (C - Psoriatic arthropathy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007573396	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cranial nerve paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007580499	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007580796	11/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving -), Muscle disorder (n/a - Recovering/Resolving -), Muscle tightness (n/a - Recovering/Resolving -), Neck pain (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007580803	11/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Facial paralysis (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-10007584544	11/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007586882	11/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved - Other Medically Important Condition), Erythema (n/a - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Feeling hot (n/a - Recovered/Resolved - Other Medically Important Condition), Reduced facial expression (n/a - Recovered/Resolved - Other Medically Important Condition), Sensation of blood flow (n/a - Recovered/Resolved - Other Medically Important Condition), Tremor (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMETICONE, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-	11/02/2021	Spontaneous	Healthcare	Non	Not	18-64	Not	Female	No	Corneal reflex decreased (n/a -	TOZINAMERAN	HYDROCORTISONE	ICSR

10007587430			Professional	European Economic Area	available	Years	Specified				Recovering/Resolving - Disabling), Dysphagia (n/a - Recovering/Resolving - Disabling), Ear pain (n/a - Recovering/Resolving - Disabling), Facial paralysis (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Hypoaesthesia (n/a - Recovering/Resolving - Disabling), Mastoid disorder (n/a - Recovering/Resolving - Disabling), Maternal exposure during pregnancy (n/a - Unknown -), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -), Speech disorder (n/a - Recovering/Resolving - Disabling), Tinnitus (n/a - Recovering/Resolving - Disabling)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[HYDROCORTISONE, HYDROCORTISONE SODIUM SUCCINATE] (C - n/a - n/a - [n/a - n/a - n/a]), IRON [IRON] (C - n/a - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID, RIBOFLAVIN, THIAMINE NITRATE, ZINC, CALCIUM, FERROUS FUMARATE, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS] (C - Immunisation - n/a - [1d - n/a - n/a]), [DOCUSATE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10007590253	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Ear pain (n/a - Recovering/Resolving - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oropharyngeal pain (n/a - Recovering/Resolving - Other Medically Important Condition), Parotitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10007590871	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Drooling (1d - Recovered/Resolved -), Ear pain (1d - Recovered/Resolved -), Facial paralysis (1d - Recovered/Resolved - Other Medically Important Condition), Oropharyngeal pain (1d - Recovered/Resolved -), Tonsillar hypertrophy (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10007565150	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Aggression (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10007565282	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[HYDROCHLOROTHIAZIDE, CANDESARTAN CILEXETIL] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROXYZINE DIHYDROCHLORIDE, HYDROXYZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL, CODEINE PHOSPHATE, PARACETAMOL, CODEINE PHOSPHATE HEMIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-10007565378	10/02/2021	Spontaneous	Healthcare Professional	European Economic	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (1d - Recovered/Resolved - Other	COMIRNATY [TOZINAMERAN]	Not reported	ICSR	

				Area						Medically Important Condition), Lip oedema (1d - Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
EU-EC-10007566665	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007566726	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Blepharospasm (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dry eye (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in jaw (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-10007566857	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Drooling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Muscle twitching (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-10007566964	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [FINASTERIDE] (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]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007566966	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lacunar infarction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ACETYLSALICYLIC ACID] (C - Platelet aggregation abnormal - n/a - [n/a - 81mg - n/a]), [CARVEDILOL] (C - Hypertension - n/a - [n/a - 25mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - 137ug - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - 10mg - n/a]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Coronary artery disease - n/a - [n/a - 40mg - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - Urinary incontinence - n/a - [n/a - .4mg - n/a])	ICSR
EU-EC-10007566997	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Migraine (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007567182	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Balance disorder (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR

EU-EC-10007568167	10/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site pain (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) [CLONAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TOPIRAMATE] (C - n/a - n/a - [n/a - n/a - n/a]), [VERAPAMIL, VERAPAMIL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	IRBESARTAN [IRBESARTAN] (C - n/a - n/a - [n/a - n/a - n/a]), [ACETYLSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [CLONAZEPAM] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMSULOSIN, TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TOPIRAMATE] (C - n/a - n/a - [n/a - n/a - n/a]), [VERAPAMIL, VERAPAMIL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007568176	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Influenza like illness (n/a - Unknown -), Nasal congestion (n/a - Unknown -), Rhinoorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007568191	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paresis (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	LINAGLIPTIN [LINAGLIPTIN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007568577	10/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), [BCG (BACILLUS CALMETTE-GUÉRIN), LIVE ATTENUATED] (S - Bladder cancer - Unknown - [n/a - n/a - n/a])	ESOMEPRAZOLE [ESOMEPRAZOLE] (C - Gastroesophageal reflux disease - n/a - [n/a - n/a - n/a]), [BECLOMETASONE DIPROPIONATE] (C - Asthma-chronic obstructive pulmonary disease overlap syndrome - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a]), [MOMETASONE FUROATE] (C - Sinusitis - n/a - [n/a - n/a - n/a]), [PARACETAMOL, CODEINE] (C - Sinus pain - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007569578	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cardiac failure congestive (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007571315	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Ear infection (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved -), Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007572353	10/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (3d - Recovered/Resolved - Other Medically Important Condition), Haemorrhage subcutaneous (n/a - Unknown - Other Medically Important Condition), Hypoaesthesia (3d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Paraesthesia (1d - Recovered/Resolved - Other Medically Important Condition), Swelling face (3d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10007572578	10/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (6d - Recovered/Resolved With Sequelae - Other Medically Important Condition), Seizure (6d - Recovered/Resolved With Sequelae - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007575039	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), Ileus paralytic (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Microcytic anaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Pneumonia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007578846	10/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ENTECAVIR [ENTECAVIR] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007579250	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Dry eye (n/a - Recovering/Resolving -), Exophthalmos (n/a - Recovering/Resolving - Other Medically Important Condition), Eye pain (n/a - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving -), Ocular discomfort (n/a - Recovering/Resolving -), Paraesthesia (n/a - Recovering/Resolving -), Photophobia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[FLUVOXAMINE MALEATE] (C - n/a - n/a - [n/a - 100mg - n/a]), [TRAZODONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 100mg - n/a])	ICSR
EU-EC-10007553133	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007554620	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ALLOPURINOL] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [CALCIUM CARBONATE] (C - n/a - n/a - [n/a - 4{DF} - n/a]), [CODEINE PHOSPHATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DOXAZOSIN, DOXAZOSIN MESILATE] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [FERROUS FUMARATE] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [IBUPROFEN, IBUPROFEN PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - n/a - n/a - [n/a - 30mL - n/a]), [LAMOTRIGINE] (C - n/a - n/a -	ICSR

											[n/a - 2{DF} - n/a), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SIMVASTATIN] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [10d - n/a - n/a]), [SODIUM VALPROATE] (C - n/a - n/a - [n/a - 1{DF} - n/a])		
EU-EC-10007554624	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Hypertension (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007554630	09/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Hypoaesthesia (n/a - Unknown -), Pain (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007554920	09/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Diarrhoea (n/a - Unknown -), Headache (n/a - Unknown -), Nausea (n/a - Unknown -), Vith nerve paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ASCORBIC ACID, CALCIUM GLUBIONATE, CALCIUM CARBONATE, CALCIUM, CALCIUM GLUBIONATE, CALCIUM CARBONATE, COLECALCIFEROL, CALCIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN, VITAMIN B12] (C - n/a - n/a - [n/a - n/a - n/a]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - n/a - n/a - [n/a - 20mg - n/a])	ICSR
EU-EC-10007554921	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007555022	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007556442	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Dysmorphism (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paresis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sensory loss (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMITRIPTYLINE, AMITRIPTYLINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007557223	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Diplopia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vith nerve paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	09/02/2021	Spontaneous	Healthcare	European	Not	More	Elderly	Male	No	Facial paralysis (10d -	COMIRNATY	Not reported	ICSR

