

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-10010923637	10/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arrhythmia (3d - Recovered/Resolved - Other Medically Important Condition), Chest pain (10d - Recovered/Resolved - Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010923687	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blindness (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cold sweat (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Deafness (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysarthria (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Illness (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sick relative (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Skin temperature (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010923789	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Tongue erythema (n/a - Recovered/Resolved -), Tongue oedema (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-10010923828	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic shock (n/a - Fatal - Results in Death, Life Threatening,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

EU-EC-10010923845	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Caused/Prolonged Hospitalisation) Bundle branch block right (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Electrocardiogram ST segment elevation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010923897	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anosmia (62d - Unknown -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010925739	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010925754	10/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash pruritic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010926124	10/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010926185	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Not Recovered/Not Resolved -), Pain of skin (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010926819	10/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dry eye (n/a - Not Recovered/Not Resolved -), Eye swelling (n/a - Not Recovered/Not Resolved -), Ocular hyperaemia (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-10010928130	10/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (34d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	10/12/2021	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	Headache (n/a - Not	COMIRNATY	Not reported	ICSR

10010928195			Healthcare Professional	European Economic Area		Years	Specified			Recovered/Not Resolved - Other Medically Important Condition), Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC-10010928418	10/12/2021	Spontaneous	Non Healthcare Professional	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), Limb discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tension headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010928634	10/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010928647	10/12/2021	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, Other Medically Important Condition), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010899629	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (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 - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010899639	09/12/2021	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

EU-EC-10010899651	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blister (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling abnormal (n/a - Unknown - Other Medically Important Condition), Herpes zoster (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inflammation (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Pain (n/a - Recovering/Resolving - Other Medically Important Condition), Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Rash macular (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010899660	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Electrocardiogram abnormal (n/a - Not Recovered/Not Resolved -), Liver function test abnormal (n/a - Not Recovered/Not Resolved -), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010899679	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Haemorrhage subcutaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Seizure (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010899682	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved -), Chest pain (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Dyspnoea (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Recovered/Resolved -), Electrocardiogram abnormal (n/a - Recovered/Resolved -), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Palpitations (n/a - Recovered/Resolved -), Troponin increased (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -)			
EU-EC-10010899692	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010899693	09/12/2021	Spontaneous	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010899697	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (82min - Recovered/Resolved -), Fall (n/a - Unknown -), Loss of consciousness (82min - Recovered/Resolved - Other Medically Important Condition), Syncope (82min - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (82min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010899701	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hyperhidrosis (1h - Recovered/Resolved -), Syncope (1h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010899949	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010899950	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -), Electrocardiogram PR segment depression (n/a - Recovering/Resolving -), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Troponin increased (n/a - Recovering/Resolved -), Vaccination site pain (n/a - Recovering/Resolved -)			
EU-EC-10010899959	09/12/2021	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), Endocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Lethargy (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010899968	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (3709min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010899972	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anxiety (n/a - Unknown -), Dizziness (n/a - Unknown -), Dyskinesia (n/a - Unknown -), Fatigue (n/a - Unknown -), Gaze palsy (n/a - Unknown - Other Medically Important Condition), Palpitations (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010899984	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010899989	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010899992	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (0d - Recovered/Resolved -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010899994	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010899995	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pruritus (n/a -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Swelling (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10010900011	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010900061	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010900062	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angioedema (n/a - Unknown - Other Medically Important Condition), Arthralgia (n/a - Unknown -), Headache (n/a - Unknown -), Lethargy (n/a - Unknown -), Myalgia (n/a - Unknown -), Rash (n/a - Unknown -), Vaccination site reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010900066	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010900068	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving -), Balance disorder (n/a - Recovering/Resolving -), Chest discomfort (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -), Confusional state (n/a - Recovering/Resolving -), Disturbance in attention (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Memory impairment (n/a - Recovering/Resolving -), Photophobia (n/a - Recovering/Resolving -), Vomiting (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10010900137	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Faeces discoloured (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Haematemesis (11021min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Immune thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010900421	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010900426	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (1h - Recovered/Resolved -), Hypotension (1h - Recovered/Resolved -), Seizure (1h - Recovered/Resolved - Other Medically Important Condition), Syncope (1h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010900436	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Contusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Erythema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Haematemesis (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Unknown - Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010900446	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010900593	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (30min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Presyncope (30min - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010900600	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cold sweat (0d - Recovered/Resolved -), Hypotension (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Syncopal (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10010900601	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (45min - Recovered/Resolved -), Syncopal (45min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010900606	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (4h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010900609	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Altered state of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Contusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Disorientation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown -), Dizziness postural (n/a - Unknown -), Fall (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Head injury (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Postural orthostatic tachycardia syndrome (n/a - Unknown -), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Retrograde amnesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010900956	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bradycardia (20min - Recovered/Resolved - Other Medically Important Condition), Dizziness (20min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010900980	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncopal (50min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010900989	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Presyncopal (n/a - Recovering/Resolving - Other Medically Important Condition), Syncopal (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010900992	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal distension (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

										Hospitalisation), Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (9d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	applicable - [1d - n/a - n/a]		
EU-EC-10010901162	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abortion spontaneous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010901454	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010901460	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Recovering/Resolved -), Nausea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[CETIRIZINE DIHYDROCHLORIDE] (C - Seasonal allergy - n/a - [n/a - 15mg - n/a])	ICSR
EU-EC-10010901751	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 immunisation (n/a - Not Recovered/Not Resolved - Life Threatening), Myocarditis (n/a - Not Recovered/Not Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010901885	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010901912	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010901915	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (204min - Recovered/Resolved - Other Medically Important Condition), Diplopia (204min - Recovered/Resolved - Other Medically Important Condition), Urticaria (204min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010901920	09/12/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Pruritus (n/a - Recovered/Resolved)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

			Professional	Economic Area						- Other Medically Important Condition), Rash (1d - Recovered/Resolved - Other Medically Important Condition), Rash pruritic (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination site rash (n/a - Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a])		
EU-EC-10010901953	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (0d - Recovered/Resolved -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition), Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010901979	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (30min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (30min - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010901987	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypertension (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010901991	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010901997	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bone pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Confusional state (30min - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hallucination (30min - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010902007	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Discomfort (n/a - Unknown - Other Medically Important Condition), Immunisation (n/a - Unknown - Other Medically Important Condition), Insomnia (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral])	[LORATADINE] (C - III-defined disorder - n/a - [n/a - n/a - n/a])	ICSR

