

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-10009070303	18/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (48h - Recovered/Resolved -), Nausea (48h - Recovered/Resolved -), Pain (48h - Recovered/Resolved -), Pyrexia (48h - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009070419	18/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[DOCUSATE SODIUM] (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]), [THIAMINE HYDROCHLORIDE, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009071106	18/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Headache (n/a - Unknown -), Inappropriate affect (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009045631	17/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved -), Nasopharyngitis (1d - Recovered/Resolved -), Oropharyngeal pain (1d - Recovered/Resolved -), Pain in extremity (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009046597	17/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Pain in extremity (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-10009046614	17/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009047728	17/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Feeling abnormal (n/a - Not Recovered/Not Resolved -), Hyperpyrexia (n/a - Not Recovered/Not Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BECLOMETASONE DIPROPIONATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [EPINEPHRINE, EPINEPHRINE, SODIUM METABISULFITE, SODIUM	ICSR

										Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved -)		CHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10009047890	17/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Appetite disorder (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Malaise (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-10009049080	17/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Circulatory collapse (n/a - Unknown - Caused/Prolonged Hospitalisation), Infection (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation), Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009050317	17/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash (0d - Recovering/Resolving - Other Medically Important Condition), Swelling face (0d - Recovering/Resolving - Other Medically Important Condition), Swelling of eyelid (0d - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009051415	17/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Psychotic disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[BACLOFEN] (C - n/a - n/a - [n/a - n/a - n/a]), [CHLORPROTHIXENE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009052374	17/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood glucose increased (n/a - Unknown -), Bone pain (n/a - Unknown -), Chest pain (n/a - Recovered/Resolved -), Chills (n/a - Unknown -), Dehydration (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Heart rate increased (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Illness (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	LANTUS [INSULIN GLARGINE] (C - Type 1 diabetes mellitus - n/a - [n/a - n/a - n/a]), [INSULIN ASPART] (C - Type 1 diabetes mellitus - n/a - [n/a - n/a - n/a]), [LORATADINE] (C - Seasonal allergy - n/a - [n/a - n/a - Oral])	ICSR

										Unknown -), Nausea (n/a - Unknown -), Pallor (n/a - Unknown -), Pericarditis (n/a - Unknown - Other Medically Important Condition), Sleep disorder (n/a - Unknown -), Vomiting (n/a - Unknown -)			
EU-EC-10009052472	17/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009055865	17/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fall (n/a - Recovering/Resolving - Other Medically Important Condition), Lip injury (n/a - Recovering/Resolving - Other Medically Important Condition), Seizure (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009029807	16/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site pain (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009031619	16/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Haematoma (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009031839	16/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (2d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (2d - Recovered/Resolved - Other Medically Important Condition), Headache (2d - Recovered/Resolved - Other Medically Important Condition), Injection site pain (2d - Recovered/Resolved - Other Medically Important Condition), Lymphadenopathy (2d - Recovered/Resolved - Other Medically Important Condition), Peripheral swelling (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	[MESALAZINE] (C - Colitis ulcerative - n/a - [n/a - 1{DF} - Oral])	ICSR
EU-EC-10009031991	16/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Echymosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Epistaxis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR

										Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10009032363	16/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009032944	16/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving -), Dyskinesia (n/a - Recovering/Resolving -), Heart rate increased (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pallor (n/a - Recovering/Resolving -), Seizure (n/a - Recovering/Resolving - Other Medically Important Condition), Tremor (n/a - Recovering/Resolving -), Vision blurred (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a]) [BIFIDOBACTERIUM LACTIS] (C - n/a - n/a - [n/a - n/a - n/a]), [FISH OIL] (C - n/a - n/a - [n/a - n/a - n/a]), [MAGNESIUM CITRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMINE, PYRIDOXINE HYDROCHLORIDE, VITAMIN B] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])		ICSR
EU-EC-10009034306	16/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Brain natriuretic peptide increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Troponin increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009035487	16/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Acute coronary syndrome (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Dysphagia (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Condition), Headache (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - Other Medically Important Condition), Myopericarditis (n/a - Unknown - Other Medically Important Condition), Odynophagia (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10009037143	16/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition), Throat tightness (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[FEXOFENADINE HYDROCHLORIDE] (C - Hypersensitivity, Rhinitis allergic - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10009039274	16/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic shock (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-10009040007	16/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Generalised tonic-clonic seizure (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009017976	15/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved -), Tonsillitis (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009018020	15/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009018471	15/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009019611	15/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypoaesthesia (n/a - Recovered/Resolved - Other Medically Important Condition), Pharyngeal swelling (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009019867	15/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	Yes	Burning sensation (n/a - Recovered/Resolved -), Disorientation (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Ear discomfort (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Recovered/Resolved -), Flatulence (n/a - Recovered/Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Heart rate decreased (n/a - Recovered/Resolved -), Hyperhidrosis (n/a - Recovered/Resolved -), Muscle tightness (n/a - Recovered/Resolved -), Oropharyngeal discomfort (n/a - Recovered/Resolved -), Pallor (n/a - Unknown -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10009025234	15/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009027682	15/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown -), Cough (n/a - Unknown -), Fatigue (n/a - Unknown -), Feeling cold (n/a - Unknown -), Feeling hot (n/a - Unknown -), Headache (n/a - Recovering/Resolving -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009028947	15/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain (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-10009029184	15/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Balance disorder (3d - Recovered/Resolved - Other Medically Important Condition), Dizziness (3d - Recovered/Resolved - Other Medically Important Condition), Vomiting (3d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PROCHLORPERAZINE, PROCHLORPERAZINE MALEATE, PROCHLORPERAZINE MALEATE BP] (C - Dizziness - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009014563	14/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (15h - Recovered/Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[CEFALEXIN] (C - n/a - n/a - [n/a - n/a - n/a]), [PHENPROCOUMON] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008996198	12/06/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Injection site swelling (n/a - Not	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