10007557618			Professional	Economic Area	available	than 85 Years					Recovered/Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC-10007558398	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No		Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007558684	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No		Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), IIIrd nerve paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ischaemic neuropathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vertigo (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007560106	09/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No		Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Cough (1d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (1d - Recovered/Resolved - Other Medically Important Condition), Headache (1d - Recovered/Resolved - Other Medically Important Condition), Hypokinesia (n/a - Recovering/Resolving - Other Medically Important Condition), Nasal congestion (1d - Recovered/Resolved - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007560467	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No		Facial paralysis (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-10007560699	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Not Specified	No		Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007561615	09/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No		Facial paralysis (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - n/a])	[AMLODIPINE BESILATE, PERINDOPRIL ARGININE, AMLODIPINE, PERINDOPRIL] (C - n/a - n/a -), [INDAPAMIDE, PERINDOPRIL ARGININE] (C - n/a - n/a -), [METHOTREXATE] (C - Rheumatoid arthritis - n/a - [n/a - 20mol - n/a]), [RILMENIDINE, RILMENIDINE DIHYDROGEN PHOSPHATE] (C - n/a - n/a -)	ICSR
EU-EC-10007562098	09/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No		Asthenia (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition), Feeling cold (n/a - Recovered/Resolved - Other Medically Important Condition), Hallucination (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Pain (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Sleep disorder (n/a - Recovered/Resolved - Other Medically Important Condition), Sleep paralysis (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10007563878	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	Complication associated with device (n/a - Recovered/Resolved -), Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007563920	09/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -), Balance disorder (n/a - Unknown -), Blood glucose decreased (n/a - Unknown -), Chest discomfort (n/a - Unknown -), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown -), Feeding disorder (n/a - Unknown -), Gastric disorder (n/a - Unknown -), Headache (n/a - Unknown -), Hypoaesthesia (n/a - Unknown -), Malaise (n/a - Unknown -), Muscle tightness (n/a - Unknown -), Myocardial infarction (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown -), Speech disorder (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	MELATONIN [MELATONIN] (C - Sleep disorder - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Sleep disorder - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007563922	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown - Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other Medically Important Condition), Sensory disturbance (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007564015	09/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Vaccination site pain (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[ASCORBIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [METOPROLOL TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007564297	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Aphasia (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Odynophagia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular - More in ICSR]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007564660	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

										Pyrexia (n/a - Unknown -)	applicable - [1d - n/a - n/a]		
EU-EC-10007541936	08/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	2 Months - 2 Years	Not Specified	Female	No	External ear pain (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007541972	08/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (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-10007542421	08/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Hypoaesthesia (n/a - Unknown -), Hypoaesthesia teeth (n/a - Unknown -), Lip disorder (n/a - Unknown -), Pulpitis dental (n/a - Not Recovered/Not Resolved -), Speech disorder (n/a - Unknown -), Swelling face (n/a - Unknown -), Tooth injury (n/a - Not Recovered/Not Resolved -), Toothache (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007543356	08/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[OLMESARTAN MEDOXOMIL] (C - n/a - n/a - [n/a - n/a - Intramuscular]), [VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007543680	08/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Dysgeusia (n/a - Not Recovered/Not Resolved - Disabling), Ear pain (n/a - Not Recovered/Not Resolved - Disabling), Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[OMEPRAZOLE] (C - Gastrooesophageal reflux disease - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007545498	08/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Monoplegia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007548781	08/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoaesthesia (n/a - Unknown -), Paraesthesia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PAROXETINE, PAROXETINE HYDROCHLORIDE HEMIHYDRATE, PAROXETINE HYDROCHLORIDE, ANHYDROUS] (C - Depression - n/a - [9743d - n/a - n/a])	ICSR
EU-EC-10007548967	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	Off label use (n/a - Unknown - Caused/Prolonged Hospitalisation), Paresis (n/a - Unknown - Caused/Prolonged Hospitalisation), Product use issue (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Suppressed lactation (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC-10007549340	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	No	Arthropathy (n/a - Unknown -), Musculoskeletal stiffness (n/a - Unknown -), Pain in extremity (n/a - Recovered/Resolved -), Paresis (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Swelling (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[GABAPENTIN] (C - Migraine - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007549940	08/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Diplopia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Disorientation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Headache (3d - Recovered/Resolved - Other Medically Important Condition), IIIrd nerve paralysis (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-10007550089	08/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (45min - Recovered/Resolved - Other Medically Important Condition), Paraesthesia (45min - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007550920	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	IVth nerve paralysis (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - Disabling), Malaise (n/a - Not Recovered/Not Resolved - Disabling), Migraine (n/a - Not Recovered/Not Resolved - Disabling), Nausea (n/a - Not Recovered/Not Resolved - Disabling), Pyrexia (n/a - Not Recovered/Not Resolved - Disabling), Visual impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC-10007551377	08/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007551423	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (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-10007551613	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007540815	07/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Adult	Male	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

EU-EC-10007540935	07/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (3d - Recovered/Resolved - Other Medically Important Condition)	immunisation - Not applicable - [1d - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYLSALICYLIC ACID, ASPIRIN BP] (C - Polycythaemia - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007535162	06/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chills (6d - Recovered/Resolved - Other Medically Important Condition), Dysgeusia (6d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (6d - Recovered/Resolved - Other Medically Important Condition), Flushing (6d - Recovered/Resolved - Other Medically Important Condition), Headache (6d - Recovered/Resolved - Other Medically Important Condition), Hypersensitivity (6d - Recovered/Resolved - Other Medically Important Condition), Hypertension (6d - Recovered/Resolved - Other Medically Important Condition), Malaise (6d - Recovered/Resolved - Other Medically Important Condition), Nausea (6d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (6d - Recovered/Resolved - Other Medically Important Condition), Tachycardia (6d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007535464	06/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007537764	06/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Ear discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Facial pain (n/a - Recovering/Resolving - Other Medically Important Condition), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007523924	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Arthralgia (9d - Recovered/Resolved -), Facial paralysis (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007524364	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Facial paralysis (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007526448	05/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Not Specified	No	Facial paralysis (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-10007526573	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL -	Not reported	ICSR