										Pruritus (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10010902013	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Cough (n/a - Recovering/Resolving -), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition), Nasopharyngitis (n/a - Recovering/Resolving -), Oropharyngeal pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010902020	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (4d - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010902066	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010902162	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Conjunctival hyperaemia (n/a - Recovering/Resolving -), Eye pruritus (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010902195	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Bronchitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010902508	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010902560	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Disturbance in attention (1d - Recovered/Resolved - Disabling), Fatigue (1d - Recovered/Resolved - Disabling), Headache (1d - Recovered/Resolved - Disabling), Injection site reaction (1d - Recovered/Resolved - Disabling), Pain in extremity (1d - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010902667	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Appendicitis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010902674	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -), Headache (n/a - Unknown -), Hunger (n/a - Unknown -), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Pallor (n/a - Unknown -), Presyncope (35min -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10010902967	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010903429	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Tachycardia (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-10010904115	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (2d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010904636	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Unknown -), Ear pain (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -), Periorbital swelling (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010904706	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (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-10010904747	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (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-10010904818	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Disabling), Blood pressure decreased (n/a - Unknown - Disabling), Chills (n/a - Unknown - Disabling), Decreased appetite (n/a - Unknown - Disabling), Delirium febrile (n/a - Unknown - Disabling), Fatigue (n/a - Unknown - Disabling), Headache (n/a - Unknown - Disabling), Injection site reaction (n/a - Unknown - Disabling), Malaise (n/a - Unknown - Disabling), Myalgia (n/a - Unknown - Disabling), Nausea (n/a - Unknown - Disabling), Pain in extremity (n/a - Unknown - Disabling), Pyrexia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[PARACETAMOL] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR

EU-EC-10010905359	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Unknown - Disabling) Polymenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010906327	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Head injury (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Orthostatic hypotension (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010906544	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving -), Chest pain (1d - Recovered/Resolved -), Myalgia (n/a - Recovering/Resolving -), Palpitations (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010906547	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Irritability (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-10010906893	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Hyperhidrosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010906896	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Rash macular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling face (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010906904	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Vision blurred (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	09/12/2021	Spontaneous	Non	European	Not available	12-17	Not	Male	No	Chills (2d -	COMIRNATY	Not reported	ICSR

10010906905			Healthcare Professional	Economic Area		Years	Specified			Recovering/Resolving -), Fatigue (2d - Recovering/Resolving -), Headache (2d - Recovering/Resolving -), Limb discomfort (2d - Recovering/Resolving -), Myalgia (2d - Recovering/Resolving -), Peripheral vascular disorder (2d - Recovering/Resolving -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC-10010906915	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (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), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010906946	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tachycardia (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-10010906947	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Petechiae (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	AZATHIOPRINE [AZATHIOPRINE] (C - Liver transplant - n/a - [n/a - n/a - n/a]), TACROLIMUS [TACROLIMUS, TACROLIMUS MONOHYDRATE] (C - Liver transplant - n/a - [n/a - n/a - n/a]), [LAMOTRIGINE] (C - Seizure - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - Gastritis - n/a - [n/a - n/a - n/a]), [PREDNISOLONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010906948	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010906949	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Presyncope (30min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010906970	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010906985	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010906987	09/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

				Economic Area						Hospitalisation), Palpitations (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	immunisation - Not applicable - [1d - n/a - n/a]		
EU-EC-10010906990	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (129h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Palpitations (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010907242	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Aplastic anaemia (n/a - Unknown - Life Threatening, Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Life Threatening), Thrombosis (n/a - Unknown - Life Threatening, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010907247	09/12/2021	Spontaneous	Non 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), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	Not reported	ICSR
EU-EC-10010907254	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Altered state of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Muscle spasms (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010907266	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Paralysis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010907272	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema (n/a - Unknown -), Fall (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown -), Hypotension (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown -), Pyrexia (n/a - Unknown - Other Medically Important Condition), Rash macular (n/a - Unknown -), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC-10010907438	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Narcolepsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010907451	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010907926	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010907941	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (11h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Conversion disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fall (11h - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010907982	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -), Headache (n/a - Recovering/Resolved -), Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolved -), Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010908100	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010908103	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010908142	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash papular (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010908195	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Gastrointestinal disorder (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR

										Headache (n/a - Recovering/Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Testicular pain (n/a - Not Recovered/Not Resolved -)			
EU-EC-10010908201	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -), Dyspnoea exertional (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010908204	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Gastrointestinal disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010908215	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010908572	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Chills (1d - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolved - Other Medically Important Condition), Headache (n/a - Recovering/Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolved - Other Medically Important Condition), Peripheral swelling (2d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolved - Other Medically Important Condition), Vision blurred (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010908626	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Recovering/Resolved - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Insomnia (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Condition), Sneezing (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10010908833	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (1d - Unknown -), Pain (1d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010908884	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010909189	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash pruritic (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010909566	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010909571	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (4d - Recovered/Resolved -), Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Orthostatic hypotension (n/a - Not Recovered/Not Resolved -), Pyrexia (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010909579	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Suspected COVID-19 (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	FLUENZ TETRA [A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE STRAIN (A/HAWAII/66/2019, MEDI 326775), A/HONG KONG/2671/2019 (H3N2) - LIKE STRAIN (A/HONG KONG/2671/2019, MEDI 325078), B/PHUKET/3073/2013 - LIKE STRAIN (B/PHUKET/3073/2013, MEDI 306444), B/WASHINGTON/02/2019 - LIKE STRAIN (B/WASHINGTON/02/2019, MEDI 323797), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, MEDI 237514), B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (A/CALIFORNIA/7/2009, MEDI 228029), B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (A/BOLIVIA/559/2013, MEDI 255962), B/PHUKET/3073/2013 (YAMAGATA LINEAGE)-LIKE STRAIN (B/PHUKET/3073/2013, MEDI 254977), A/HONG	ICSR