			Professional	Area						Recovered/Not Resolved -)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a])		
EU-EC-10009002235	12/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008988446	11/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fall (n/a - Unknown -), Gait disturbance (n/a - Not Recovered/Not Resolved -), Head injury (n/a - Unknown -), Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Pain (n/a - Unknown -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008989238	11/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Recovering/Resolving -), Paraesthesia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008965856	10/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008966089	10/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (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-10008966649	10/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Aggression (n/a - Not Recovered/Not Resolved -), Condition aggravated (n/a - Not Recovered/Not Resolved -), Coprolalia (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Ear pain (n/a - Not Recovered/Not Resolved -), Emotional distress (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Feeling abnormal (n/a - Not Recovered/Not Resolved -), Head discomfort (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) [DULOXETINE, DULOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ATOMOXETINE, ATOMOXETINE HYDROCHLORIDE] (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]), [LORATADINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	

										Seizure like phenomena (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Somnolence (n/a - Not Recovered/Not Resolved -), Tic (n/a - Not Recovered/Not Resolved -)			
EU-EC-10008967185	10/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Puncture site hypoesthesia (n/a - Not Recovered/Not Resolved -), Puncture site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[ETHINYLESTRADIOL, LEVONORGESTREL, LACTOSE, LACTOSE ANHYDROUS, LACTOSE MONOHYDRATE] (C - Hormonal contraception - Dose not changed - [n/a - n/a - Oral])	ICSR
EU-EC-10008967420	10/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10008968808	10/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Pruritus (4d - Recovered/Resolved -), Pruritus (n/a - Recovering/Resolving -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008971535	10/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -), Blood pressure fluctuation (n/a - Not Recovered/Not Resolved -), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Disturbance in attention (n/a - Unknown -), Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Heart rate abnormal (n/a - Not Recovered/Not Resolved -), Loss of personal independence in daily activities (n/a - Unknown -), Muscle atrophy (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown -), Weight decreased (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[TIMOLOL, TIMOLOL MALEATE] (C - Eye injury - n/a - [n/a - n/a - n/a])	ICSR

EU-EC-10008973754	10/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Unknown -), Dizziness (n/a - Unknown -), Headache (n/a - Unknown -), Injection site pain (n/a - Unknown -), Malaise (n/a - Unknown -), Nausea (n/a - Unknown -), Pyrexia (5d - Unknown -), Tachycardia (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008974736	10/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving -), Injection site swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[LEVOCABASTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOCABASTINE, LEVOCABASTINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008979043	10/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008953895	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - 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-10008956188	09/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (12h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (12h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Muscular weakness (8h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Sensory level abnormal (12h - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008960307	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Blood creatine phosphokinase increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electrocardiogram ST segment elevation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial injury (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericardial effusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Troponin increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10008961642	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypersensitivity (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-10008961872	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Kidney infection (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Urinary tract infection (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[VITAMIN D] (C - Product used for unknown indication - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008962541	09/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved -), Pain in extremity (3d - Recovered/Resolved -), Sluggishness (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008963210	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Glossodynia (n/a - Not Recovered/Not Resolved - Disabling), Odynophagia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[FLUTICASON PROPRIONATE] (C - Hypersensitivity - n/a - [n/a - 200ug - n/a]), [LORATADINE] (C - Hypersensitivity - n/a - [n/a - 10mg - n/a])	ICSR

										Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Disabling), Speech disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tongue movement disturbance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10008963839	09/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10008934341	08/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008938724	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10008938768	08/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (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-10008938778	08/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008939303	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10008940002	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10008940308	08/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypersensitivity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008941919	08/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (1d - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

										Choking sensation (n/a - Unknown -), Dysphagia (n/a - Unknown -), Hypertension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	applicable - [n/a - n/a - n/a]		
EU-EC-10008943427	08/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Appendicitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008943493	08/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (Od - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008944263	08/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Post viral fatigue syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008948255	08/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pharyngeal swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Pruritus (n/a - Unknown -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR

										Caused/Prolonged Hospitalisation), Spinal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Swelling face (n/a - Unknown - Caused/Prolonged Hospitalisation), Swollen tongue (n/a - Unknown - Caused/Prolonged Hospitalisation), Throat irritation (n/a - Unknown - Caused/Prolonged Hospitalisation), Tremor (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC-10008949928	08/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10008922570	07/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Unknown -), Heart rate increased (n/a - Recovering/Resolving - Other Medically Important Condition), Hyperventilation (n/a - Recovering/Resolving - Other Medically Important Condition), Muscle spasms (n/a - Unknown -), Respiratory rate increased (n/a - Recovering/Resolving -), Tremor (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008922657	07/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008923484	07/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nasal dryness (n/a - Recovering/Resolving - Other Medically Important Condition), Restless legs syndrome (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a]), [CLINDAMYCIN, CLINDAMYCIN HYDROCHLORIDE, CLINDAMYCIN PHOSPHATE] (C - Acne - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Anxiety - n/a - [110d - n/a - n/a])	ICSR

EU-EC-10008929036	07/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Colitis ulcerative (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AZATHIOPRINE] (C - Colitis ulcerative - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008929788	07/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Facial paresis (24h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008934887	07/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anaphylactic reaction (4h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Depressed level of consciousness (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Feeling hot (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypotension (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vision blurred (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10008914048	05/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -), Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Injection site warmth (n/a - Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008914096	05/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (0d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Malaise (2d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-1000895639	04/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Medically Important Condition)			
EU-EC-10008896364	04/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Postural orthostatic tachycardia syndrome (n/a - Not Recovered/Not Resolved - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008899521	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Haematoma (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008902760	04/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Central nervous system vasculitis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Diarrhoea haemorrhagic (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Eosinophilia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Eosinophilic colitis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Gastrointestinal motility disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hemiplegia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Hypokinesia (n/a - Unknown - Life	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	HYDROXYCARBAMIDE [HYDROXYCARBAMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [CO-TRIMOXAZOLE, SULFAMETHOXAZOLE, TRIMETHOPRIM, TRIMETHOPRIM BP, SULFAMETHOXAZOLE BP] (C - n/a - n/a - [n/a - n/a - n/a]), [CYCLOPHOSPHAMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [DALTEPARIN] (C - n/a - n/a - [n/a - n/a - n/a]), [IVERMECTIN] (C - n/a - n/a - [n/a - n/a - n/a]), [METHYLPREDNISOLONE, METHYLPREDNISOLONE SODIUM SUCCINATE] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Leukocytosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Nervous system disorder (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Photophobia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Venous thrombosis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)			
EU-EC-10008909593	04/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (2d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Heart rate increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypersensitivity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash pruritic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rhinorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [CLOTRIMAZOLE] (C - n/a - n/a - [n/a - n/a - Topical])	ICSR
EU-EC-10008912152	04/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic shock (n/a - Unknown - Life Threatening), Cardiovascular disorder (n/a - Unknown - Life Threatening), Crying (n/a - Unknown - Life Threatening), Erythema (n/a - Unknown - Life	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR

										Threatening), Heart rate increased (n/a - Recovering/Resolving - Life Threatening), Pain in extremity (n/a - Unknown -), Rash (n/a - Recovering/Resolving - Life Threatening), Swelling (n/a - Unknown - Life Threatening)			
EU-EC-10008912207	04/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolving - Other Medically Important Condition)	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]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008912284	04/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sepsis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008877491	03/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving -), Escherichia urinary tract infection (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Thrombocytopenia (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-10008887075	03/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (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-10008863048	02/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -), Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10008863533	02/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Influenza (n/a - Recovered/Resolved -), Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10008864333	02/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved -), Dizziness (n/a - Recovering/Resolving -), Feeling abnormal (n/a - Not Recovered/Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[BECLOMETASONE DIPROPIONATE] (C - Asthma - n/a - [n/a - 40ug - n/a]), [CALCIUM FLUORATUM D15, CALCIUM PHOSPHORICUM D15, CALCIUM CARBONICUM HAHNEMANNI D10, MATRICARIA RECUTITA D10, SULFUR D12,	ICSR

										Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hypoaesthesia (1d - Recovered/Resolved -), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (n/a - Unknown -), Nausea (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Unknown -), Paraesthesia (1d - Recovered/Resolved -), Rash (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Recovering/Resolving -), Vascular injury (n/a - Unknown -)	MERCURIUS SOLUBILIS HAHNEMANNI D15] (C - Hypersensitivity - n/a - [n/a - 4[drp] - n/a]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - 20mg - Oral]), [ISOTRETINOIN] (C - Acne - n/a - [n/a - 80mg - Oral]), [MOMETASONE FUROATE] (C - Hypersensitivity - n/a - [n/a - 100ug - n/a]), [PARACETAMOL] (C - Pain - n/a - [n/a - 1000mg - Oral]), [SODIUM CHLORIDE] (C - Hypersensitivity - n/a - [n/a - n/a - Nasal])		
EU-EC-10008864457	02/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Cough (3d - Recovered/Resolved -), Fatigue (3d - Recovered/Resolved -), Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008865080	02/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Appendicitis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008865134	02/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008865146	02/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - 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])	ICSR
EU-EC-	02/06/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Coagulopathy (n/a -	TOZINAMERAN	Not reported	ICSR

10008866940			Professional	European Economic Area	available	Years	Specified			Unknown -), Hepatic function abnormal (n/a - Unknown -), Pyrexia (n/a - Unknown -), Renal impairment (n/a - Unknown - Other Medically Important Condition), Swelling (n/a - Unknown -), Systemic inflammatory response syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Troponin increased (n/a - Unknown -), Urticaria (n/a - Unknown -), Vasculitic rash (n/a - Unknown -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])		
EU-EC-10008868340	02/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Unknown -), Tremor (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008869170	02/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved -), Diarrhoea (1d - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Hypokinesia (n/a - Recovered/Resolved -), Lethargy (n/a - Recovered/Resolved -), Limb discomfort (n/a - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[CETIRIZINE DIHYDROCHLORIDE] (C - Seasonal allergy - n/a - [n/a - n/a - Oral]), [MOMETASONE FUROATE] (C - Seasonal allergy - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR

										Tinnitus (n/a - Recovered/Resolved -)			
EU-EC-10008869373	02/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypersensitivity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lip swelling (n/a - Unknown - Other Medically Important Condition), Pruritus (n/a - Unknown -), Rash (n/a - Unknown - Other Medically Important Condition), Rash macular (n/a - Unknown -), Swelling face (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-10008869413	02/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (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-10008870922	02/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angiopathy (n/a - Unknown - Other Medically Important Condition), Autoimmune disorder (n/a - Unknown - Other Medically Important Condition), Rash (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-10008873299	02/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	Yes	Accidental exposure to product (n/a - Unknown -), Needle issue (n/a - Unknown -), Underdose (n/a - Unknown -), Vaccination site haemorrhage (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008873976	02/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (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-10008875880	02/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Arthralgia (n/a - Unknown - Other Medically Important Condition), C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), Hypersensitivity (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Serum sickness (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral]), [EPINEPHRINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FAMOTIDINE] (C - n/a - n/a - [n/a - 40mg - Oral]), [HYDROXYZINE DIHYDROCHLORIDE, HYDROXYZINE HYDROCHLORIDE] (C - Urticaria - n/a - [n/a - 75mg - Oral]), [MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - n/a - [n/a - 10mg - Oral])	ICSR
EU-EC-10008876640	02/06/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN]	ROACTEMRA 162 MG [TOCILIZUMAB] (C - n/a -	ICSR

			Professional	Area						Resolved -), Fatigue (n/a - Recovering/Resolving -), Myalgia (n/a - Not Recovered/Not Resolved -)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a])	n/a - [n/a - n/a - n/a])	
EU-EC-10008847772	01/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Vertigo (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10008849425	01/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Flushing (7d - Recovered/Resolved -), Swelling (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008852060	01/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	Yes	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ISOTRETINOIN] (C - Acne - n/a - [79d - n/a - Oral])	ICSR
EU-EC-10008852404	01/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Incorrect dose administered (n/a - Unknown -), Product leakage (n/a - Unknown -), Sneezing (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site erythema (3d - Recovered/Resolved - Other Medically Important Condition), Vaccination site swelling (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[NORETHISTERONE ACETATE, ETHINYLESTRADIOL, FERROUS FUMARATE] (C - Contraception - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10008853125	01/06/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Product administered to patient of inappropriate age (n/a - Unknown -), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	METHOTREXATE [METHOTREXATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - 100[iU] - n/a])	ICSR
EU-EC-10008855676	01/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[LISDEXAMFETAMINE DIMESYLATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Recovered/Not Resolved -)			
EU-EC-10008856137	01/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Discomfort (n/a - Unknown -), Feeling abnormal (n/a - Unknown -), Feeling hot (n/a - Unknown -), Headache (n/a - Unknown -), Rash erythematous (n/a - Unknown -), Thrombosis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008857438	01/06/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008859927	01/06/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asymptomatic COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008860327	01/06/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008836746	31/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral])	[DESOGESTREL, ETHINYLESTRADIOL] (C - Ill-defined disorder - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008837782	31/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Lethargy (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -), Neck pain (n/a - Unknown -), Pain (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Pyrexia (n/a - Unknown - Other Medically Important Condition), Swelling (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008837787	31/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - 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]), [LYMECYCLINE] (C - Acne - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-	31/05/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Seizure (n/a -	TOZINAMERAN	Not reported	ICSR