										Recovering/Resolving - Other Medically Important Condition), Pain (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination site pain (n/a - Recovering/Resolving - Other Medically Important Condition)	Intramuscular])		
EU-EC-10007526785	05/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved -), Facial pain (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007526911	05/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Not Specified	No	Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007526914	05/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (3d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	FLUTICASONE FUROATE [FLUTICASONE FUROATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007526995	05/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007526998	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved -), Hypoesthesia (n/a - Recovering/Resolving -), Lethargy (3d - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -), Pain (3d - Recovered/Resolved -), Paraesthesia (n/a - Recovered/Resolved -), Product administered at inappropriate site (n/a - Unknown -), Somnolence (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	NEOCLARITYN [DESLOTRATADINE] (C - Hypersensitivity - n/a - [n/a - 5mg - n/a]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Depression - n/a - [n/a - 100mg - n/a])	ICSR
EU-EC-10007527432	05/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Dysarthria (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Lethargy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Mobility decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Somnolence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Vaccination site pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)			
EU-EC-10007528261	05/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007528538	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	Chills (n/a - Unknown -), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007528982	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paresis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramedullar (bone marrow)])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - 5mg - n/a]), [BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Hypertension - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-10007529685	05/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation), Dysarthria (n/a - Unknown - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	PROLIA [DENOSUMAB] (C - n/a - n/a - [n/a - n/a - Subcutaneous]), [LERCANIDIPINE, LERCANIDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [LEVOTHYROXINE] (C - n/a - n/a - [n/a - n/a - Oral]), [METOPROLOL SUCCINATE, METOPROLOL TARTRATE, METOPROLOL TARTRATE PH. EUR.] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10007534668	05/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Balance disorder (n/a - Recovered/Resolved -), Blood glucose increased (n/a - Unknown -), Dizziness (n/a - Recovered/Resolved -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling abnormal (n/a - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -), Rash (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Blood cholesterol - 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]), [THIOCTIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007535996	05/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Atrial fibrillation (n/a - Unknown - Other Medically Important Condition), Dysarthria (1d - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	SIMBRINZA [BRINZOLAMIDE, BRIMONIDINE TARTRATE] (C - Glaucoma - n/a - [n/a - n/a - n/a]), [ACETYSALICYLIC ACID] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a])	ICSR

										Facial paralysis (1d - Recovered/Resolved - Other Medically Important Condition), Facial paresis (1d - Recovered/Resolved -), Muscular weakness (1d - Recovered/Resolved -), Transient ischaemic attack (3h - Recovered/Resolved - Other Medically Important Condition)		- n/a - n/a)), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [ATENOLOL, ATENOLOL BP] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - Myocardial ischaemia - n/a - [n/a - n/a - n/a]), [RAMIPRIL] (C - Hypertension - n/a - [n/a - n/a - n/a])	
EU-EC-10007514134	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Conjunctivitis (19d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (19d - Recovered/Resolved - Other Medically Important Condition), Swelling face (19d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - .3mL - Intramuscular])	[BISOPROLOL FUMARATE] (C - Hypertension - n/a - [n/a - 2{DF} - Oral]), [INDAPAMIDE, AMLODIPINE BESILATE, PERINDOPRIL ARGININE] (C - Hypertension - n/a - [n/a - 1{DF} - Oral])	ICSR
EU-EC-10007515005	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chills (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Dysaesthesia (n/a - Unknown -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown -), Feeling hot (n/a - Recovered/Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hot flush (n/a - Unknown -), Hypoaesthesia (n/a - Unknown -), Limb discomfort (5d - Recovered/Resolved -), Muscular weakness (103h - Recovered/Resolved -), Musculoskeletal stiffness (n/a - Unknown -), Nausea (n/a - Unknown -), Pain in extremity (5d - Recovered/Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -), Paresis cranial nerve (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling (103h - Recovered/Resolved -), Tachycardia (n/a - Recovered/Resolved -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007515126	04/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Dysarthria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Hypoaesthesia oral (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[INFLUENZA VIRUS] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007515530	04/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [TERBINAFINE, TERBINAFINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

EU-EC-10007516068	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling), Migraine (n/a - Recovered/Resolved - Disabling), Nausea (n/a - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007516369	04/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cerebrovascular accident (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	ELIQUIS [APIXABAN] (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]), [CANDESARTAN] (C - n/a - n/a - [n/a - n/a - n/a]), [LERCANIDIPINE, LERCANIDIPINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007517382	04/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007517442	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Monoparesis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Movement disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007517448	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Elderly	Male	No	Atrial fibrillation (n/a - Not Recovered/Not Resolved - Disabling), Dizziness (n/a - Not Recovered/Not Resolved - Disabling), Dysarthria (n/a - Not Recovered/Not Resolved - Disabling), Dysphagia (n/a - Not Recovered/Not Resolved - Disabling), Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Head discomfort (n/a - Not Recovered/Not Resolved - Disabling), Heart rate irregular (n/a - Not Recovered/Not Resolved - Disabling), Loss of control of legs (n/a - Not Recovered/Not Resolved - Disabling), Malaise (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	LYRICA [PREGABALIN] (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, ATORVASTATIN CALCIUM, ATORVASTATIN CALCIUM TRIHYDRATE] (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]), [COLECALCIFEROL, CALCIUM, COLECALCIFEROL, CALCIUM CARBONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROXYZINE DIHYDROCHLORIDE, HYDROXYZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [NALOXONE HYDROCHLORIDE, OXYCODONE HYDROCHLORIDE, NALOXONE, OXYCODONE, OXYCODONE HYDROCHLORIDE, NALOXONE, OXYCODONE	ICSR

										Disabling), Productive cough (n/a - Not Recovered/Not Resolved - Disabling), Pyrexia (n/a - Not Recovered/Not Resolved - Disabling), Visual impairment (n/a - Not Recovered/Not Resolved - Disabling), Wheezing (n/a - Not Recovered/Not Resolved - Disabling)		HYDROCHLORIDE, NALOXONE HYDROCHLORIDE DIHYDRATE] (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]), [PERINDOPRIL ARGININE] (C - n/a - n/a - [n/a - n/a - n/a]), [TAMSULOSIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10007520942	04/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Dysarthria (n/a - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Hypoaesthesia (n/a - Recovering/Resolving -), Hypoaesthesia oral (n/a - Recovering/Resolving -), Mental impairment (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving -), Taste disorder (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CYCLOBENZAPRINE, CYCLOBENZAPRINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [IBUPROFEN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007522314	04/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (1d - Recovered/Resolved - Other Medically Important Condition), Fatigue (3d - Recovered/Resolved - Other Medically Important Condition), Hypertension (1d - Recovered/Resolved - Other Medically Important Condition), Nausea (2d - Recovered/Resolved - Other Medically Important Condition), Palpitations (1d - Recovered/Resolved - Other Medically Important Condition), Pruritus (2d - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (2d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [FLUTICASONE PROPIONATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [SALMETEROL] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007522430	04/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Dysarthria (n/a - Unknown - Other Medically Important Condition), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Familial hemiplegic migraine (1d - Recovered/Resolved - Other Medically Important Condition), Muscular weakness (n/a - Unknown - Other Medically Important Condition), Vision blurred (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-10007522569	04/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Cerebral haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [FAMOTIDINE] (C - n/a - n/a - [n/a - n/a - n/a]), [NEBIVOLOL, NEBIVOLOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR

										Hospitalisation), Musculoskeletal disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sensory loss (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)		[OLMESARTAN, OLMESARTAN MEDOXOMIL] (C - n/a - n/a - [n/a - n/a - n/a]), [TERAZOSIN, TERAZOSIN HYDROCHLORIDE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10007502265	03/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007502933	03/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Pain - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007503132	03/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Joint stiffness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	LANTUS [INSULIN GLARGINE] (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]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [EZETIMIBE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007503166	03/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - Influenza immunisation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007503274	03/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Allergy to vaccine (n/a - Unknown -), Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Neck pain (n/a - Unknown -), Nerve degeneration (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown -), Trigeminal neuralgia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007505243	03/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Dysphagia (n/a - Unknown - Other Medically Important Condition), Facial paralysis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007507872	03/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Face oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Herpes zoster (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007508524	03/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007509663	03/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (9d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007510002	03/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Male	No	Facial paralysis (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-10007510673	03/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoesthesia (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a])	Not reported	ICSR