												KONG/4801/2014 (H3N2)-LIKE STRAIN (A/NEW CALEDONIA/71/2014, MEDI 263122), B/PHUKET/3073/2013 (YAMAGATA LINEAGE)-LIKE STRAIN (B/PHUKET/3073/2013, MEDI 254977), A/MICHIGAN/45/2015 (H1N1)PDM09 - LIKE STRAIN (A/SLOVENIA/2903/2015, MEDI 279432), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, MEDI 291690), B/COLORADO/06/2017-LIKE STRAIN (B/COLORADO/06/2017, MEDI 293454)] (C - Influenza immunisation - n/a - [1d - n/a - n/a])		
EU-EC-10010909615	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved -), Cold sweat (n/a - Recovered/Resolved -), Loss of consciousness (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-10010909859	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010910249	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anosmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Eye swelling (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (4d - Recovered/Resolved - Other Medically Important Condition), Ocular hyperaemia (n/a - Recovering/Resolving - Other Medically Important Condition), Oropharyngeal pain (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition), Rhinorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010910251	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Autonomic nervous system imbalance (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hypokinesia (n/a - Unknown - Other Medically Important Condition), Physical deconditioning (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-	09/12/2021	Spontaneous	Non	European	Not available	12-17	Adolescent	Male	No	Ear pain (n/a -	COMIRNATY	[AZATHIOPRINE,	ICSR	

10010910536			Healthcare Professional	Economic Area		Years				Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	AZATHIOPRINE SODIUM] (C - n/a - n/a -)	
EU-EC-10010910602	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Malaise (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010910724	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiomyopathy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Erythema multiforme (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010910766	09/12/2021	Spontaneous	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 -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010911085	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	[AZATHIOPRINE, AZATHIOPRINE SODIUM] (C - n/a - n/a -)	ICSR
EU-EC-10010911086	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	[AZATHIOPRINE, AZATHIOPRINE SODIUM] (C - n/a - n/a -)	ICSR
EU-EC-10010911239	09/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010911298	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Recovered/Resolved - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Hyperventilation (n/a - Recovered/Resolved - Other Medically Important Condition), Hypoaesthesia (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10010911426	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hepatic cytolysis (14d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hyperbilirubinaemia (14d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Mononucleosis syndrome (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010911526	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -), Heart rate increased (n/a - Recovering/Resolving -), Infection (n/a - Recovering/Resolving -), Oropharyngeal pain (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -), Rhinorrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010911794	09/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cold sweat (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nasopharyngitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pallor (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiration abnormal (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - Influenza immunisation - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10010911866	09/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Recovering/Resolving - Disabling), Cough (n/a - Recovering/Resolving - Disabling), Insomnia (n/a - Recovering/Resolving - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010911918	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

										Malaise (n/a - Unknown - Other Medically Important Condition), Muscle spasms (0d - Recovered/Resolved - Other Medically Important Condition), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	Unknown - [n/a - 1{DF} - n/a]		
EU-EC-10010912066	09/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Infectious mononucleosis (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-10010887433	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Administration site pain (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Ocular hyperaemia (n/a - Not Recovered/Not Resolved -), Somnolence (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010887546	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010887613	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ecchymosis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10010887845	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Meningitis aseptic (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010887936	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intracranial pressure increased (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010887951	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010887953	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blindness (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown -), Nausea (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010887960	08/12/2021	Spontaneous	Healthcare Professional	Non 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 - Not	Not reported	ICSR

										Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	applicable - [n/a - n/a - n/a]		
EU-EC-10010888091	08/12/2021	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), Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010888172	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chills (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010888177	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010888234	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010888240	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	CSF test abnormal (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving -), Lethargy (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010888251	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angioedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010888272	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bradycardia (n/a - Unknown - Other Medically Important Condition), Cold sweat (n/a - Unknown -), Dizziness (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Fatigue (n/a - Unknown -), Nausea (n/a - Unknown -), Pallor (n/a - Unknown -)			
EU-EC-10010888307	08/12/2021	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), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myalgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010888309	08/12/2021	Spontaneous	Non 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)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010888327	08/12/2021	Spontaneous	Non 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), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010888334	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness postural (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pallor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Presyncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10010888338	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved -), Pain in jaw (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010888477	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010888481	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Tourette's disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010888515	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pallor (n/a - Recovered/Resolved -), Syncope (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-10010888544	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10010888550	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

										<p>Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Tremor (n/a - Not Recovered/Not Resolved -),</p> <p>Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Vomiting (n/a - Not Recovered/Not Resolved -)</p>	immunisation - Not applicable - [n/a - n/a - n/a]		
EU-EC-10010888554	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	<p>Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),</p> <p>Left ventricular dysfunction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),</p> <p>Loss of personal independence in daily activities (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),</p> <p>Oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010888568	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	<p>Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010888595	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	<p>Dehydration (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation),</p> <p>Myocarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),</p> <p>Palpitations (1d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),</p> <p>Ventricular tachycardia (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation),</p> <p>Wheezing (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010888599	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	<p>Abdominal pain upper (n/a - Recovered/Resolved - Other Medically Important Condition),</p> <p>Inappropriate schedule of product administration (n/a - Unknown -),</p> <p>Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010888602	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	<p>Chest discomfort (16d - Recovered/Resolved - Other Medically Important Condition),</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR

										Chest pain (8d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (16d - Recovered/Resolved - Other Medically Important Condition), Pericardial effusion (8d - Recovered/Resolved - Other Medically Important Condition), Respiratory arrest (16d - Recovered/Resolved - Other Medically Important Condition)	n/a - Intramuscular]		
EU-EC-1001088617	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Mycarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-1001088620	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved -), Chest pain (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Pericarditis (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-1001088624	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Overdose (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - n/a])	Not reported	ICSR
EU-EC-10010889384	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Inflammation (n/a - Recovering/Resolving - Other Medically Important Condition), Palpitations (10min - Recovering/Resolving - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010890437	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Crohn's disease (n/a - Not Recovered/Not Resolved -), 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 - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010890880	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epilepsy (1d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hallucination (1d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR

										Headache (1d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10010891322	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Petechiae (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010891554	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (n/a - Recovered/Resolved -), Obstruction (n/a - Recovered/Resolved -), Oxygen saturation decreased (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010891715	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Unknown -), Chills (n/a - Unknown -), Headache (n/a - Unknown -), Myalgia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010891801	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tonic convulsion (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010892208	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010892486	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010892513	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -), Heavy menstrual bleeding (n/a - Unknown -), Menstrual disorder (n/a - Unknown -), Menstruation delayed (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010892589	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010892737	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pruritus (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010892743	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition), Electrocardiogram T wave amplitude increased (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR

										- Other Medically Important Condition), Lung infiltration (n/a - Recovered/Resolved - Other Medically Important Condition), Oropharyngeal pain (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10010892744	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiac disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea exertional (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Ejection fraction decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Electrocardiogram ST segment elevation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (13830min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Troponin I increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Troponin abnormal (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010892745	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010892748	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown - Other Medically Important Condition), Lung infiltration (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Sinus tachycardia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010892753	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Palpitations (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010892754	08/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

				Economic Area						- Other Medically Important Condition)	immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC-10010892758	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angina pectoris (n/a - Recovering/Resolving - Other Medically Important Condition), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Pericardial effusion (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010892760	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010892764	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010892765	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Lung infiltration (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010892770	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Gastritis (n/a - Unknown - Caused/Prolonged Hospitalisation), Gastrointestinal sounds abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Tonsillitis (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Hospitalisation), Vaccination site pain (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC-10010892772	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Palpitations (n/a - Recovering/Resolving - Other Medically Important Condition), Sinus arrhythmia (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010892775	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010892784	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericardial effusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010892786	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010892791	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010892805	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Haemoptysis (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neck pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR

										Rash (n/a - Unknown -), Renal injury (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10010892921	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (17d - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - III-defined disorder - n/a - [n/a - n/a])	ICSR
EU-EC-10010892926	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (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-10010892928	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Electrocardiogram QT prolonged (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Electrocardiogram T wave inversion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Supraventricular tachycardia (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010892934	08/12/2021	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), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010892985	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blindness transient (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown -), Cough (n/a - Unknown -), Fall (n/a - Unknown -), Fatigue (n/a - Unknown -), Hallucination, visual (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Pyrexia (2d - Recovered/Resolved -), Vertigo (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Vision blurred (n/a - Unknown -), Visual impairment (n/a - Unknown -)			
EU-EC-10010892989	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving - Other Medically Important Condition), Hallucination (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Illness (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of personal independence in daily activities (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Recovered/Resolved - Other Medically Important Condition), Musculoskeletal stiffness (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[INFLUENZA VIRUS] (C - Immunisation - n/a - [n/a - n/a]), [PARACETAMOL] (C - Nasopharyngitis - n/a - [n/a - n/a])	ICSR
EU-EC-10010893035	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010893060	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Lethargy (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination site reaction (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010893061	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010893079	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pruritus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Urticaria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Urticarial vasculitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010893080	08/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

				Economic Area						Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	immunisation - Not applicable - [1d - .3mL - Intramuscular])		
EU-EC-10010893090	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown -), Chest pain (n/a - Unknown -), Malaise (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010893095	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Aggression (n/a - Unknown -), Depressed mood (n/a - Unknown -), Hypervigilance (n/a - Unknown -), Somnolence (n/a - Unknown -), Suicidal ideation (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010893104	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (80min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010893106	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Other Medically Important Condition), Dyspnoea exertional (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010893112	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arrhythmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dehydration (n/a - Not Recovered/Not Resolved -), Lethargy (n/a - Not Recovered/Not Resolved -), Photophobia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010893113	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arrhythmia (n/a - Recovering/Resolving - Other Medically Important Condition), Atrioventricular block (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10010893114	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dehydration (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Mouth ulceration (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Stevens-Johnson syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010893115	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown -), Chapped lips (n/a - Unknown -), Conjunctival hyperaemia (n/a - Unknown -), Cough (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Dizziness (n/a - Unknown -), Erythema (n/a - Unknown -), Headache (n/a - Unknown -), Multisystem inflammatory syndrome in children (n/a - Unknown - Other Medically Important Condition), Oedema peripheral (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pyrexia (n/a - Unknown -), Rash (n/a - Unknown -), Vision blurred (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010893121	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (33d - Unknown -), Chest discomfort (33d - Recovered/Resolved - Other Medically Important Condition), Palpitations (33d - Recovered/Resolved - Other Medically Important Condition), Respiration abnormal (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010893125	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR

										Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Electrocardiogram T wave peaked (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Lung infiltration (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10010893188	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Vaccination site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010893320	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (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-10010893352	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ANTICONCEPTIVEPIL [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010893473	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved -), Lethargy (n/a - Not Recovered/Not Resolved -), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010893482	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (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-10010893495	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010893544	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR

										Sinus tachycardia (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10010893567	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Lung infiltration (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010893594	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bundle branch block right (n/a - Not Recovered/Not Resolved -), Chest pain (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Hyperhidrosis (n/a - Not Recovered/Not Resolved -), Hypotension (n/a - Not Recovered/Not Resolved -), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pallor (n/a - Not Recovered/Not Resolved -), Pleuritic pain (n/a - Not Recovered/Not Resolved -), Presyncope (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010893598	08/12/2021	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010893606	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR

										Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10010893829	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (20d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fatigue (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (20d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010893830	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	Not reported	ICSR
EU-EC-10010893905	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10010893927	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10010894065	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Altered state of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aphasia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cerebrovascular accident (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010894100	08/12/2021	Spontaneous	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	applicable - [1d - .3mL - Intramuscular])		
EU-EC-10010894118	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Unknown - Other Medically Important Condition), Blindness (n/a - Unknown - Other Medically Important Condition), Disturbance in attention (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Other Medically Important Condition), Lethargy (n/a - Unknown - Other Medically Important Condition), Ocular hyperaemia (n/a - Unknown - Other Medically Important Condition), Screaming (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010894132	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Eye pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Flank pain (n/a - Unknown -), Headache (14d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (14d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), Tremor (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010894147	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR

										Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC-10010894152	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010894162	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Faeces soft (n/a - Unknown - Caused/Prolonged Hospitalisation), Nasal obstruction (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010894166	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthritis (n/a - Unknown - Caused/Prolonged Hospitalisation), Factitious disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Immune system disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Neuropathy peripheral (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pharyngitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Viral infection (n/a - Unknown -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR

EU-EC-10010894168	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (2d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010894174	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010894176	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Myocarditis (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-10010894204	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Apnoea (n/a - Unknown - Other Medically Important Condition), Chest discomfort (n/a - Unknown -), Chest pain (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Headache (n/a - Unknown -), Palpitations (n/a - Unknown -), Vertigo (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010894208	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (16min - Recovered/Resolved - Other Medically Important Condition), Heart rate decreased (n/a - Recovered/Resolved -), Pallor (19min - Recovered/Resolved -), Peripheral coldness (16min - Recovered/Resolved -), Physical deconditioning (n/a - Recovered/Resolved -), Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010894213	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (34d - Recovered/Resolved - Other Medically Important Condition), Hypotension (34d - Recovered/Resolved - Other Medically Important Condition), Pallor (34d - Recovered/Resolved - Other Medically Important Condition), Syncope (34d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010894218	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Lung infiltration (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR

										- Recovering/Resolving - Caused/Prolonged Hospitalisation), Mouth ulceration (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10010894282	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bundle branch block right (6d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Cardiomyopathy (n/a - Unknown - Other Medically Important Condition), Chest discomfort (8d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Chest pain (7d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Dyspnoea (8d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Headache (8d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Malaise (26h - Recovered/Resolved With Sequelae -), Myalgia (9d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Myocardial fibrosis (1d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Myocardial oedema (7d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (9d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral coldness (7d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pyrexia (194h - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Tachycardia (7d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010894297	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010894309	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR

										Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC-10010894310	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown - Other Medically Important Condition), Nasal congestion (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010894316	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pneumomediastinum (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010894321	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010894334	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumothorax (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010894349	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest discomfort (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Electrocardiogram ST segment elevation (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electrocardiogram abnormal (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Troponin I increased (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10010894361	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Palpitations (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010894375	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dental alveolar anomaly (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Feeling abnormal (n/a - Unknown - Other Medically Important Condition), Loose tooth (n/a - Unknown - Other Medically Important Condition), Presyncope (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Tooth fracture (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010894393	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Unknown -), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Lung infiltration (n/a - Unknown - Other Medically Important Condition), Sinus rhythm (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010894418	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010894441	08/12/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Vaccination site erythema (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

				Area						Recovering/Resolving -)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC-10010894512	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010894513	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010894618	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010894628	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema (n/a - Unknown -), Paraesthesia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010894690	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010894694	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Eczema infected (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010894736	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovered/Resolved -), Dyspnoea exertional (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010894781	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Flank pain (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (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-10010894811	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010894818	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain lower (n/a - Unknown - Caused/Prolonged Hospitalisation), Gastrointestinal inflammation (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010894822	08/12/2021	Spontaneous	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), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Overdose (n/a - Unknown -), Somnolence (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - n/a])	Not reported	ICSR

										Resolved - Other Medically Important Condition)			
EU-EC-10010894825	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010894847	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010894853	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Electrocardiogram T wave abnormal (n/a - Unknown - Other Medically Important Condition), Sinus arrhythmia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010894854	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010894864	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Discomfort (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Lung infiltration (n/a - Unknown - Other Medically Important Condition), Sinus tachycardia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010894870	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal distension (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Pruritus (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010894877	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (14d - Recovered/Resolved - Other Medically Important Condition), Vomiting (14d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010894887	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diplopia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Extraocular muscle disorder (n/a - Not Recovered/Not Resolved -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nystagmus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10010894892	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (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 - Intramuscular])	Not reported	ICSR
EU-EC-10010894904	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cold sweat (n/a - Unknown -), Feeling cold (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010894910	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010895025	08/12/2021	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), Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspepsia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Electrocardiogram ST segment elevation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Exfoliative rash (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nasal congestion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pleuritic pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10010895056	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010895066	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR

EU-EC-10010895072	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal discomfort (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010895121	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myopericarditis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010895319	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown -), Disturbance in attention (n/a - Unknown -), Visual analogue scale (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010895338	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -), Seizure (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010895346	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Palpitations (n/a - Recovering/Resolving -), Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010895347	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010895370	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myalgia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[PARACETAMOL] (C - Headache - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-	08/12/2021	Spontaneous	Healthcare	Non	Not available	12-17	Not	Male	No	Chest pain (n/a -	COMIRNATY	Not reported	ICSR

10010895384			Professional	European Economic Area		Years	Specified			Recovered/Resolved - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC-10010895405	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Lethargy (n/a - Not Recovered/Not Resolved -), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010895417	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Presyncope (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010895429	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -), Lethargy (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010895433	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (n/a - Unknown -), Myocardial fibrosis (n/a - Unknown -), Myocarditis (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010895469	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010895488	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010895502	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010895505	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010895520	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010895539	08/12/2021	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), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

EU-EC-10010895545	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Resolved - Caused/Prolonged Hospitalisation) Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Encephalitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Meningitis aseptic (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Photophobia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010895558	08/12/2021	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 ST segment elevation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myopericarditis (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

										Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sinus bradycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ventricular extrasystoles (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10010895562	08/12/2021	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), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010895598	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (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-10010895647	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin abnormal (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-10010895654	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Endocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010895655	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Papule (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pruritus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Rash erythematous (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sinus tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010895657	08/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

				Economic Area						Recovered/Resolved - Other Medically Important Condition), Rash (n/a - Recovered/Resolved -)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a])		
EU-EC-10010895661	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010895671	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Multisystem inflammatory syndrome in children (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Rash (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation), Shock (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010895687	08/12/2021	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 ST segment elevation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Rhinovirus infection (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sinus bradycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010895688	08/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Impaired quality of life (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010895757	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

										Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Overdose (n/a - Unknown - Caused/Prolonged Hospitalisation)	applicable - [1d - .5mL - Intramuscular])		
EU-EC-10010895774	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010895923	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Recovered/Resolved - Other Medically Important Condition), Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition), Troponin increased (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010895949	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tonic clonic movements (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urinary incontinence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular])	KEPPRA [LEVETIRACETAM] (C - n/a - n/a - [n/a - n/a - n/a]), [OXCARBAZEPINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010895998	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010896011	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Meningitis viral (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010896083	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Type 1 diabetes mellitus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010896092	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Febrile neutropenia (14d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Lymphopenia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (14d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010896115	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Paraesthesia (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010896245	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (23d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010896286	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Ecchymosis (10d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR

										Influenza like illness (n/a - Recovered/Resolved - Other Medically Important Condition)	1{DF} - Intramuscular]]		
EU-EC-10010896364	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Cystic lung disease (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Respiration abnormal (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010896491	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (1d - Recovering/Resolving - Disabling), Headache (1d - Recovering/Resolving - Disabling), Malaise (1d - Recovering/Resolving - Disabling), Pyrexia (1d - Recovering/Resolving - Disabling), Rhinorrhoea (1d - Recovering/Resolving - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010896587	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (11d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (11d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Overdose (n/a - Unknown -), Supraventricular tachycardia (11d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .5mL - Intramuscular])	[HUMAN PAPILLOMAVIRUS VACCINE] (C - n/a - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10010896589	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (46d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Musculoskeletal chest pain (41d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myalgia (46d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010896611	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010896751	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved -), Pericarditis (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-10010896917	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010897017	08/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

				Economic Area						Important Condition), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Orthopnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	immunisation - Not applicable - [1d - n/a - n/a]		
EU-EC-10010897019	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspepsia (n/a - Not Recovered/Not Resolved -), Palpitations (n/a - Not Recovered/Not Resolved -), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010897023	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	C-reactive protein increased (159h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (159h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Electrocardiogram ST segment elevation (159h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), N-terminal prohormone brain natriuretic peptide increased (159h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (159h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (159h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Systemic lupus erythematosus (159h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010897029	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cardiac failure acute (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010897220	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Gastritis (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR

										Pancreatitis acute (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC-10010897492	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling hot (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pruritus (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010897672	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Buchhorn, Reiner. Autoantibody Release in Children after Corona Virus mRNA Vaccination: A Risk Factor of Multisystem Inflammatory Syndrome?. vaccines, 2021;9	12-17 Years	Not Specified	Female	No	Antibody test abnormal (n/a - Unknown - Other Medically Important Condition), Arrhythmia supraventricular (n/a - Unknown - Other Medically Important Condition), Atrioventricular block (n/a - Unknown - Other Medically Important Condition), Blood thyroid stimulating hormone increased (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010897701	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Palpitations (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010897709	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010897853	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Buchhorn, Reiner. Autoantibody Release in Children after Corona Virus mRNA Vaccination: A Risk Factor of Multisystem Inflammatory Syndrome?. vaccines, 2021;9	12-17 Years	Not Specified	Female	No	Antibody test abnormal (n/a - Unknown - Other Medically Important Condition), Arrhythmia supraventricular (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010897869	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pneumothorax (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010897874	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown -), Angioedema (n/a - Unknown - Other Medically Important Condition), Arthralgia (n/a - Unknown -), Cough (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Dyspnoea (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR

										Extensive swelling of vaccinated limb (n/a - Unknown -), Headache (n/a - Unknown -), Lethargy (n/a - Unknown -), Myalgia (n/a - Unknown -), Pyrexia (n/a - Unknown -), Rash (n/a - Unknown -), Seizure (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)			
EU-EC-10010898080	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (2d - Recovered/Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (2d - Recovered/Resolved -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010898228	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Neuralgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	[INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED)] (C - n/a - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10010898474	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Adhesion (n/a - Unknown -), Vaccination site lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010898631	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010898685	08/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR

										Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC-10010898692	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Rash erythematous (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), SARS-CoV-2 test positive (n/a - Recovering/Resolving - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010898749	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (10h - Recovered/Resolved -), Nausea (24h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010898868	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Axillary pain (2d - Recovered/Resolved -), Lymphadenopathy (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010898896	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Erythema migrans (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[DOCUSATE SODIUM, GLYCEROL, DOCUSATE SODIUM, GLYCEROL 85%] (C - Constipation - n/a - [n/a - n/a - Rectal]), [PHENOXYMETHYLPENICILLIN POTASSIUM] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10010898960	08/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema multiforme (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOVORAPID [INSULIN ASPART] (C - Diabetes mellitus - n/a - [n/a - n/a - Subcutaneous])	ICSR
EU-EC-10010899047	08/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (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-10010873768	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010873776	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR

EU-EC-10010873783	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010873813	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dysgeusia (n/a - Recovering/Resolved -), SARS-CoV-2 test positive (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010873817	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anosmia (n/a - Recovering/Resolved -), SARS-CoV-2 test positive (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010873828	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovering/Resolved -), Conjunctivitis (n/a - Recovering/Resolved -), Rhinitis (n/a - Recovering/Resolved -), SARS-CoV-2 test positive (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010873920	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (21d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010874165	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Otitis media (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Rhinitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010874499	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010874508	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovered/Resolved -), Vertigo (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010874578	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010874591	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Balance disorder (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010874895	07/12/2021	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), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tremor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10010874897	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (2d - Recovered/Resolved - Other Medically Important Condition), Cough (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness postural (0d - Recovered/Resolved - Other Medically Important Condition), Feeling abnormal (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (2d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Tremor (1d - Recovered/Resolved - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010875029	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010875319	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010875321	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010875378	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010875744	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010875777	07/12/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