10008843569			Professional	European Economic Area	available	Years	Specified			Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		
EU-EC-10008847479	31/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving -), Dysphonia (n/a - Recovering/Resolving -), Extremity contracture (n/a - Recovering/Resolving -), Fall (n/a - Recovering/Resolving -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Musculoskeletal stiffness (n/a - Recovering/Resolving -), Seizure (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-10008849003	31/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Left ventricular dysfunction (n/a - Unknown - Other Medically Important Condition), Myocardial necrosis marker increased (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-10008835544	30/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Autism spectrum disorder (n/a - Unknown - Other Medically Important Condition), Cerebral palsy (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-10008824750	29/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10008824905	29/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Herpes zoster (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008825155	29/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [AMYLASE, LIPASE, PROTEASE, PANCREALIPASE, PANCREAS POWDER, PANCREAS POWDER FROM PORCINE, PANCREATIN, PANCREATIN BP] (C - Blood cholesterol - n/a - [n/a - 150mg - n/a])	ICSR
EU-EC-10008825649	29/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Influenza (n/a - Recovered/Resolved -), Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10008825901	29/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Not Recovered/Not Resolved -)	applicable - [n/a - n/a]		
EU-EC-10008813700	28/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (7d - Recovered/Resolved -), Delirium (n/a - Recovering/Resolving - Other Medically Important Condition), Dysarthria (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (7d - Recovered/Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - Other Medically Important Condition), Myalgia (5d - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving -), Off label use (n/a - Unknown - Other Medically Important Condition), Overdose (n/a - Unknown - Other Medically Important Condition), Peripheral swelling (n/a - Recovering/Resolving -), Rash (5d - Recovered/Resolved - Other Medically Important Condition), Swelling face (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008817261	28/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Palpitations (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-10008817304	28/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition), Rash erythematous (n/a - Recovering/Resolving - Other Medically Important Condition), Rash pruritic (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BECLOMETASONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008817709	28/05/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Cyanosis (1d - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

				Economic Area						Important Condition), Hyperhidrosis (1d - Recovered/Resolved - Other Medically Important Condition), Peripheral circulatory failure (1d - Recovered/Resolved - Other Medically Important Condition)	immunisation - Not applicable - [1d - n/a - n/a]		
EU-EC-10008817810	28/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mydriasis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008820941	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008821180	28/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Recovering/Resolving -), Headache (1d - Recovering/Resolving -), Influenza like illness (1d - Recovering/Resolving -), Limb discomfort (1d - Recovering/Resolving -), Pyrexia (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008824417	28/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10008824513	28/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (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-10008783324	26/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown -), Ligament rupture (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-10008786478	26/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008788011	26/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10008790294	26/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Unknown - Other Medically Important Condition), Lymphadenopathy (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										- Other Medically Important Condition)			
EU-EC-10008794644	26/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (2d - Recovering/Resolving -), Chills (2d - Recovering/Resolving -), Injection site pain (2d - Recovering/Resolving -), Vaccination site pain (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008767139	25/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BUTYLSCOPOLAMINE, HYOSCINE BUTYLBROMIDE] (C - Irritable bowel syndrome - n/a - [n/a - n/a - n/a]), [FLUTICASONE PROPIONATE, SALMETEROL, FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008768779	25/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Somnolence (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Syncope (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10008769739	25/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[NORETHISTERONE ACETATE, ETHINYLESTRADIOL] (C - Menstrual disorder - n/a - [n/a - n/a - Oral]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10008771889	25/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (2d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008772533	25/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood ketone body (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	INSULIN DEGLUDEC [INSULIN DEGLUDEC] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008773382	25/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved - Disabling), Fatigue (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										- Disabling), Headache (1d - Recovered/Resolved - Disabling), Myalgia (1d - Recovered/Resolved - Disabling), Nausea (1d - Recovered/Resolved - Disabling), Pyrexia (1d - Recovered/Resolved - Disabling)			
EU-EC-10008760972	24/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (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])	Not reported	ICSR
EU-EC-10008762576	24/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Vision blurred (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a])	[CANDESARTAN] (C - Migraine - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008726375	21/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10008731031	21/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008732058	21/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008735722	21/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (1d - Recovered/Resolved -)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008737677	21/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown - Other Medically Important Condition), Learning disorder (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	SOMATROPIN [SOMATROPIN] (C - n/a - n/a - [n/a - n/a - n/a]), [SOMATROPIN, SOMATROPIN, METACRESOL] (C - Blood growth hormone - n/a - [n/a - n/a - n/a])	ICSR

										Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10008741056	21/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate abnormal (29d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hunger (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Increased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malabsorption (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Taste disorder (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-10008711292	20/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving -), Decreased appetite (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Hyperglycaemia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR

EU-EC-10008712186	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Papule (n/a - Recovered/Resolved With Sequelae - Disabling), Scab (n/a - Recovered/Resolved With Sequelae - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008713242	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncopal (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008714433	20/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Aphasia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Blood lactic acid increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dysstasia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hyperglycaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Incoherent (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Mobility decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Off label use (n/a - Unknown -), Paraesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Product use issue (n/a - Unknown -), Somnolence (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008716412	20/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Recovering/Resolving -), Seizure (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Tremor (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-10008723663	20/05/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved)	TOZINAMERAN [TOZINAMERAN]	Not reported	ICSR

				Economic Area						- Caused/Prolonged Hospitalisation), Troponin increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		
EU-EC-10008697240	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Electrocardiogram abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Unknown - Other Medically Important Condition), Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008697284	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Generalised tonic-clonic seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypokalaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008705454	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Basal ganglia infarction (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Ischaemic cerebral infarction (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Motor dysfunction (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[SOTALOL, SOTALOL HYDROCHLORIDE] (C - Arrhythmia - n/a - [n/a - n/a - n/a]), [WARFARIN, WARFARIN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008707751	19/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown -), Presyncope (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008686592	18/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Streptococcus infection (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

											applicable - [1d - n/a - n/a]		
EU-EC-10008667853	17/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (1d - Recovered/Resolved - Other Medically Important Condition), Neck pain (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL, CAFFEINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008674310	17/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Disease recurrence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), IgA nephropathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ENALAPRIL, ENALAPRIL MALEATE] (C - n/a - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-10008676430	17/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Rash pruritic (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-10008681528	17/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -), Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition), White blood cell count increased (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[PARACETAMOL] (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-10008653272	15/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008643456	14/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a]), [FERROUS SULFATE] (C - Blood iron decreased - n/a - [n/a - n/a - n/a]), [FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - n/a - n/a])	ICSR

										Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10008644014	14/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Confusional state (n/a - Recovering/Resolving -), Dysarthria (n/a - Recovering/Resolving -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving -), Somnolence (n/a - Recovering/Resolving -), Tongue discomfort (n/a - Recovering/Resolving -), Vision blurred (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008631844	13/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved -), Chills (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Hyperglycaemia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10008632578	13/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Not Recovered/Not Resolved -), Eye haemorrhage (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Influenza like illness (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008632776	13/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Aphasia (30min - Recovered/Resolved -), Balance disorder (n/a - Not Recovered/Not Resolved -), Body temperature increased (n/a - Unknown -), Burning sensation (n/a - Unknown -), Chest discomfort (n/a - Unknown -), Chills (n/a - Unknown -), Feeling abnormal (n/a - Unknown -), Insomnia (n/a - Recovering/Resolving -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C - Acne - n/a - [n/a - n/a - n/a]), [ONDANSETRON, ONDANSETRON HYDROCHLORIDE, ONDANSETRON MONOHYDRATE] (C - Nausea - n/a - [n/a - n/a - n/a])	ICSR

										Tremor (n/a - Unknown -), Trismus (30min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10008639252	13/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Feeling of body temperature change (n/a - Unknown - Other Medically Important Condition), Flushing (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008640544	13/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Anaphylactic shock (0d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (0d - Recovered/Resolved - Other Medically Important Condition), Swelling face (0d - Recovered/Resolved - Other Medically Important Condition), Urticaria (0d - Recovered/Resolved - Other Medically Important Condition), Vomiting (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008604525	11/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BUSPIRONE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MEDROXYPROGESTERONE ACETATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008604559	11/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deafness unilateral (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-10008611878	11/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (15d - Recovered/Resolved -), Feeding disorder (15d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10008578597	08/05/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (3d - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN]	Not reported	ICSR

			Professional	Economic Area						- Other Medically Important Condition), Feeling hot (1d - Recovered/Resolved - Other Medically Important Condition), Headache (3d - Recovered/Resolved - Other Medically Important Condition), Myalgia (3d - Recovered/Resolved - Other Medically Important Condition), Nausea (3d - Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC-10008561325	07/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10008561453	07/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	[LAMOTRIGINE] (C - Epilepsy - n/a - [n/a - 50mg - Oral]), [RISPERIDONE] (C - Behaviour disorder - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008563866	07/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved -), Rash (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10008564342	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Unknown - Other Medically Important Condition), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Sensory loss (n/a - Unknown - Other Medically Important Condition), Tension (n/a - Unknown - Other Medically Important Condition), Throat tightness (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-10008569147	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (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-10008569743	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (4d - Recovered/Resolved -), Multisystem inflammatory syndrome in children (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Product administered to patient of inappropriate age (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008576583	07/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blister (n/a - Not Recovered/Not Resolved -), Cellulitis (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

										Hypersensitivity (n/a - Not Recovered/Not Resolved -), Overdose (n/a - Not Recovered/Not Resolved -), Pemphigoid (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved -), Pruritus (n/a - Not Recovered/Not Resolved -), Skin disorder (n/a - Not Recovered/Not Resolved -)			
EU-EC-10008576611	07/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arterial thrombosis (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008556376	06/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	KEPPRA [LEVETIRACETAM] (C - Epilepsy - n/a - [n/a - 2000mg - n/a]), [AMFETAMINE SULFATE, DEXAMFETAMINE SULFATE, AMFETAMINE ASPARTATE, DEXAMFETAMINE SACCHARATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008556394	06/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Suspected COVID-19 (n/a - Not Recovered/Not Resolved -), Thrombosis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008559021	06/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Inappropriate schedule of product administration (n/a - Unknown -), Seizure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	KEPPRA [LEVETIRACETAM] (C - Seizure - n/a - [n/a - 2000mg - n/a]), [AMFETAMINE SULFATE, DEXAMFETAMINE SULFATE, AMFETAMINE ASPARTATE, DEXAMFETAMINE SACCHARATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008536070	05/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bradycardia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008523006	04/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008524780	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008524790	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	METHOTREXATE [METHOTREXATE] (C - Arthritis - n/a - [n/a - 15mg - n/a])	ICSR

										Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC-10008528521	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008528529	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase increased (n/a - Unknown - Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Unknown -), Musculoskeletal disorder (n/a - Unknown -), Myositis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown -), Pyrexia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008528672	04/05/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10008528973	04/05/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	INFLIXIMAB [INFLIXIMAB] (C - Colitis ulcerative - n/a - [n/a - n/a - n/a]), MERCAPTOPYRINE [MERCAPTOPYRINE] (C - Colitis ulcerative - n/a - [n/a - n/a - n/a]), [MESALAZINE] (C - Colitis ulcerative - n/a - [715d - n/a - n/a]), [OMEPRAZOLE] (C - Gastritis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008530276	04/05/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition aggravated (n/a - Recovering/Resolving - Other Medically Important Condition), Confusional state (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved -), Memory impairment (n/a - Recovering/Resolving - Other Medically Important Condition), Seizure (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-10008534522	04/05/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cerebral infarction (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	INSULIN ASPART [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - n/a]), INSULIN DETEMIR [INSULIN DETEMIR] (C -	ICSR

										Important Condition), Cerebrovascular accident (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Jugular vein thrombosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lacrimation increased (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Superior sagittal sinus thrombosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)		n/a - n/a - [n/a - n/a - n/a]	
EU-EC-10008493390	30/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature abnormal (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Headache (n/a - Not Recovered/Not Resolved - Disabling), Nausea (n/a - Not Recovered/Not Resolved - Disabling)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008473735	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (2d - Recovered/Resolved -), Chills (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008473924	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain (4d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

											Pyrexia (4d - Recovered/Resolved -)	immunisation - n/a - [n/a - .3mL - Intramuscular])		
EU-EC-10008474717	29/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No		Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008483813	29/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		Syncope (n/a - Unknown - Other Medically Important Condition), Tinnitus (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])	Not reported	ICSR
EU-EC-10008483864	29/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		Chills (3d - Recovered/Resolved -), Facial paralysis (3d - Recovered/Resolved - Other Medically Important Condition), Facial spasm (3d - Recovered/Resolved - Other Medically Important Condition), Headache (2985min - Recovered/Resolved -), Muscle twitching (3030min - Recovered/Resolved -), Musculoskeletal discomfort (51h - Recovered/Resolved -), Nausea (2985min - Recovered/Resolved -), Piloerection (3d - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[BIOTIN] (C - Supplementation therapy - n/a - [n/a - n/a - n/a]), [ETHINYLESTRADIOL, LEVONORGESTREL] (C - Menstrual cycle management - n/a - [n/a - n/a])	ICSR
EU-EC-10008485067	29/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No		Arthralgia (n/a - Unknown -), Paraesthesia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10008485130	29/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No		Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10008460364	28/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Dizziness (n/a - Recovered/Resolved -), Hyperhidrosis (n/a - Recovered/Resolved -), Hyperventilation (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008468787	28/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		Chills (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR

				Economic Area						Fatigue (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Migraine (n/a - Unknown -), Myalgia (n/a - Unknown -)	immunisation - Not applicable - [n/a - n/a - n/a]		
EU-EC-10008455481	27/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Hypersensitivity (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-10008456472	27/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Recovering/Resolving -), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ETHINYLESTRADIOL, NORETHISTERONE, FERROUS FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008438167	26/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angioedema (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition), Wheezing (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-10008429112	25/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactoid reaction (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - 3{DF} - n/a]), METHOTREXATE [METHOTREXATE] (C - n/a - n/a - [n/a - 12.5mg - n/a]), [AMOXICILLIN TRIHYDRATE, CLAVULANIC ACID, AMOXICILLIN TRIHYDRATE, POTASSIUM CLAVULANATE, AMOXICILLIN, CLAVULANIC ACID, AMOXICILLIN, POTASSIUM CLAVULANATE] (C - n/a - n/a - [7d - 3{DF} - n/a]), [BETAMETHASONE, BETAMETHASONE VALERATE] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [CALCIPOTRIOL] (C - Rash - n/a - [n/a - 1{DF} - n/a]), [CALCITRIOL] (C - Psoriasis - n/a - [n/a - 1{DF} - n/a]), [CASSIA] (C - n/a - n/a - [n/a - 6{DF} - n/a]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [COAL TAR SOLUTION BP, PRECIPITATED SULPHUR BP, SALICYLIC ACID PH. EUR., COAL TAR SOLUTION, SALICYLIC ACID, SULFUR] (C - n/a - n/a - [n/a - n/a - n/a]), [EPINEPHRINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FOLIC ACID] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [METOCLOPRAMIDE] (C -	ICSR

												n/a - n/a - [n/a - 1{DF} - n/a]), [MICONAZOLE NITRATE, HYDROCORTISONE] (C - n/a - n/a - [n/a - n/a - n/a]), [PIZOTIFEN, PIZOTIFEN MALATE] (C - n/a - n/a - [n/a - 2{DF} - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - n/a - [n/a - n/a - n/a]), [SALSALATE] (C - n/a - n/a - [n/a - 1{DF} - n/a]), [SENNA ALEXANDRINA LEAF] (C - n/a - n/a - [n/a - 6{DF} - n/a])	
EU-EC-10008397799	22/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Erythema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ACRIVASTINE, DIPHENHYDRAMINE HYDROCHLORIDE, DIPHENHYDRAMINE HYDROCHLORIDE, ZINC ACETATE] (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]), [FISH OIL] (C - n/a - n/a - [n/a - n/a - n/a]), [IBUPROFEN, IBUPROFEN LYSINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008383998	21/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Immunisation reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008391075	21/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (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-10008374755	20/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (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-10008377751	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10008377754	20/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (12h - Recovered/Resolved -), Nausea (12h - Recovered/Resolved -), Pain in extremity (12h - Recovered/Resolved -), Vomiting (12h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10008379252	20/04/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

			Professional	Economic Area						Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])		
EU-EC-10008359796	19/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008360251	19/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic shock (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-10008364168	19/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008331492	16/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008333553	16/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008335243	16/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (16d - Recovered/Resolved - Other Medically Important Condition), Diarrhoea (6d - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mobility decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (16d - Recovered/Resolved - Other Medically Important Condition), Vomiting (2d - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) [CASSIA] (C - Faecaloma - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Gastrooesophageal reflux disease - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Faecaloma - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008313721	15/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (1d - Recovering/Resolving - Life Threatening), Chest pain (n/a - Unknown - Life Threatening), Hot flush (n/a - Unknown - Life Threatening), Platelet count decreased (n/a - Unknown - Life Threatening), Thrombosis (n/a - Unknown - Life Threatening),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

											Vomiting (n/a - Unknown - Life Threatening), Wheezing (n/a - Unknown - Life Threatening)			
EU-EC-10008315283	15/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), SARS-CoV-2 antibody test (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10008303775	14/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Seizure (1min - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10008287937	13/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (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-10008287968	13/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving -), Hypersensitivity (5d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10008292594	13/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[LAMOTRIGINE] (C - Seizure - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-10008275678	12/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypotension (1d - Recovered/Resolved - Other Medically Important Condition), Nervousness (1d - Recovered/Resolved - Other Medically Important Condition), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10008280814	12/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sleep disorder due to general medical condition, insomnia type (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-10008247728	09/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymph node pain (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	HUMIRA 80 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN [ADALIMUMAB] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-	09/04/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Chest pain (n/a -	TOZINAMERAN	Not reported	ICSR	

10008248222			Professional	European Economic Area	available	Years	Specified			Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC-10008248229	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008248258	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008252941	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Headache (n/a - Recovered/Resolved -), Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008252943	09/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008235196	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008237832	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (n/a - Unknown -), Hyperventilation (n/a - Unknown -), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10008237922	08/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008237955	08/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (n/a - Unknown - Other Medically Important Condition), Disease recurrence (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Migraine (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [DOMPERIDONE] (C - Migraine - n/a - [n/a - n/a - n/a])	ICSR

										Important Condition), Pineal gland cyst (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10008243577	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown -), Chest pain (n/a - Unknown -), Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Productive cough (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008245846	08/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown -), Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008216424	07/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Lip swelling (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[EPINEPHRINE] (C - Anaphylactic reaction - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008218298	07/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Unknown - Other Medically Important Condition)	CANNABIDIOL [CANNABIDIOL] (S - n/a - Unknown - [n/a - 7mL - n/a]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), ZONISAMIDE [ZONISAMIDE] (S - n/a - Unknown - [n/a - 800mg - n/a])	Not reported	ICSR
EU-EC-10008224932	07/04/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown -), Chest pain (n/a - Unknown -), Headache (n/a - Unknown -), Myalgia (n/a - Unknown -), Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10008227240	07/04/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving -)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	[BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - Asthma - 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-10008206544	06/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood glucose increased (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown -), Nasal congestion (n/a - Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Recovered/Not Resolved -)			
EU-EC-10008209685	06/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vertigo (n/a - Unknown - 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 - Parenteral])	[LAMOTRIGINE] (C - n/a - n/a - [n/a - n/a - n/a]), [SODIUM VALPROATE, VALPROIC ACID, SODIUM VALPROATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008174742	02/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008176129	02/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hypoaesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Myalgia (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-10008158570	01/04/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ENALAPRIL MALEATE] (C - Hypoplastic left heart syndrome - n/a - [n/a - n/a - n/a]), [WARFARIN, WARFARIN SODIUM] (C - Fontan procedure - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008160478	01/04/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paresis (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-10008143640	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (3d - Recovered/Resolved -), Decreased appetite (3d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008143839	31/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain (2d - Recovered/Resolved -), Vaccination site joint swelling (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10008144917	31/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypoaesthesia (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR

										Pain in extremity (n/a - Recovered/Resolved - Other Medically Important Condition), Paraesthesia (n/a - Recovered/Resolved - Other Medically Important Condition), Product use issue (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10008148246	31/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fall (n/a - Unknown - Other Medically Important Condition), Head injury (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition), Wound haemorrhage (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-10008153554	31/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Electrocardiogram abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocarditis (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-10008141445	30/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood glucose increased (n/a - Unknown -), Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[SOMATROPIN] (C - Hypopituitarism - n/a - [n/a - .8mg - Subcutaneous])	ICSR
EU-EC-10008120530	29/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Migraine (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - n/a - n/a]), [MEDROXYPROGESTERONE ACETATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008094065	27/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (2d - Recovered/Resolved -), Paraesthesia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[ETHINYLESTRADIOL PROPANESULPHONATE, LEVONORGESTREL, ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - 1{DF} - Oral])	ICSR
EU-EC-10008082387	26/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (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-10008085488	26/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (1d - 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-10008053546	24/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypoaesthesia (n/a - Not Recovered/Not Resolved -), Multiple sclerosis (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

										Pain in extremity (n/a - Not Recovered/Not Resolved -), Sensory loss (n/a - Not Recovered/Not Resolved -)			
EU-EC-10008056449	24/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epilepsy (1d - Recovered/Resolved - Other Medically Important Condition), Seizure (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	KEPPRA [LEVETIRACETAM] (C - Epilepsy - n/a - [n/a - n/a]), [SODIUM VALPROATE] (C - Epilepsy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008056496	24/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (2d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - Anxiety - n/a - [n/a - n/a - n/a]), [FAMOTIDINE] (C - Abdominal pain upper - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008060186	24/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood urine present (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urine analysis abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10008040952	23/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dry throat (n/a - Recovering/Resolving - Other Medically Important Condition), Influenza (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Unknown - Other Medically Important Condition), Sinus disorder (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10008045582	23/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Seizure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Vision blurred (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10008025800	22/03/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Off label use (n/a - Unknown -),	COMIRNATY [TOZINAMERAN]	CANNABIDIOL [CANNABIDIOL] (C -	ICSR

			Professional	Area						Product use issue (n/a - Unknown -), Pyrexia (n/a - Unknown -)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a]) [LAMOTRIGINE] (C - Epilepsy - n/a - [n/a - 100mg - n/a]), [PARACETAMOL] (C - n/a - n/a - [1d - 250mg - n/a]), [SODIUM VALPROATE, VALPROIC ACID] (C - Epilepsy - n/a - [n/a - 600mg - n/a])	Epilepsy - n/a - [n/a - 2mL - n/a]),	
EU-EC-10007993749	19/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007971661	17/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (0d - Unknown -), Fatigue (0d - Unknown -), Pain in extremity (0d - Unknown -), Vaccination site pain (0d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007951711	16/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Lethargy (n/a - Recovered/Resolved -), Seizure (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-10007929845	15/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dysgeusia (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Parosmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) [PARACETAMOL] (C - Pyrexia - n/a - [n/a - n/a - n/a])	INSULIN HUMAN [INSULIN HUMAN] (C - Diabetes mellitus - n/a - [n/a - n/a - n/a]),	ICSR
EU-EC-10007908508	12/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Pain (n/a - Unknown -), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007892972	11/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (3d - Recovered/Resolved -), Hot flush (3d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007878771	10/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Hyperhidrosis (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - Intramuscular]) [VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a])	MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - n/a - n/a]),	ICSR

										Recovered/Resolved - Other Medically Important Condition), Malaise (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10007885864	10/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular - More in ICSR])	Not reported	ICSR
EU-EC-10007863172	09/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Asthenia (1d - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Recovering/Resolving - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition), Vaccination site reaction (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ERYTHROMYCIN] (C - Acne - n/a - [n/a - n/a - n/a]), [FLUDROCORTISONE] (C - Postural orthostatic tachycardia syndrome - n/a - [n/a - n/a - n/a]), [SODIUM CHLORIDE] (C - Postural orthostatic tachycardia syndrome - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007865752	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (3d - Recovered/Resolved -), Nausea (3d - Recovered/Resolved -), Rash (7d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007865757	09/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (5d - Recovered/Resolved -), Nausea (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007868826	09/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fall (n/a - Unknown -), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	METHOTREXATE [METHOTREXATE] (C - Arthritis - n/a - [n/a - n/a - n/a]), [INFLUENZA VIRUS] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007850932	08/03/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epilepsy (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Unknown -), Seizure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007852893	08/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICSR

										Dizziness (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	- n/a - [n/a - n/a - Intramuscular])		
EU-EC-10007797531	05/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (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])	ICSR
EU-EC-10007786467	04/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Migraine (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-10007790604	04/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DESOGESTREL] (C - n/a - n/a - [n/a - n/a - n/a]), [PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C - Migraine - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007773290	03/03/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007779054	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (3d - Recovered/Resolved -), Lymphadenopathy (3d - Recovered/Resolved -), Myalgia (3d - Recovered/Resolved -), Nausea (3d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 30ug - n/a])	Not reported	ICSR
EU-EC-10007782357	03/03/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthma (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007763262	02/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (11d - Recovered/Resolved - Other Medically Important Condition), Diarrhoea (3d - Recovered/Resolved - Other Medically Important)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CITALOPRAM HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a]), [DIAZEPAM] (C - Anxiety - n/a - [n/a - n/a - n/a]), [INFLUENZA VIRUS] (C - Nephrotic syndrome - n/a -	ICSR

										Condition), Musculoskeletal stiffness (10d - Recovered/Resolved - Other Medically Important Condition), Nausea (8d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (8d - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (3d - Recovered/Resolved - Other Medically Important Condition), Vomiting (7d - Recovered/Resolved - Other Medically Important Condition)	[n/a - n/a - n/a]), [LEVAMISOLE] (C - Nephrotic syndrome - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Gastroesophageal reflux disease - n/a - [n/a - n/a - n/a]), [SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - Nephrotic syndrome - n/a - [n/a - n/a - n/a])		
EU-EC-10007767761	02/03/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arteriospasm coronary (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Chest discomfort (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-10007743815	28/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10007719432	25/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (1d - Recovered/Resolved - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Dizziness postural (1d - Recovered/Resolved - Other Medically Important Condition), Headache (1d - Recovered/Resolved - Other Medically Important Condition), Pain in extremity (2d -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR


										Recovered/Resolved - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10007696878	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Product use in unapproved indication (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007696928	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Product use in unapproved indication (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007696958	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Product use in unapproved indication (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007701374	23/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Seizure (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10007684044	22/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Product use in unapproved indication (n/a - Recovered/Resolved -), Pyrexia (n/a - Unknown -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	NOT AVAILABLE (C - n/a - Dose not changed - [n/a - 1g - n/a]), [CHLORAL HYDRATE] (C - n/a - Dose not changed - [n/a - n/a - n/a]), [CLOBAZAM] (C - n/a - Dose not changed - [n/a - 5mg - n/a]), [CLONIDINE HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - 25ug - n/a]), [POTASSIUM, SODIUM, MACROGOL 3350, CHLORIDE ION, HYDROGEN CARBONATE, SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - n/a - Dose not changed - [n/a - n/a - n/a]), [PROMETHAZINE, PROMETHAZINE HYDROCHLORIDE] (C - n/a - Dose not changed - [n/a - n/a - n/a]), [SALBUTAMOL] (C - n/a - Dose not changed - [n/a - .1mg - n/a])	ICSR
EU-EC-10007657767	18/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Palpitations (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown -)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	[DESGESTREL] (C - Dysmenorrhoea - n/a - [n/a - n/a - n/a])	ICSR

										Caused/Prolonged Hospitalisation)			
EU-EC-10007633581	16/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007612164	14/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007584292	11/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Product use in unapproved indication (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	CIRCADIN 2 MG [MELATONIN] (C - n/a - Not applicable - [n/a - 2mg - n/a]), [CLOBAZAM] (C - n/a - Not applicable - [n/a - 10mg - n/a]), [LAMOTRIGINE] (C - n/a - Not applicable - [n/a - 125mg - n/a]), [LEVOTHYROXINE SODIUM] (C - n/a - Not applicable - [n/a - n/a - n/a])	ICSR
EU-EC-10007574660	10/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Flushing (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypersensitivity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007557615	09/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Anaphylactic shock (30min - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Dyspnoea (30min - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Hypotension (30min - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007547751	08/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (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	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Condition), Tremor (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10007549382	08/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10007535185	06/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	C-reactive protein increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Face oedema (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rhinorrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007516066	04/02/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10007522203	04/02/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (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-10007509084	03/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Mobility decreased (1d - Unknown -), Pain in extremity (1d - Unknown -), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMITRIPTYLINE, AMITRIPTYLINE HYDROCHLORIDE] (C - Migraine - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007499072	02/02/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10007478131	01/02/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10007467420	29/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), Peripheral swelling (n/a - Recovered/Resolved - Other Medically Important Condition), Pharyngeal swelling (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR

										- Other Medically Important Condition), Rash (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination site movement impairment (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10007458093	28/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10007436145	26/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea exertional (4d - Recovered/Resolved -), Malaise (4d - Recovered/Resolved -), Tachycardia (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10007424301	25/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10007399721	21/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Erythema (2d - Recovered/Resolved -), Peripheral swelling (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[CLINDAMYCIN, ANHYDROUS BENZOYL PEROXIDE, CLINDAMYCIN, BENZOYL PEROXIDE] (C - Acne - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10007358701	15/01/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (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-10007358739	15/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Skin haemorrhage (2d - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007346221	14/01/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (1d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -), Muscle spasms (2d - Recovered/Resolved -), Pustule (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10007350953	14/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10007342639	13/01/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (3d - Recovered/Resolved -), Hypotonia (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -), Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

											-), Vomiting (3d - Recovered/Resolved -)		
EU-EC-10007344483	13/01/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Unknown -), Fatigue (n/a - Unknown -), Feeling abnormal (n/a - Unknown -), Headache (n/a - Unknown -), Nausea (n/a - Unknown -), Sleep disorder (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR

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