EU-EC-10007511765	03/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Psoriasis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007489194	02/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007489412	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007489587	02/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Hypoaesthesia (n/a - Recovering/Resolving -), Lymphadenopathy (n/a - Recovering/Resolving -), Ocular discomfort (n/a - Recovering/Resolving -), Oropharyngeal pain (n/a - Recovering/Resolving -), Pruritus (2min - Recovered/Resolved -), Respiratory disorder (n/a - Recovering/Resolving -), Throat tightness (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007490443	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (4d - Recovered/Resolved - Other Medically Important Condition), Paraesthesia (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007490481	02/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Hypoaesthesia (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 40mg - Oral]), [FLUTICASON] (C - n/a - n/a - [n/a - 200ug - n/a]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - 25mg - Oral]), [LISINOPRIL, LISINOPRIL DIHYDRATE] (C - n/a - n/a - [n/a - 10mg - Oral]), [LORATADINE] (C - n/a - n/a - [n/a - 10mg - Oral]), [MELOXICAM] (C - n/a - n/a - [n/a - 15mg - Oral]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - Oral]), [OXYCODONE, OXYCODONE HYDROCHLORIDE] (C - Pain - n/a - [n/a - 5mg - Oral]), [PARACETAMOL, ACETYLSALICYLIC ACID, CAFFEINE] (C - n/a - n/a - [n/a - n/a - Oral]), [SODIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007490549	02/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007490567	02/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Hallucinations, mixed (n/a - Recovered/Resolved - Other Medically Important Condition), Sleep paralysis (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007491559	02/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial pain (n/a - Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in jaw (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10007493187	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Chills (n/a - Recovering/Resolving -), Disturbance in attention (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Muscle tightness (n/a - Recovering/Resolving -), Sleep paralysis (n/a - Recovering/Resolving -), Sleep terror (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007494495	02/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007494617	02/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (10min - Recovered/Resolved - Other Medically Important Condition), Incomplete course of vaccination (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007494849	02/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Male	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007495662	02/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (1d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (1d - Recovered/Resolved - Other Medically Important Condition), Myalgia (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007497640	02/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007478067	01/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (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-10007478264	01/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paralysis (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-10007478271	01/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Erythema (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling (n/a - Not Recovered/Not Resolved -), Swelling face (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - Depressed mood - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007478345	01/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Cough (n/a - Unknown -), Diarrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (n/a - Recovered/Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Medically Important Condition), Gait disturbance (n/a - Unknown -), Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10007478358	01/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Haemorrhagic stroke (n/a - Fatal - Results in Death, Other Medically Important Condition), Hemiparesis (n/a - Unknown - Other Medically Important Condition), Pneumonia aspiration (n/a - Fatal - Results in Death, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007478367	01/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Aphasia (1d - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Facial paralysis (1d - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Respiration abnormal (1d - Recovered/Resolved - Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - 75mg - n/a]), [ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 5mg - n/a]), [FUROSEMIDE] (C - n/a - n/a - [n/a - 80mg - n/a])	ICSR
EU-EC-10007479635	01/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial pain (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Stress (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007479645	01/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Recovering/Resolving - Other Medically Important Condition), Ear pain (n/a - Recovering/Resolving - Other Medically Important Condition), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	CENTRUM SILVER WOMEN 50+ [ASCORBIC ACID, BETA-CAROTENE, BIOTIN, CALCIUM, CHLORIDE, CHROMIUM, COPPER, FOLIC ACID, IODINE, IRON, MAGNESIUM, MANGANESE, MOLYBDENUM, NICKEL, NICOTINIC ACID, PANTOTHENIC ACID, PHOSPHORUS, POTASSIUM, PYRIDOXINE HYDROCHLORIDE, RIBOFLAVIN, SELENIUM, SILICON, THIAMINE, VANADIUM, VITAMIN B12 NOS, VITAMIN D NOS, VITAMIN E NOS, VITAMIN K NOS, XANTOXYL, ZINC] (C - n/a - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROXYZINE, HYDROXYZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [VENLAFAXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007480799	01/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	DULOXETINE [DULOXETINE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007481333	01/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LITHIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007481975	01/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR

EU-EC-10007481980	01/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Dysarthria (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Headache (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Pain (n/a - Recovering/Resolving - Other Medically Important Condition)</p>	n/a - Intramuscular) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007482362	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	<p>Facial paralysis (10h - Recovered/Resolved - Caused/Prolonged Hospitalisation),</p> <p>Hypoaesthesia (10h - Recovered/Resolved - Caused/Prolonged Hospitalisation),</p> <p>Muscular weakness (10h - Recovered/Resolved - Caused/Prolonged Hospitalisation),</p> <p>Visual impairment (10h - Recovered/Resolved - Caused/Prolonged Hospitalisation)</p>	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10007484027	01/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Disease recurrence (n/a - Recovering/Resolving -),</p> <p>Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Hyperaesthesia (n/a - Recovering/Resolving -),</p> <p>Hypoaesthesia (n/a - Recovering/Resolving -)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	<p>[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 40mg - Oral]),</p> <p>[FLUTICASON] (C - n/a - n/a - [n/a - 100ug - Nasal]),</p> <p>[HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - 25mg - Oral]),</p> <p>[LISINOPRIL, LISINOPRIL DIHYDRATE] (C - n/a - n/a - [n/a - 10mg - Oral]),</p> <p>[LORATADINE] (C - n/a - n/a - [n/a - 10mg - Oral]),</p> <p>[MELOXICAM] (C - n/a - n/a - [n/a - 15mg - Oral]),</p> <p>[OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - Oral]),</p> <p>[OXYCODONE, OXYCODONE HYDROCHLORIDE] (C - Pain - n/a - [n/a - 20mg - Oral]),</p> <p>[PARACETAMOL, ACETYLSALICYLIC ACID, CAFFEINE] (C - n/a - n/a - [n/a - n/a - Oral]),</p> <p>[SODIUM CHLORIDE] (C - n/a - n/a - [n/a - n/a - Nasal])</p>	ICSR
EU-EC-10007484500	01/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	XARELTO [RIVAROXABAN] (C - Atrial fibrillation - n/a - [n/a - 15mg - Oral])	ICSR
EU-EC-10007485838	01/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Facial pain (n/a - Recovering/Resolving -),</p> <p>Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Headache (n/a - Not Recovered/Not Resolved -),</p> <p>Hypoaesthesia (n/a - Not Recovered/Not Resolved -),</p> <p>Neck pain (n/a - Recovering/Resolving -),</p> <p>Pain (n/a - Recovering/Resolving -),</p> <p>Pain in extremity (n/a - Recovering/Resolving -),</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	<p>PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]),</p> <p>[FLUTICASON PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a])</p>	ICSR

										Pain in jaw (n/a - Recovering/Resolving -), Swelling face (n/a - Unknown -)			
EU-EC-10007486901	01/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lacrimation increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - n/a - n/a - [1d - n/a - n/a]), [NAPROXEN, NAPROXEN SODIUM] (C - Back pain - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007487254	01/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypertension (n/a - Recovering/Resolving - Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved -), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CANDESARTAN CILEXETIL] (C - Hypertension - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a]), [DAPAGLIFLOZIN PROPANEDIOL MONOHYDRATE] (C - Migraine - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007474297	30/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Dizziness (5min - Recovered/Resolved -), Facial paralysis (2d - Recovered/Resolved -), Peripheral vascular disorder (5min - Recovered/Resolved -), Seizure (5min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007462118	29/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Crying (n/a - Recovered/Resolved -), Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Swelling face (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007462266	29/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Female	No	Crying (n/a - Recovering/Resolving - Other Medically Important Condition), Eye disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Mastication disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Ocular hyperaemia (n/a - Recovering/Resolving - Other Medically Important Condition), Vision blurred (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Analgesic therapy - n/a - [n/a - n/a - n/a]), LINAGLIPTIN [LINAGLIPTIN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), METHOTREXATE [METHOTREXATE] (C - Rheumatoid arthritis - n/a - [n/a - n/a - n/a]), RIVAROXABAN [RIVAROXABAN] (C - Anticoagulant therapy - n/a - [n/a - n/a - n/a]), [ALENDRONATE SODIUM, ALENDRONIC ACID] (C - Knee arthroplasty - n/a - [n/a - n/a - n/a]), [DIHYDROCODEINE, DIHYDROCODEINE TARTRATE BP] (C - Knee arthroplasty - n/a - [n/a - n/a - n/a]), [DOCUSATE SODIUM, SENNOSIDE A+B] (C - Constipation - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [INFLUENZA VIRUS] (C - Influenza immunisation - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Procedural pain - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007464098	29/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

											immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
EU-EC-10007466350	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	LEVEMIR [INSULIN DETEMIR] (C - Diabetes mellitus - n/a - [n/a - n/a - Subcutaneous]), NOVORAPID [INSULIN ASPART] (C - Diabetes mellitus - n/a - [n/a - n/a - Subcutaneous]), TRAJENTA [LINAGLIPTIN] (C - n/a - n/a - [n/a - 5mg - Oral]), [ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - 1{DF} - Oral]), [DIPYRIDAMOLE] (C - n/a - n/a - [n/a - 200mg - Oral]), [METFORMIN, METFORMIN HYDROCHLORIDE] (C - Diabetes mellitus - n/a - [n/a - n/a - Nasal])	ICSR
EU-EC-10007466748	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Cerebrovascular accident (0d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Facial paralysis (0d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Hemiparesis (0d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [45min - .3mL - Intramuscular])	[ACETYSALICYLIC ACID] (C - n/a - n/a -), [ATORVASTATIN] (C - n/a - n/a -), [CARVEDILOL] (C - n/a - n/a -), [EPLERENONE] (C - n/a - n/a -), [FUROSEMIDE, FUROSEMIDE SODIUM] (C - n/a - n/a -)	ICSR
EU-EC-10007467255	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved -), Facial paresis (n/a - Unknown -), Hypoesthesia (n/a - Unknown -)	[TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007467257	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Not Specified	No	Vith nerve paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007467278	29/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10007467284	29/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	Not Specified	Elderly	Not Specified	No	COVID-19 (n/a - Not Recovered/Not Resolved - Life Threatening), Facial paralysis (n/a - Recovering/Resolving - Life Threatening), Fatigue (n/a - Unknown - Life Threatening)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	RIVAROXABAN [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007467353	29/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (2d - Recovered/Resolved - Other Medically Important Condition), Insomnia (n/a - Unknown -), Malaise (n/a - Unknown -), Pain in extremity (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007467469	29/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial pain (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Stress (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007467958	29/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BECLOMETASONE DIPROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BECLOMETASONE, BECLOMETASONE DIPROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [BUTYLSCOPOLAMINE, HYOSCINE BUTYLBROMIDE] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR

											[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])		
EU-EC-10007468789	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - .3mL - Intramuscular])	[BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (C - Product used for unknown indication - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10007470845	29/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[LOSARTAN, LOSARTAN POTASSIUM] (C - Blood pressure abnormal - n/a - [n/a - n/a - n/a]), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Blood cholesterol abnormal - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007472334	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoaacusis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoaesthesia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007472873	29/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Eye disorder (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ENTECAVIR [ENTECAVIR] (C - n/a - n/a - [n/a - n/a - n/a]), [METFORMIN, METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE BP] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007452030	28/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Cerebellar infarction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Facial paralysis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ischaemic stroke (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007452757	28/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Facial paresis (3h - Recovered/Resolved - Other Medically Important Condition), Hypoaesthesia (3h - Recovered/Resolved - Other Medically Important Condition), Paraesthesia (3h -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	CYMBALTA [DULOXETINE, DULOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [AMFETAMINE SULFATE, DEXAMFETAMINE SULFATE, AMFETAMINE ASPARTATE, DEXAMFETAMINE SACCHARATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10007454993	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007455775	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10007455804	28/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (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-10007456700	28/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Facial paralysis (n/a - Recovering/Resolving -), Swelling face (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007459227	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Neuralgic amyotrophy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paresis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007459301	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (6h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10007460069	28/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Depersonalisation/derealisation disorder (1d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Flushing (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (1d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Stiff leg syndrome (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007460741	28/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [3d - 1{DF} - Unknown])	NOT AVAILABLE (C - n/a - n/a -), REVELA 2.4 G POWDER FOR ORAL SUSPENSION [SEVELAMER CARBONATE] (C - n/a - n/a -), VELPHORO 500 MG CHEWABLE TABLETS [IRON, SUCROFERRIC OXYHYDROXIDE] (C - n/a - n/a -), [ATORVASTATIN, EZETIMIBE] (C - n/a - n/a -), [BETAHISTINE DIHYDROCHLORIDE] (C - n/a - n/a -), [BISOPROLOL FUMARATE] (C - n/a - n/a -), [CALCIFEDIOL] (C - n/a - n/a -), [DOXAZOSIN, DOXAZOSIN MESILATE] (C - n/a - n/a -), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE] (C - n/a - n/a -), [FUROSEMIDE] (C - n/a - n/a -), [PARICALCITOL] (C - n/a - n/a -)	ICSR
EU-EC-10007441156	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

										Hospitalisation)	immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])		
EU-EC-10007442373	27/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Disease recurrence (12d - Recovered/Resolved - Other Medically Important Condition), Ear pain (12d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (12d - Recovered/Resolved - Other Medically Important Condition), Facial paresis (12d - Recovered/Resolved - Other Medically Important Condition), Headache (12d - Recovered/Resolved - Other Medically Important Condition), Hypoaesthesia (12d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	RELVAR ELLIPTA [FLUTICASON FUROATE, VILANTEROL] (C - Asthma - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - Vitamin supplementation - n/a - [n/a - n/a - n/a]), [ETHINYLESTRADIOL, LEVONORGESTREL] (C - Dysmenorrhoea - n/a - [n/a - n/a - n/a]), [INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007443876	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Eyelid disorder (0d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (0d - Recovered/Resolved - Other Medically Important Condition), Paraesthesia (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007444774	27/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[TAMOXIFEN CITRATE] (C - Breast cancer female - n/a - [n/a - 20mg - Oral])	ICSR
EU-EC-10007444865	27/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - Disabling), IVth nerve paralysis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved - Disabling), Migraine (n/a - Not Recovered/Not Resolved - Disabling), Nausea (n/a - Not Recovered/Not Resolved - Disabling), Pyrexia (n/a - Not Recovered/Not Resolved - Disabling), Visual impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC-10007448504	27/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (1d - Recovered/Resolved With Sequelae - Disabling), Hypoaacusis (n/a - Recovered/Resolved - Disabling), Hypoaesthesia (1d - Not Recovered/Not Resolved - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007431073	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Asthenia (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chills (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Facial paralysis (4h - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

										Myalgia (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10007431657	26/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling face (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-10007432381	26/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007432403	26/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Facial paralysis (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-10007432547	26/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007432977	26/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007434942	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Face oedema (1d - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007436963	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Administration site pain (1d - Unknown - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (1d - Unknown - Other Medically Important Condition), Headache (0d - Unknown - Other Medically Important Condition), Oral herpes (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[NAPROXEN SODIUM] (C - n/a - n/a - [n/a - 550mg - n/a]), [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - 20mg - n/a])	ICSR
EU-EC-10007439409	26/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cough (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved - Disabling), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Eye pain (n/a - Not Recovered/Not Resolved - Disabling), Facial pain (n/a - Not Recovered/Not Resolved - Disabling), Facial paralysis (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Malaise (n/a - Not Recovered/Not Resolved - Disabling), Neck pain (n/a - Not Recovered/Not Resolved - Disabling), SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	JANUMET [METFORMIN HYDROCHLORIDE, SITAGLIPTIN, METFORMIN HYDROCHLORIDE, SITAGLIPTIN PHOSPHATE, METFORMIN HYDROCHLORIDE, SITAGLIPTIN PHOSPHATE MONOHYDRATE] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [ALENDRONATE SODIUM, ALENDRONIC ACID] (C - Osteoporosis - n/a - [n/a - n/a - n/a]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM CARBONATE] (C - Osteoporosis - n/a - [n/a - n/a - n/a]), [GLICLAZIDE] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]), [INDAPAMIDE, INDAPAMIDE HEMIHYDRATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [INSULIN, INSULIN HUMAN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]),	ICSR

												[PREDNISONE] (C - Obliterative bronchiolitis - n/a - [n/a - n/a - n/a])	
EU-EC-10007439516	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (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-10007440331	26/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Abdominal distension (n/a - Unknown -), Appendicitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown -), Nausea (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) HUMALOG [INSULIN LISPRO] (C - n/a - n/a - [n/a - n/a - n/a]), PROPRANOLOL HYDROCHLORIDE [PROPRANOLOL HYDROCHLORIDE] (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]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - 12.5mg - n/a]), [LOSARTAN, LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [PRAVASTATIN, PRAVASTATIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-10007420074	25/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (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-10007420215	25/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Paraesthesia oral (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007420668	25/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[NAPROXEN, NAPROXEN SODIUM] (C - Pain - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10007421020	25/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Back pain (n/a - Recovering/Resolving -), Chest discomfort (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Ear pain (n/a - Recovering/Resolving -), Facial pain (n/a - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Facial paresis (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Hypoaesthesia (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Palpitations (n/a - Recovering/Resolving -), Paraesthesia (n/a - Recovering/Resolving -), Peripheral coldness (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) [BIOTIN] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL, CALCIUM PHOSPHATE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [FAMOTIDINE, FAMOTIDINE, CALCIUM CARBONATE, MAGNESIUM HYDROXIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MESALAZINE] (C - n/a - n/a - [n/a - n/a - n/a]), [MINERALS NOS, VITAMINS NOS] (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-10007421026	25/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (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-10007421065	25/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[OMEPRAZOLE] (C - n/a - n/a - [n/a - 20mg - n/a])	ICSR

										Caused/Prolonged Hospitalisation, Disabling), Fatigue (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	n/a - Intramuscular]		
EU-EC-10007421069	25/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Ageusia (n/a - Not Recovered/Not Resolved -), Eye movement disorder (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007424469	25/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Disease recurrence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Ear pain (n/a - Not Recovered/Not Resolved -), Eye swelling (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Recovering/Resolving -), Hypoaesthesia (n/a - Not Recovered/Not Resolved -), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved -), Neck pain (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Pain in jaw (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -), Swelling face (n/a - Not Recovered/Not Resolved -), Toothache (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMINE HYDROCHLORIDE, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007424471	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007424641	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (4d - Recovered/Resolved - Other Medically Important Condition), Paraesthesia (4d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007427692	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Blepharospasm (n/a - Not Recovered/Not Resolved - Disabling), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myokymia (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC-10007428081	25/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Ear pain (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved -), Taste disorder (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

EU-EC-10007428096	25/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Allergy to vaccine (n/a - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Hypersensitivity (3d - Recovered/Resolved With Sequelae -), Hypertension (n/a - Recovering/Resolving -), Inappropriate schedule of product administration (n/a - Unknown -), Paraesthesia oral (n/a - Recovering/Resolving -), Sensory disturbance (n/a - Recovering/Resolving -), Swollen tongue (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [3d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007419256	24/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Depressed level of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Facial paresis (0d - Recovered/Resolved - Other Medically Important Condition), Paraparesis (0d - Recovered/Resolved - Other Medically Important Condition), Paresis (0d - Recovered/Resolved - Other Medically Important Condition), Presyncope (0d - Recovered/Resolved - Other Medically Important Condition), Vomiting (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10007418421	23/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10007409412	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007409729	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1.3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007412780	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007412945	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (8d - Recovered/Resolved -), Hyperpyrexia (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007413079	22/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Conjunctivitis (n/a - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular])	[RABEPRAZOLE, RABEPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 10mg - Oral]), [RAMIPRIL] (C - Hypertension - n/a - [n/a - 5mg - Oral])	ICSR
EU-EC-10007413963	22/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -), Chills (2d - Recovered/Resolved -), Dizziness (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	BEXAROTENE [BEXAROTENE] (C - Cutaneous T-cell lymphoma - n/a - [n/a - 75mg - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Thyroid disorder - n/a - [n/a -	ICSR

										Eye contusion (n/a - Unknown -), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Head discomfort (n/a - Unknown -), Headache (n/a - Recovering/Resolving -), Hypersensitivity (n/a - Unknown -), Hypoaesthesia (2d - Recovered/Resolved -), Hypoaesthesia (n/a - Unknown -), Influenza like illness (n/a - Unknown -), Lethargy (n/a - Unknown -), Nausea (2d - Recovered/Resolved -), Ocular discomfort (n/a - Unknown -), Ocular hyperaemia (n/a - Unknown -), Swelling face (n/a - Unknown -)		150ug - n/a)), [ROSUVASTATIN, ROSUVASTATIN CALCIUM] (C - Blood cholesterol - n/a - [n/a - 20mg - n/a])	
EU-EC-10007414118	22/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Herpes zoster (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[LISINAPRIL, LISINAPRIL DIHYDRATE] (C - Hypertension - n/a - [n/a - 5mg - Oral])	ICSR
EU-EC-10007415161	22/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (2d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	IVABRADINE [IVABRADINE, IVABRADINE HYDROCHLORIDE] (C - Sinus tachycardia - n/a - [n/a - n/a])	ICSR
EU-EC-10007415443	22/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	DULOXETINE [DULOXETINE] (C - n/a - n/a - [n/a - n/a - n/a]), FENTANYL [FENTANYL, FENTANYL CITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), LEVETIRACETAM [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]), OLANZAPINE [OLANZAPINE] (C - n/a - n/a - [n/a - n/a - n/a]), [BISACODYL] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROMORPHONE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007392059	21/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007392525	21/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Allergy to vaccine (n/a - Recovered/Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paraesthesia (n/a - Recovered/Resolved -), Paraesthesia oral (n/a - Recovered/Resolved -), Rash erythematous (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[EPINEPHRINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASON PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007392836	21/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved -), Muscular weakness (n/a - Unknown -), Overdose (n/a - Unknown -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular])	Not reported	ICSR
EU-EC-10007393844	21/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR

EU-EC-10007393853	21/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -)	n/a - Intramuscular) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007395628	21/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Cheilitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dry eye (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lacrimation decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Muscle twitching (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Swelling face (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007385209	20/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007389602	20/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (3d - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007371706	19/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Disabling, Other Medically Important Condition), Balance disorder (n/a - Unknown - Disabling, Other Medically Important Condition), Confusional state (n/a - Unknown - Disabling, Other Medically Important Condition), Costochondritis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Diplopia (1d - Recovered/Resolved - Disabling, Other Medically Important Condition), Dizziness (n/a - Unknown - Disabling, Other Medically Important Condition), Dysarthria (1d - Recovered/Resolved -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[LEVOTHYROXINE SODIUM] (C - Thyroid disorder - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - Carpal tunnel syndrome - n/a - [n/a - n/a - n/a])	ICSR

										<p>Disabling, Other Medically Important Condition),</p> <p>Erythema (n/a - Unknown - Disabling, Other Medically Important Condition),</p> <p>Eye pain (1d - Recovered/Resolved - Disabling, Other Medically Important Condition),</p> <p>Facial pain (n/a - Unknown - Disabling, Other Medically Important Condition),</p> <p>Facial paralysis (2d - Recovering/Resolving - Disabling, Other Medically Important Condition),</p> <p>Fatigue (n/a - Unknown - Disabling, Other Medically Important Condition),</p> <p>Hypoaesthesia (n/a - Unknown - Disabling, Other Medically Important Condition),</p> <p>Lacrimation increased (n/a - Unknown - Disabling, Other Medically Important Condition),</p> <p>Lymphadenopathy (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),</p> <p>Middle ear inflammation (4d - Recovered/Resolved - Disabling, Other Medically Important Condition),</p> <p>Migraine with aura (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),</p> <p>Nausea (4d - Recovering/Resolving - Disabling, Other Medically Important Condition),</p> <p>Oropharyngeal pain (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),</p> <p>Pain (n/a - Unknown - Disabling, Other Medically Important Condition),</p> <p>Rales (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),</p> <p>Somnolence (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition),</p> <p>Swelling face (2d - Recovered/Resolved With Sequelae - Disabling, Other Medically Important Condition)</p>			
EU-EC-10007373262	19/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	<p>Ear pain (n/a - Recovering/Resolving -),</p> <p>Eye pain (n/a - Recovering/Resolving -),</p> <p>Facial pain (n/a - Recovering/Resolving -),</p> <p>Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Hypoaesthesia (n/a - Recovering/Resolving -),</p> <p>Pain in jaw (n/a - Recovering/Resolving -)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007373381	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	<p>Eyelid function disorder (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Facial paresis (n/a - Recovering/Resolving - Other Medically Important Condition),</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	[AMLODIPINE BESILATE, PERINDOPRIL ARGININE, AMLODIPINE, PERINDOPRIL ARGININE] (C - Hypertension - Unknown - [n/a - n/a - Oral])	ICSR

										Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia oral (n/a - Recovering/Resolving - Other Medically Important Condition), Skin burning sensation (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10007376034	19/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007378243	19/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	More than 85 Years	Not Specified	Not Specified	No	Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Haemorrhage intracranial (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007363518	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (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-10007363521	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (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-10007363599	18/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paresis (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -), Paraesthesia oral (n/a - Not Recovered/Not Resolved -), Vaccination site paraesthesia (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[IBUPROFEN, NAPROXEN, NAPROXEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007363726	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Tachycardia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007364453	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving -), Lethargy (3d - Recovered/Resolved -), Pain (3d - Recovered/Resolved -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - Not applicable - [n/a - .3mL - n/a])	NEOCLARITYN [DESLOXATADINE] (C - n/a - Dose not changed -), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - n/a - n/a -)	ICSR
EU-EC-10007364795	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007364939	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Paresis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a -)	Not reported	ICSR

EU-EC-10007367447	18/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	<p>Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Feeling hot (5d - Recovered/Resolved - Other Medically Important Condition),</p> <p>Head discomfort (n/a - Unknown - Other Medically Important Condition),</p> <p>Headache (n/a - Unknown - Other Medically Important Condition),</p> <p>Monoparesis (0d - Recovered/Resolved - Other Medically Important Condition),</p> <p>Monoparesis (15min - Recovered/Resolved - Other Medically Important Condition),</p> <p>Muscular weakness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Paraesthesia (5d - Recovering/Resolving - Other Medically Important Condition),</p> <p>Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Paresis (0d - Recovered/Resolved - Other Medically Important Condition),</p> <p>Paresis (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Presyncope (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Sensory loss (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),</p> <p>Vision blurred (n/a - Recovering/Resolving - Other Medically Important Condition)</p>	Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007367567	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	<p>Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Off label use (n/a - Unknown -),</p> <p>Product use issue (n/a - Unknown -)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007369324	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007369329	18/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	<p>Facial paralysis (n/a - Unknown - Other Medically Important Condition),</p> <p>Nasopharyngitis (n/a - Recovered/Resolved -),</p> <p>Periorbital swelling (n/a - Unknown -),</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Pruritus (n/a - Unknown -), Rash (n/a - Unknown -), Swelling face (n/a - Unknown -), Swelling of eyelid (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)			
EU-EC-10007369346	18/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007369441	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Eye pruritus (n/a - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR
EU-EC-10007369450	18/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Eye disorder (n/a - Unknown - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Occipital neuralgia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007363018	17/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (2h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007354148	15/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -), Limb discomfort (n/a - Recovering/Resolving -), Paresis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10007355043	15/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Elderly	Female	No	Diarrhoea (1h - Recovered/Resolved - Other Medically Important Condition), Dysarthria (1h - Recovered/Resolved - Other Medically Important Condition), Facial paralysis (1h - Recovered/Resolved - Other Medically Important Condition), Unresponsive to stimuli (1h - Recovered/Resolved - Other Medically Important Condition), Vomiting (1h - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a])	[SIMVASTATIN] (C - Blood cholesterol - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007356796	15/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (2d - Recovered/Resolved - Other Medically Important Condition), Fatigue (16d - Recovered/Resolved - Other Medically Important Condition), Headache (7d - Recovered/Resolved - Other Medically Important Condition), Injection site pain (5d - Recovered/Resolved -), Myalgia (13d - Recovered/Resolved - Other Medically Important Condition), Nausea (9d - Recovered/Resolved - Other Medically Important Condition), Palpitations (13d - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - Influenza immunisation - n/a - [n/a - n/a - n/a])	ICSR





										Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (7d - Recovered/Resolved -), Sensory disturbance (n/a - Unknown -), Spinal pain (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination site erythema (7d - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (5d - Recovered/Resolved - Other Medically Important Condition), Vaccination site swelling (16d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10007357899	15/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved -), Lip pain (n/a - Not Recovered/Not Resolved -), Toothache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	DESLORATADINE ACTAVIS [DESLORATADINE] (C - Hypersensitivity - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007360283	15/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial pain (n/a - Not Recovered/Not Resolved - Disabling), Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling), Noninfective encephalitis (n/a - Not Recovered/Not Resolved - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007346801	14/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007352598	14/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Blood pressure systolic increased (n/a - Unknown -), Facial paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Otitis media (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM, ESOMEPRAZOLE MAGNESIUM TRIHYDRATE, ESOMEPRAZOLE SODIUM] (C - Dyspepsia - n/a - [n/a - 40mg - n/a])	ICSR
EU-EC-10007352940	14/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Dysarthria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007353672	14/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Herpes zoster oticus (n/a - Unknown - Other Medically Important Condition), Rash vesicular (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-10007341040	13/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	More than 85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - n/a]), [ATORVASTATIN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007341517	13/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)] (C - Immunisation - n/a - [n/a - n/a - n/a]), [LOSARTAN POTASSIUM] (C - Hypertension - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007341974	13/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	65-85 Years	Elderly	Male	No	Facial paralysis (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a -	Not reported	ICSR

EU-EC-10007343135	13/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	65-85 Years	Not Specified	Female	No	COVID-19 (3d - Recovered/Resolved -), Facial paralysis (2d - Recovered/Resolved -), Infection (n/a - Unknown -)	Intramuscular]) [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) [MIRTAZAPINE] (C - Depression - n/a - [n/a - n/a - n/a])	RIVAROXABAN [RIVAROXABAN] (C - n/a - n/a - [n/a - n/a - n/a]), [MIRTAZAPINE] (C - Depression - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007343142	13/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved -), Paralysis (n/a - Unknown -)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007344586	13/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[OMEPRAZOLE] (C - Reflux gastritis - n/a - [n/a - 20mg - n/a])	ICSR
EU-EC-10007344854	13/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Influenza like illness (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	Not reported	ICSR
EU-EC-10007345051	13/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Blood pressure increased (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoaesthesia oral (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Paraesthesia oral (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 10mg - n/a])	ICSR
EU-EC-10007347508	13/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Ileus paralytic (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination site pain (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	[CALCIFEDIOL] (C - n/a - n/a -)	ICSR
EU-EC-10007347593	13/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007347668	13/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Back pain (n/a - Not Recovered/Not Resolved -), Cerebral ischaemia (n/a - Unknown - Other Medically Important Condition), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown -), Neck pain (n/a - Not Recovered/Not Resolved -), Pain (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Sensory disturbance (n/a - Unknown -), Swelling face (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007333321	12/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Female	No	Facial paralysis (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-	12/01/2021	Spontaneous	Non	Non	Not	Not	Not	Female	No	Facial paralysis (n/a -	TOZINAMERAN	Not reported	ICSR

10007337048			Healthcare Professional	European Economic Area	available	Specified	Specified			Recovered/Resolved - Other Medically Important Condition), Influenza like illness (2wk - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC-10007339585	12/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Disabling), Lacrimation increased (n/a - Not Recovered/Not Resolved - Disabling), Vision blurred (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	BYDUREON [EXENATIDE] (C - n/a - n/a - [n/a - 2mg - Subcutaneous]), [AMLODIPINE, AMLODIPINE BESILATE] (C - n/a - n/a - [n/a - 10mg - n/a]), [HYDROCHLOROTHIAZIDE] (C - n/a - n/a - [n/a - 12.5mg - n/a]), [LISINOPRIL, LISINOPRIL DIHYDRATE] (C - n/a - n/a - [n/a - 40mg - n/a]), [OMEPRAZOLE, PANTOPRAZOLE, PANTOPRAZOLE SODIUM] (C - n/a - n/a - [n/a - 40mg - n/a]), [PNEUMOCOCCAL VACCINE] (C - n/a - n/a - [1d - n/a - n/a]), [TETANUS VACCINES] (C - n/a - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10007325577	11/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Facial paralysis (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-10007325813	11/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved -), Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (3d - Recovered/Resolved -), Pain (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Paraesthesia (5d - Recovered/Resolved - Other Medically Important Condition), Paraesthesia oral (5d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMFETAMINE SULFATE, DEXAMFETAMINE SULFATE, AMFETAMINE ASPARTATE, DEXAMFETAMINE SACCHARATE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - 30mg - Oral])	ICSR
EU-EC-10007326689	11/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Migraine (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	DEXAMETHASONE [DEXAMETHASONE, DEXAMETHASONE SODIUM PHOSPHATE] (C - n/a - n/a - [n/a - 4mg - n/a]), [ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - n/a - n/a - [n/a - 500mg - n/a]), [BUTALBITAL, PARACETAMOL, CAFFEINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN, VITAMIN B12] (C - n/a - n/a - [n/a - 500mg - n/a]), [DICLOFENAC, DICLOFENAC DIETHYLAMINE, DICLOFENAC EPOLAMINE, DICLOFENAC POTASSIUM, DICLOFENAC RESINATE, DICLOFENAC SODIUM, DICLOFENAC SODIUM PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 200ug - n/a]), [LOSARTAN POTASSIUM] (C - n/a - n/a - [n/a - 25mg - n/a]), [VALSARTAN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007331645	11/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoaesthesia (n/a - Unknown -), Paraesthesia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007318826	08/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Adult	Male	No	Facial paralysis (1d - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

										Condition)	immunisation - Not applicable - [n/a - n/a - Intramuscular])		
EU-EC-10007319816	08/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	65-85 Years	Not Specified	Male	No	Cerebrovascular accident (n/a - Recovering/Resolving - Other Medically Important Condition), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007322605	08/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007312194	07/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007314300	07/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Dry eye (n/a - Unknown -), Ear disorder (n/a - Unknown -), Ear pain (n/a - Not Recovered/Not Resolved -), Eye irritation (n/a - Unknown -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Hypoaesthesia oral (n/a - Not Recovered/Not Resolved -), Limb discomfort (n/a - Unknown -), Wrong technique in product usage process (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Urticaria - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-10007304749	06/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Eye pain (n/a - Unknown -), Eyelid ptosis (n/a - Unknown - Other Medically Important Condition), Facial pain (n/a - Unknown -), Facial paralysis (n/a - Unknown - Other Medically Important Condition), Swelling face (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007304759	06/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Ear pruritus (n/a - Not Recovered/Not Resolved -), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoaesthesia (n/a - Not Recovered/Not Resolved -), Vaccination site paraesthesia (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CLONIDINE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDRALAZINE] (C - n/a - n/a - [n/a - n/a - n/a]), [SPIRONOLACTONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007306001	06/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	Not Specified	Not Specified	Female	No	Facial paralysis (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-10007309958	06/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Ear discomfort (n/a - Recovering/Resolving -), Eye disorder (n/a - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Hypoaesthesia (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007292819	04/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	18-64 Years	Not Specified	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in jaw (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	04/01/2021	Spontaneous	Healthcare	Non	Not	18-64	Not	Female	No	Facial paralysis (n/a - Not	TOZINAMERAN	Not reported	ICSR

10007296117		Professional	European Economic Area	available	Years	Specified	Recovered/Not Resolved - Other Medically Important Condition), Lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	
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 Rows 1 - 477 (All Rows)

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