			Professional	Area						Recovering/Resolving -), Insomnia (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Vaccination site swelling (n/a - Recovering/Resolving -)	(S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC-10010875889	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010876096	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010876099	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (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-10010876408	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Uveitis (n/a - Recovered/Resolved -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	INFLIXIMAB [INFLIXIMAB] (C - n/a - n/a -), [METHOTREXATE] (C - n/a - n/a -)	ICSR
EU-EC-10010876449	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010876464	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blister (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Contusion (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dysgeusia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Nasopharyngitis (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tongue blistering (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Tongue disorder (n/a - Unknown - Other Medically Important Condition), Vision blurred (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10010876933	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010876941	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010877050	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown - Disabling), Dizziness (n/a - Unknown - Disabling), Fatigue (n/a - Unknown - Disabling), Headache (n/a - Unknown - Disabling), Injection site reaction (n/a - Unknown - Disabling), Malaise (n/a - Unknown - Disabling), Myalgia (n/a - Unknown - Disabling), Nausea (n/a - Unknown - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010877094	07/12/2021	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), Myopericarditis (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-10010877103	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Respiratory distress (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										- Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving -)			
EU-EC-10010877113	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Unknown - Other Medically Important Condition), Sensory loss (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-10010877122	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (3wk - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010877124	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (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 - n/a])	Not reported	ICSR
EU-EC-10010877134	07/12/2021	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), Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Hypotension (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010877202	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Dysphagia (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Loss of personal independence in daily activities (n/a - Unknown -), Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010877205	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Atrioventricular block second degree (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood pressure decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Heart rate irregular (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Liver function test increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010877249	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010877260	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)			
EU-EC-10010877271	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness postural (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pallor (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Palpitations (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Presyncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010877281	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Presyncope (n/a - Unknown - Other Medically Important Condition), Weight decreased (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-10010877295	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bell's palsy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sepsis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Septic shock (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010877306	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-1001087443	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010878064	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hepatic enzyme increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Leukopenia (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Spinal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010878442	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular - More in ICSR])	[ETONOGESTREL] (C - Contraception - 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-10010878459	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[DOCONESENT, ICOSAPENT, FISH OIL, ICOSAPENT ETHYL, DOCOSAHEXAENOIC ACID ETHYL ESTER, OMEGA-3-ACID ETHYL ESTERS 90, OMEGA-3-ACID ETHYL ESTERS 90, DOCOSAHEXAENOIC ACID ETHYL ESTER] (C - n/a - n/a - [n/a - n/a - n/a]), [ETHINYLESTRADIOL, LEVONORGESTREL] (C - Product used for unknown indication - n/a - [n/a - 1{DF} - n/a])	ICSR
EU-EC-10010878460	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dry skin (n/a - Not Recovered/Not Resolved -), Dysmenorrhoea (1mo - Recovered/Resolved -), Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010878474	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Ear discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Ear pain (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (3d - Recovered/Resolved - Other Medically Important Condition), Hypoacusis (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Condition), Myalgia (3d - Recovered/Resolved - Other Medically Important Condition), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10010878490	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (3wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010878493	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -), Injection site erythema (n/a - Not Recovered/Not Resolved -), Swelling (n/a - Not Recovered/Not Resolved -), Tenderness (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -), Vaccination site swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010878552	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Coagulopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[DESLORATADINE] (C - n/a - Unknown - [n/a - n/a - n/a]), [DESOGESTREL] (C - n/a - Unknown - [n/a - n/a - n/a])	ICSR
EU-EC-10010878554	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amnesia (0d - Recovered/Resolved - Other Medically Important Condition), Blindness (0d - Recovered/Resolved - Other Medically Important Condition), Chills (0d - Recovered/Resolved - Other Medically Important Condition), Cold sweat (0d - Recovered/Resolved - Other Medically Important Condition), Headache (0d - Recovered/Resolved - Other Medically Important Condition), Muscular weakness (0d - Recovered/Resolved - Other Medically Important Condition), Palpitations (0d - Recovered/Resolved - Other Medically Important Condition), Paraesthesia (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010879050	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (4d - Not Recovered/Not Resolved -), Cough (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Nasopharyngitis (4d - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Unknown -)			
EU-EC-10010879264	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (0d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Peripheral vascular disorder (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010879331	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Blood loss anaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Presyncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010879532	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010879940	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Anxiety (n/a - Unknown -), Eczema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown -), Influenza like illness (n/a - Unknown -), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[BILASTINE] (C - Hypersensitivity - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10010880108	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved - Disabling), Headache (n/a - Recovered/Resolved - Disabling), Malaise (n/a - Recovered/Resolved - Disabling), Myalgia (n/a - Recovered/Resolved - Disabling), Nausea (n/a - Recovered/Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

											Vomiting (n/a - Recovered/Resolved - Disabling)			
EU-EC-10010880331	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Musculoskeletal stiffness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-10010880376	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Recovered/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-10010880423	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010880656	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Respiration abnormal (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR	
EU-EC-10010880657	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Depression (n/a - Unknown - Caused/Prolonged Hospitalisation), Disturbance in attention (n/a - Unknown - Caused/Prolonged Hospitalisation), Suicidal ideation (n/a - Unknown - Caused/Prolonged Hospitalisation), Systemic lupus erythematosus (n/a - Unknown - Caused/Prolonged Hospitalisation), Vasculitis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR	
EU-EC-10010880661	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010880675	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Ageusia (n/a - Unknown -), Anosmia (n/a - Unknown -), Dysstasia (n/a - Unknown -), Gait disturbance (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	

										- Unknown -), Grip strength decreased (n/a - Unknown -), Guillain-Barre syndrome (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving -), Periorbital swelling (n/a - Unknown -), Pruritus (n/a - Unknown -), Sensory disturbance (n/a - Unknown -)			
EU-EC-10010880697	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Presyncope (522min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (522min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010880708	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myositis (n/a - Not Recovered/Not Resolved -), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010880726	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Acute sinusitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Asthma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dehydration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pharyngeal erythema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sleep disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010880733	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - Intramuscular])	Not reported	ICSR

										Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10010880741	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving - Other Medically Important Condition), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010880750	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving -), Campylobacter colitis (n/a - Recovering/Resolving - Other Medically Important Condition), Diarrhoea (11d - Recovered/Resolved -), Enterocolitis haemorrhagic (n/a - Recovering/Resolving - Other Medically Important Condition), Haematochezia (6d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010880783	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fall (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved -), Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010880786	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Respiratory distress (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010880790	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Muscular weakness (n/a - Unknown -), Syncope (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

EU-EC-10010880804	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Medically Important Condition) Anaphylactic reaction (n/a - Recovering/Resolving - Other Medically Important Condition), Pruritus (n/a - Recovering/Resolving -), Scratch (n/a - Recovering/Resolving -), Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010880811	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010880842	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea exertional (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010880920	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (19d - Not Recovered/Not Resolved -), Fatigue (19d - Not Recovered/Not Resolved -), Nasopharyngitis (19d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010880995	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010881325	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010881381	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypotension (n/a - Recovered/Resolved - Life Threatening), Loss of consciousness (n/a - Recovered/Resolved - Life Threatening), Urinary incontinence (n/a - Recovered/Resolved - Life Threatening), Vomiting (n/a - Recovered/Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010881393	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Immunisation (n/a - Unknown - Other Medically Important Condition), Influenza (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										- Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10010881414	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arrhythmia (n/a - Recovering/Resolving - Other Medically Important Condition), Contusion (n/a - Recovering/Resolving -), Epilepsy (n/a - Recovering/Resolving - Other Medically Important Condition), Fall (n/a - Recovering/Resolving -), Lack of spontaneous speech (n/a - Recovering/Resolving -), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Orthostatic intolerance (n/a - Recovering/Resolving -), Postictal paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving -), Quadriplegia (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Visual impairment (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010881416	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CALCIUM CARBONATE, MAGNESIUM HYDROXIDE, CALCIUM, MAGNESIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [LACTIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [OMEPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010881433	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea exertional (n/a - Not Recovered/Not Resolved -), Impaired quality of life (n/a - Unknown -), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving -), Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[MINOCYCLINE] (C - n/a - n/a - [n/a - 100mg - n/a])	ICSR

EU-EC-10010881444	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (11d - Recovered/Resolved -), Headache (n/a - Unknown -), Lymphadenitis (17d - Recovered/Resolved -), Lymphadenopathy (13d - Recovered/Resolved -), Neutrophil percentage decreased (n/a - Unknown - Other Medically Important Condition), Pyrexia (382h - Recovered/Resolved -), White blood cell count decreased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010881521	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (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-10010881738	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10010881740	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010881785	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Electrocardiogram abnormal (n/a - Unknown -), Pericarditis (n/a - Unknown - Other Medically Important Condition), Troponin increased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010881872	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Aphthous ulcer (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (13d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hepatic enzyme increased (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hepatic function abnormal (19d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Platelet count decreased (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Stomatitis (13d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Viral infection (295h - Recovered/Resolved - Caused/Prolonged Hospitalisation), White blood cell count decreased (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	07/12/2021	Spontaneous	Healthcare	Non	Not available	12-17	Not	Female	No	Myocarditis (n/a -	COMIRNATY	Not reported	ICSR

10010881879			Professional	European Economic Area		Years	Specified			Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		
EU-EC-10010881885	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010881899	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Inflammation (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocardial necrosis marker increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Toothache (n/a - Unknown - Caused/Prolonged Hospitalisation), Troponin T increased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010882038	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10010882043	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Other Medically Important Condition), Diarrhoea (2d - Recovered/Resolved -), Hydrometra (n/a - Recovering/Resolving - Other Medically Important Condition), Intra-abdominal fluid collection (n/a - Recovering/Resolving - Other Medically Important Condition), Rash (n/a - Unknown -), Ulcer (n/a - Unknown -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010882181	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (5d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010882182	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	COMPLEMENT ALIMENTAIRE [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010882205	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Head injury (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

										- Other Medically Important Condition), Malaise (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10010882233	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Petit mal epilepsy (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [107d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010882279	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hepatic cytolysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Jaundice cholestatic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010882294	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hallucination (n/a - Not Recovered/Not Resolved -), Hyperthermia (n/a - Not Recovered/Not Resolved -), Insomnia (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010882352	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010882385	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Disturbance in attention (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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010882443	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovering/Resolving -), Heart rate decreased (n/a - Recovering/Resolving -), Palpitations (n/a - Recovering/Resolving -), Respiration abnormal (n/a - Recovering/Resolving -), Respiratory distress (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										- Other Medically Important Condition)			
EU-EC-10010882506	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Psoriasis (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-10010882865	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010882943	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10010883011	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (1d - Recovered/Resolved -), Chills (1d - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010883034	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010883060	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010883145	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site bruising (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010883190	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010883240	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Pain in extremity (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010883321	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash erythematous (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010883384	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010883405	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010883448	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	[DESOGESTREL] (C - Contraception - Unknown - [n/a - n/a - Oral])	ICSR
EU-EC-10010883604	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR

										Nausea (n/a - Recovered/Resolved -), Vertigo (24h - Recovered/Resolved -)			
EU-EC-10010883605	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (2d - Recovered/Resolved -), Axillary pain (2h - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -), Pain in extremity (1d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010883609	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (6d - Recovering/Resolving -), Pain in extremity (6d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010883637	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovered/Resolved -), Asthenia (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010883668	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010884183	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (2d - Recovering/Resolving -), Vaccination failure (2d - Recovering/Resolving -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010884439	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Not Recovered/Not Resolved - Disabling), Arthralgia (n/a - Not Recovered/Not Resolved - Disabling), Chest pain (n/a - Not Recovered/Not Resolved - Disabling), Chills (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Headache (n/a - Not Recovered/Not Resolved - Disabling), Migraine (n/a - Not Recovered/Not Resolved - Disabling), Myalgia (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010884613	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Oropharyngeal blistering (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

										Rash pustular (n/a - Recovering/Resolved - Other Medically Important Condition), Taste disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10010884745	07/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Underdown, M.. Thrombocytopenia in a teen with sickle cell disease following COVID-19 vaccination.. Pediatr-Blood-Cancer. 2021;68(12):e29271	12-17 Years	Not Specified	Male	No	Hypersplenism (n/a - Unknown -), Sickle cell anaemia with crisis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010884949	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Paraesthesia (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10010884987	07/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Back pain (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010885029	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10010885037	07/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Kawasaki's disease (n/a - Not Recovered/Not Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10010885215	07/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Depressed mood (n/a - Unknown - Disabling, Other Medically Important Condition), Discomfort (n/a - Unknown - Disabling, Other Medically Important Condition), Tic (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR

