

Line Listing Report

Time run: 30/11/2022 10:07:17

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-10011099092	28/12/2021	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-10011099166	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099380	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Troponin increased (n/a - Recovering/Resolving - 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-10011099482	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011099603	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099651	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Unknown -), Headache (n/a - Unknown -), Lethargy (n/a - Unknown -), Pyrexia (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-10011099744	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Alopecia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099745	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099751	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099752	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099753	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain upper (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099755	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	28/12/2021	Spontaneous	Non	European	Not available	12-17	Adolescent	Male	No	Influenza like illness	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011099758			Healthcare Professional	Economic Area		Years				(1d - Recovered/Resolved -)	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC-10011099760	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Migraine (40d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099761	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (56d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099763	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Appendicitis (5d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099766	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site pain (23d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099768	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (193d - Recovered/Resolved -), Headache (193d - Not Recovered/Not Resolved -), Headache (193d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099771	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (0d - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099772	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (2d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099773	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Muscle twitching (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099775	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Paraesthesia (23d - Unknown -), Swelling (23d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099778	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (109d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099779	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (12d - Recovered/Resolved -), Palpitations (12d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099780	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Neurodermatitis (107d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099785	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099789	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pruritus (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099796	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Eye swelling (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099800	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099820	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011099823	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Inflammation (23d - Recovered/Resolved -), Influenza (6d - Recovered/Resolved -), Injection site pain (23d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099828	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain upper (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Visual impairment (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099846	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Injection site pain (4d - Recovered/Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Tremor (n/a - Not Recovered/Not Resolved -), Visual impairment (n/a - Not Recovered/Not Resolved -)			
EU-EC-10011099865	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Feeling hot (n/a - Not Recovered/Not Resolved -), Gastrointestinal pain (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099879	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain in extremity (n/a - Unknown -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099894	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	ICSR
EU-EC-10011099911	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011099939	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	ICSR
EU-EC-10011099982	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	ICSR
EU-EC-10011100101	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (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 - n/a])	Not reported	ICSR
EU-EC-10011100119	28/12/2021	Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Behaviour disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -)	Not reported	ICSR

				Economic Area						Resolved - Caused/Prolonged Hospitalisation, Disabling), Disturbance in attention (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Facial discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Facial spasm (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Mental status changes (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Muscle twitching (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Repetitive speech (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Soliloquy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	Not applicable - [n/a - n/a - n/a])		
EU-EC-10011100130	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Petechiae (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-10011100417	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hypertension (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Palpitations (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Not Recovered/Not Resolved -), Vaccination site swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011100467	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100713	28/12/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a	Not reported	ICSR

			Professional	Area						Recovered/Not Resolved -)	- n/a - n/a)]		
EU-EC-10011100756	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Recovering/Resolving -), Back pain (3d - Recovered/Resolved -), Chest pain (6d - Recovered/Resolved -), Chills (1d - Recovered/Resolved -), Myalgia (7d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100768	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (2d - Recovered/Resolved -), Influenza (6d - Not Recovered/Not Resolved -), Injection site pain (8d - Recovering/Resolving -), Menstrual disorder (11d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100769	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (1d - Recovered/Resolved -), Chills (1d - Unknown -), Night sweats (1d - Recovered/Resolved -), Testicular pain (0d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100773	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100781	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -), Paraesthesia (1d - Recovered/Resolved -), Peripheral vascular disorder (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011100785	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100787	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100789	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100791	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Menstrual disorder (158d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100793	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100794	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100796	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (0d - Recovering/Resolving -), Myopericarditis (23d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100797	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epididymitis (8d - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10011100798	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Swelling face (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100799	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Unknown -), Malaise (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100801	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100802	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Colitis ulcerative (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100803	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100804	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tinnitus (135d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100805	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cyst (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100806	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Alopecia (132d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100814	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal discomfort (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100817	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (0d - Recovering/Resolving -), Headache (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100818	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthritis allergic (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100819	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100822	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Influenza like illness (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Paraesthesia (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100824	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011100832	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovered/Resolved -), Hypoesthesia eye (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10011100838	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011100890	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (3d - Recovered/Resolved -), Thrombocytopenia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100901	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (1d - Recovered/Resolved -), Restlessness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	28/12/2021	Spontaneous	Non	European	Not available	12-17	Adolescent	Female	No	Influenza like illness	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011100906			Healthcare Professional	Economic Area		Years				(n/a - Not Recovered/Not Resolved -)	(S - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC-10011100910	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Influenza (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100913	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (15d - Unknown -), Menstrual disorder (6d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100916	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (n/a - Not Recovered/Not Resolved -), Dysphonia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011100970	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema (n/a - Unknown - Other Medically Important Condition), Injury (n/a - Unknown - Other Medically Important Condition), Pruritus (n/a - Unknown - Other Medically Important Condition), Urticaria (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011077676	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Contusion (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Somnolence (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011077728	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Gait disturbance (n/a - Unknown -), Helplessness (n/a - Unknown -), Hyperventilation (n/a - Not Recovered/Not Resolved -), Initial insomnia (n/a - Unknown -), Malaise (n/a - Unknown -), Neurological symptom (n/a - Unknown -), Suicide attempt (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-10011078208	27/12/2021	Spontaneous	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), Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Ear discomfort (n/a - Recovered/Resolved - Other Medically Important Condition), Gait disturbance (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Heart rate decreased (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown -), Vision blurred (n/a - Unknown - Other Medically Important Condition), Visual impairment (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10011078305	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin increased (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011078317	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Illness (6d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011078344	27/12/2021	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 - 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-10011078472	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (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-10011078478	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Potts, E.. Was it COVID19 or the vaccine a rare case of SARS-COV2 infection or post-vaccine triggered flare in juvenile dermatomyositis.. Pediatric Rheumatology, 2021;19(SUPPL 1):135-136. doi:10.1186/s12969-021-00632-z	12-17 Years	Not Specified	Female	No	Condition aggravated (n/a - Unknown - Other Medically Important Condition), Dermatomyositis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011078495	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hypotonia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Stridor (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011078525	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (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-10011078538	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (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-10011078551	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

										Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	Not applicable - [n/a - n/a - n/a]		
EU-EC-10011078555	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Not Recovered/Not Resolved -), Herpes simplex (n/a - Unknown -), Lip pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Muscle twitching (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011078586	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -), Headache (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 - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011078618	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011078668	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Lymph node pain (n/a - Not Recovered/Not 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 - n/a - n/a])	Not reported	ICSR
EU-EC-10011078746	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011079015	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arrhythmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Arthralgia (n/a - Unknown -), Myalgia (n/a - Unknown -), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-	27/12/2021	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	Dizziness (2d -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011079471			Healthcare Professional	European Economic Area		Years	Specified			Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Illness (n/a - Recovering/Resolving - Other Medically Important Condition), Myalgia (2d - Recovered/Resolved - Other Medically Important Condition), Photophobia (2d - Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC-10011079544	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition), Cold sweat (0d - Recovered/Resolved -), Hyperhidrosis (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011079652	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[TOPIRAMATE] (C - Migraine - n/a - [n/a - n/a])	ICSR
EU-EC-10011079930	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Guttate psoriasis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011079933	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Unknown - Other Medically Important Condition), Heavy menstrual bleeding (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-10011079974	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Hypotonic-hyporesponsive episode (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011080155	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Migraine with aura (n/a - Unknown -	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

										Caused/Prolonged Hospitalisation), Monoparesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC-10011080216	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown - Other Medically Important Condition), Hypotonic-hyporesponsive episode (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - 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-10011080264	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Burning sensation (n/a - Recovering/Resolving -), Erythema (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -), Paraesthesia oral (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011080367	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -), Migraine (n/a - Recovering/Resolving -), Migraine (n/a - Unknown -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011080563	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Face injury (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-1001108059	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Swelling face (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011080801	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011081411	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Not Recovered/Not Resolved -),	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE	Not reported	ICSR

										Productive cough (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])		
EU-EC-10011081455	27/12/2021	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 - Caused/Prolonged Hospitalisation), Dysphoria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Insomnia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	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])	Not reported	ICSR
EU-EC-10011081509	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -), Peripheral swelling (n/a - Recovering/Resolving -), Pyrexia (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Recovering/Resolving -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011081604	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Recovering/Resolving -), Heavy menstrual bleeding (n/a - Unknown -), Menstruation irregular (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[CYANOCOBALAMIN] (C - n/a - n/a - [n/a - n/a - n/a]), [ETHINYLESTRADIOL, LEVONORGESTREL, LACTOSE ANHYDROUS] (C - Contraception, Dysmenorrhoea - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10011081849	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011082269	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011083159	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011083198	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

EU-EC-10011083265	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Aspartate aminotransferase increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase MB increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Troponin T increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (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-10011083706	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Tachycardia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3(DF) - n/a])	Not reported	ICSR
EU-EC-10011083813	27/12/2021	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-10011083980	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (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-10011083985	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Thrombosis (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-10011084011	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypotension (n/a - Recovered/Resolved -), Pallor (n/a - Unknown -), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011084017	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pneumonia (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-10011084037	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (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-10011084045	27/12/2021	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 - n/a])	Not reported	ICSR
EU-EC-10011084083	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (Od - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10011084103	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Echocardiogram abnormal (n/a - Not Recovered/Not Resolved -), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin increased (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011084198	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (2wk - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011084651	27/12/2021	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-10011084691	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -), Pain in extremity (1d - Recovered/Resolved -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011084701	27/12/2021	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011084836	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (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-10011084839	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011085352	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011085353	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ageusia (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011085392	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pigmentation disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	[ISOTRETINOIN] (C - Acne - n/a - [n/a - n/a])	ICSR
EU-EC-10011085423	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR

EU-EC-10011085451	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Recovering/Resolving -), Insomnia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	AERIUS 5 MG FILM-COATED TABLET [DESLORATADINE] (C - Antiallergic therapy - Unknown - [n/a - n/a])	ICSR
EU-EC-10011085468	27/12/2021	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-10011085469	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011085572	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Recovering/Resolving -), Allergy to vaccine (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Henoch-Schonlein purpura (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Illness (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Rash papular (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal impairment (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-10011085577	27/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (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-10011085585	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (1h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011085731	27/12/2021	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-10011085902	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011085913	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10011085921	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (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-10011085922	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011085986	27/12/2021	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-10011086241	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cardio-respiratory arrest (n/a - Recovering/Resolving - Life Threatening), Pyrexia (n/a - Not Recovered/Not Resolved -), Shock (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR

										Vomiting (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC-10011086270	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asymptomatic COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10011086317	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure diastolic decreased (0d - Recovered/Resolved - Other Medically Important Condition), Fall (n/a - Recovered/Resolved - Other Medically Important Condition), Head injury (n/a - Recovered/Resolved - Other Medically Important Condition), Heart rate decreased (0d - Recovered/Resolved - Other Medically Important Condition), Hyperventilation (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), PO2 increased (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011086474	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination failure (19d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011086479	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyskinesia (0d - Recovered/Resolved - Other Medically Important Condition), Gaze palsy (0d - Recovered/Resolved - Other Medically Important Condition), Pallor (0d - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011086722	27/12/2021	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-10011086839	27/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyskinesia (n/a - Recovering/Resolving -), Hypoaesthesia (n/a - Recovering/Resolving -), Injury (n/a - Unknown -), Mobility decreased (n/a - Recovering/Resolving -), Movement disorder (n/a - Recovering/Resolving -), Muscular weakness (n/a - Recovering/Resolving -), Neuropathy	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[RISPERIDONE] (C - Schizophrenia - n/a - [n/a - n/a - Oral])	ICSR

										peripheral (39417min - Recovered/Resolved - Other Medically Important Condition), Tremor (n/a - Recovering/Resolving -), Vaccination site irritation (n/a - Not Recovered/Not Resolved -)			
EU-EC-10011086886	27/12/2021	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-10011086925	27/12/2021	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-10011086934	27/12/2021	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-10011087290	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vulval ulceration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10011087320	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Spinal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011087467	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (2d - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011087786	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovered/Resolved -), Asthenia (n/a - Recovered/Resolved -), Ligament sprain (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Rash (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011088251	27/12/2021	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-10011088260	27/12/2021	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-10011088468	27/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Fatigue (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC-10011088653	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011088716	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10011088717	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Unknown -), Vaccination site inflammation (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10011088718	27/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10011076869	26/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011077015	26/12/2021	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-10011077091	26/12/2021	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 - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011077159	26/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (3d - Recovered/Resolved -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011077234	26/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown -), Fatigue (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), 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-10011077384	26/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (1d - Recovered/Resolved -), Injection site erythema (n/a - Recovering/Resolving -), Injection site inflammation (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Injection site pain (n/a - Recovering/Resolving -), Injection site swelling (n/a - Recovering/Resolving -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Malaise (0d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)			
EU-EC-10011077521	26/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination failure (10d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011075291	25/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011075764	25/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Injection site erythema (n/a - Recovered/Resolved -), Injection site inflammation (n/a - Recovered/Resolved -), Injection site pain (n/a - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Nausea (12h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011076158	25/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Influenza (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011076379	25/12/2021	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-10011076387	25/12/2021	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-10011076436	25/12/2021	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-10011076542	25/12/2021	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-10011065868	24/12/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Heart rate increased (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown	Not reported	ICSR

			Professional	Area							Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	- [n/a - .3mL - Intramuscular])		
EU-EC-10011065916	24/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Polymerase chain reaction (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Procalcitonin increased (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Troponin increased (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR	
EU-EC-10011066574	24/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Muscle spasms (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Myalgia (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-10011066793	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (1d - Recovered/Resolved -), Chills (1d - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10011067137	24/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Extraocular muscle disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Photophobia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Product use issue (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Status epilepticus	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	

										(n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vision blurred (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Visual impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10011067146	24/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Sinus pain (n/a - Recovering/Resolving - Other Medically Important Condition), 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-10011067694	24/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Breast pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (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-10011068292	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (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-10011068314	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Injection site pain (15d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011068386	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011068396	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (2mo - Recovered/Resolved -), Fatigue (2mo - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Heart rate increased (2mo - Recovered/Resolved -)			
EU-EC-10011068405	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011068412	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ETHINYLESTRADIOL, LEVONORGESTREL, LACTOSE ANHYDROUS] (C - Prophylaxis - n/a - [n/a - 1{DF} - n/a]), [KRILL OIL] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011068429	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011068445	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaginal haemorrhage (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011068495	24/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011069826	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Depression (n/a - Unknown -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Menstrual cycle management - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10011070621	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (3d - Recovered/Resolved -), Injection site pain (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011072158	24/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (3mo - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011072189	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rheumatic disorder (n/a - Recovering/Resolving - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011072348	24/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011072476	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Erythema multiforme (3wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011072495	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011072571	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Subcutaneous])	Not reported	ICSR
EU-EC-10011072594	24/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011072797	24/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (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-10011072929	24/12/2021	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-10011072935	24/12/2021	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-10011073639	24/12/2021	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 -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Other Medically Important Condition)			
EU-EC-10011073646	24/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Breast discomfort (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011073726	24/12/2021	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-10011051486	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Pericarditis (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011051606	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving -), Decreased appetite (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011051720	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011051764	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011052335	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Recovered/Resolved -), Seizure (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-10011052716	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dysmenorrhoea (n/a - Unknown - Other Medically Important Condition), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Immunisation (n/a - Unknown - Other Medically Important Condition), Loss of personal independence in	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										daily activities (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10011052732	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Unknown -), Pyrexia (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-10011052736	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011053316	23/12/2021	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), Dyspnoea (n/a - Recovered/Resolved -), Pain (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 - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011053727	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenitis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011053921	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oropharyngeal pain (n/a - Recovered/Resolved -), Pericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rhinitis (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10011054325	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Unknown -), Menstrual disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[DOCONESENT, ICOSAPENT, FISH OIL, OMEGA-3-ACID ETHYL ESTERS 90] (C - n/a - n/a -), [VITAMINS NOS] (C - n/a - n/a -)	ICSR
EU-EC-10011054337	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (3d - Recovered/Resolved -), Headache (n/a - Unknown -), Illness (n/a - Unknown -), Menstruation irregular (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011054338	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011054349	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved -), Mobility decreased (5d - Recovered/Resolved -), Pain in extremity (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011054353	23/12/2021	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])	TRANKAPSLER [NOT AVAILABLE] (C - n/a - n/a -), [VITAMINS NOS] (C - n/a - n/a -)	ICSR
EU-EC-10011054489	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Electrocardiogram change (82h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011054537	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved -), Back pain (n/a - Not Recovered/Not Resolved -), Chest discomfort (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Neck pain (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011054576	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deafness (n/a - Unknown - Other Medically Important Condition), Deafness bilateral (n/a - Unknown - Other Medically Important Condition), Tinnitus (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011054578	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema (n/a - Unknown -), Oculomucocutaneous syndrome (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

										Pruritus (n/a - Unknown -), Pyrexia (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Not Recovered/Not Resolved -)			
EU-EC-10011054645	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition aggravated (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Glomerulonephritis chronic (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haematuria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), IgA nephropathy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Proteinuria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vasculitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011054674	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011054715	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011055312	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10011055315	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Seizure (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-10011055381	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011056537	23/12/2021	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 - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011056540	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (3d - Not Recovered/Not Resolved -), Heavy menstrual bleeding (6d - Recovered/Resolved -), Hypomenorrhoea (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Injection site pain (3d - Recovered/Resolved -), Menstruation delayed (12d - Recovered/Resolved -), Polymenorrhoea (3d - Recovered/Resolved -)			
EU-EC-10011056543	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (91d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011057561	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Depressed level of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Lethargy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Presyncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pulmonary embolism (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Throat tightness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vision blurred (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-10011057570	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Encephalitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Eye movement disorder (n/a - Unknown -), Seizure (n/a - Recovering/Resolving - 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-10011057588	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Feeling of body temperature change (n/a - Not 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), Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Periorbital oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urticaria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vision blurred (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10011057680	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovering/Resolving - Other Medically Important Condition), Angioedema (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling of body temperature change (n/a - Recovering/Resolving - Other Medically Important Condition), Flushing (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Swelling (n/a - Recovering/Resolving - Other Medically Important Condition), Throat tightness (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										- Other Medically Important Condition), Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition), Vision blurred (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10011057704	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (102h - Recovered/Resolved -), Chest pain (102h - Recovered/Resolved -), Myocardial necrosis marker increased (5d - Recovered/Resolved - Other Medically Important Condition), Myocarditis (102h - Recovered/Resolved - Other Medically Important Condition), Pyrexia (102h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011057758	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Aneurysm (n/a - Fatal - Results in Death), Cerebellar haemorrhage (n/a - Fatal - Results in Death), Dizziness (n/a - Fatal - Results in Death), Headache (n/a - Fatal - Results in Death), Loss of consciousness (n/a - Fatal - Results in Death), Subarachnoid haemorrhage (n/a - Fatal - Results in Death), Subdural haematoma (n/a - Fatal - Results in Death), Vomiting (n/a - Fatal - Results in Death)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011057881	23/12/2021	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-10011057897	23/12/2021	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-10011058125	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (61d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011058306	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dressler's syndrome (n/a - Unknown - Other Medically Important Condition), Exercise tolerance decreased (n/a - Unknown -), Fatigue (n/a - Unknown -), Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011058311	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

EU-EC-10011058354	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Apathy (n/a - Recovering/Resolving -), Crying (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011058621	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Paraesthesia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011058639	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oral herpes (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011058652	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011058805	23/12/2021	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-10011059445	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown -), Lipase increased (n/a - Unknown -), Pancreatitis (n/a - Recovering/Resolving - 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-10011059851	23/12/2021	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-10011059882	23/12/2021	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-10011059905	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Oesophageal achalasia (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-10011059970	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (78d - Recovered/Resolved - Other Medically Important Condition), Herpes zoster meningitis (78d - Recovered/Resolved - Other Medically Important Condition), Intracranial pressure increased (78d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR

EU-EC-10011060225	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes simplex (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011060248	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ear infection (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011060252	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (12h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011060375	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011060402	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011060418	23/12/2021	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 - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011060641	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disorientation (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (0d - Recovered/Resolved - Other Medically Important Condition), Emotional distress (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (1d - Recovered/Resolved - Other Medically Important Condition), Peripheral swelling (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-10011060648	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Swelling (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-10011060675	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Gait inability (n/a - Unknown - Disabling), Malaise (n/a - Unknown - Disabling), Nerve injury (n/a - Not Recovered/Not Resolved - Disabling), Suspected COVID-19 (n/a - Unknown - Disabling), Syncope (n/a - Recovered/Resolved With Sequelae - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011060690	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (20min - Recovered/Resolved -), Syncope (20min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011060708	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Appendicitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Nausea (n/a - Unknown -), Vomiting (n/a - Unknown -)			
EU-EC-10011060977	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved - Other Medically Important Condition), Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Hyperhidrosis (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011061049	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Eye pain (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011061617	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bell's palsy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011061646	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Other Medically Important Condition), Immunisation (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	NOVORAPID [INSULIN ASPART] (C - Type 1 diabetes mellitus - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011061657	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pallor (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (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-10011061999	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10011062041	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination failure (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011062367	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye movement disorder (5min - Unknown - Life Threatening), Seizure like phenomena (5min - Unknown - Life Threatening, Other Medically Important Condition), Tremor (5min - Unknown - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011062466	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Long QT syndrome congenital (n/a - Fatal - Results in Death, Other Medically Important Condition), Sudden cardiac death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011062604	23/12/2021	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-10011062758	23/12/2021	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-10011063128	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011063155	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011063292	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011063327	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved - Other Medically Important Condition), Disorientation (n/a - Recovered/Resolved - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Visual impairment (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011063364	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown -), Diarrhoea (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Epistaxis (n/a - Unknown -), Headache (n/a - Unknown -), Vaccination site pain (n/a - Unknown -), Vomiting (n/a - Unknown -)			
EU-EC-10011063530	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (10min - Recovered/Resolved -), Syncope (10min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011063535	23/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Painful respiration (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-10011063874	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Cough (n/a - Recovering/Resolving - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Decreased appetite (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Heat exhaustion (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 - n/a])	Not reported	ICSR

										Condition), Lethargy (10d - Recovered/Resolved - Other Medically Important Condition), Nasal mucosal disorder (n/a - Unknown - Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown - Other Medically Important Condition), Pyrexia (8d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10011063875	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Haemorrhage intracranial (n/a - Recovering/Resolving - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011063968	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (n/a - Unknown -), Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10011064102	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10011064110	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10011064159	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011064239	23/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Meningoencephalitis viral (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[XYLOMETAZOLINE HYDROCHLORIDE] (C - Sinus congestion - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011064464	23/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (0d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Movement disorder (n/a - Recovered/Resolved - Other Medically Important Condition), Palpitations (0d - Recovered/Resolved - Other Medically Important Condition), Visual impairment (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10011064554	23/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye swelling (1d - Recovering/Resolving -)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011036780	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011037200	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Pallor (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011037374	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (20d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011037376	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011037386	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011037401	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Gait disturbance (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -), Migraine (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011037415	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hyperpyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), 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-10011037419	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Somnolence (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-	22/12/2021	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Asthenia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011037490			Healthcare Professional	Economic Area		Years	Specified			Recovering/Resolving - Disabling), Headache (n/a - Recovering/Resolving - Disabling), Presyncope (n/a - Recovering/Resolving - Disabling), Vertigo (n/a - Recovering/Resolving - Disabling), Vomiting (n/a - Recovering/Resolving - Disabling)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC-10011037876	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (8min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011037890	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	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-10011037895	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (15min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011037900	22/12/2021	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-10011037922	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Unknown - Other Medically Important Condition), Systemic viral infection (n/a - Unknown - Other Medically Important Condition), Unresponsive to stimuli (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011037925	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Febrile convulsion (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-10011037929	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011037941	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Unknown -), 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-10011037951	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bradycardia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011037952	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	C-reactive protein increased (n/a - Recovering/Resolving -), Chest X-ray abnormal (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -), Echocardiogram abnormal (n/a - Recovering/Resolving -), Electrocardiogram abnormal (n/a - Recovering/Resolving -), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Troponin I abnormal (n/a - Recovering/Resolving -), Troponin T increased (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

EU-EC-10011037963	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pruritus (n/a - Recovered/Resolved - Other Medically Important Condition), Rash (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-10011037996	22/12/2021	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-10011038001	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011038024	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (3578min - Recovered/Resolved -), Headache (3578min - Recovered/Resolved -), Injection site hypoaesthesia (n/a - Unknown -), Nausea (3578min - Recovered/Resolved -), Pyrexia (3578min - Recovered/Resolved -), Syncope (3578min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011038028	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011038034	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (3d - Recovered/Resolved - Other Medically Important Condition), Limb discomfort (2d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011038044	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (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-10011038049	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Malaise (0d - Recovered/Resolved - Other Medically Important Condition), Nasopharyngitis (0d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Pallor (0d - Recovered/Resolved - Other Medically Important Condition), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10011038050	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (10min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011038052	22/12/2021	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), Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011038054	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Immunisation (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vomiting (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-10011038206	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (1d - Recovered/Resolved -), Loss of consciousness (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011038207	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (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 - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011038232	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (1d - Recovered/Resolved -), Fatigue (0d - Recovered/Resolved -), Hypotension (n/a - Unknown -), Loss of consciousness (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-10011038243	22/12/2021	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-10011038258	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Confusional state (n/a - Unknown -), Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Syncope (n/a -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10011038260	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Unknown - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Pyrexia (0d - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved With Sequelae - 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-10011038546	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Discharge (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Genitourinary symptom (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus bradycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation,	[BISOPROLOL, BISOPROLOL FUMARATE, BISOPROLOL HEMIFUMARATE] (S - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), [RAMIPRIL] (S - Product used for unknown indication - Unknown - [n/a - n/a - n/a]), [TOZINAMERAN] (S - Immunisation - Not applicable - [1d - n/a - n/a])	[COLCHICINE] (C - n/a - Drug withdrawn - [n/a - n/a - n/a])	ICSR

										Other Medically Important Condition)			
EU-EC-10011038563	22/12/2021	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 - n/a])	Not reported	ICSR
EU-EC-10011038569	22/12/2021	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 - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011038583	22/12/2021	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 - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011038591	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	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-10011038612	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Abdominal rigidity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011038628	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic shock (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown -), Myocarditis (n/a - Unknown - Other Medically Important Condition), Shock (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-10011038632	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	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 - n/a])	Not reported	ICSR
EU-EC-10011038633	22/12/2021	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 - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011038636	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Atonic seizures (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Electrocardiogram ambulatory abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Orthostatic intolerance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Somatic symptom disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10011038642	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (75min - Recovered/Resolved -), Syncope (5min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011038656	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (1h - Recovered/Resolved - Other Medically Important Condition), Pallor (1h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011039256	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Facial paresis (n/a - Recovering/Resolving -), Hypoesthesia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011039388	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Immune system disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition), Tachycardia (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-10011039432	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (0d - Recovered/Resolved - Other Medically Important Condition), Anxiety (n/a - Unknown -), Chest pain (n/a - Unknown -), Dyspnoea (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), Malaise (n/a - Unknown -), Pallor (n/a - Recovering/Resolving -), Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition), Speech disorder (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10011039460	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (6930min - Recovered/Resolved -), Loss of consciousness (6930min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011039478	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysuria (n/a - Unknown -), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (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-10011039485	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Hypoaesthesia (n/a - Unknown -), 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-10011039496	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (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 - Intramuscular])	Not reported	ICSR
EU-EC-10011039505	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown -), Heart rate increased (n/a - Unknown -), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Ventricular tachycardia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011039514	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011039519	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bradycardia (20min - Recovered/Resolved - Other Medically Important Condition), Dizziness (20min -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Recovered/Resolved -), Hypotension (20min - Recovered/Resolved -), Pallor (20min - Recovered/Resolved -)			
EU-EC-10011039980	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 immunisation (n/a - Recovered/Resolved With Sequelae - Disabling), Type 1 diabetes mellitus (n/a - Recovered/Resolved With Sequelae - Disabling)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011040090	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypopnoea (n/a - Not Recovered/Not Resolved -), Nephrotic syndrome (n/a - Recovering/Resolving - Other Medically Important Condition), Oedema peripheral (n/a - Not Recovered/Not Resolved -), Protein urine present (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved -), Weight increased (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[ACTIZANOLAST] (C - n/a - n/a - [n/a - n/a - Ophthalmic]), [BEPOTASTINE BESILATE] (C - n/a - n/a - [n/a - n/a - Oral]), [MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10011040219	22/12/2021	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 - Other Medically Important Condition), Hiccups (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Musculoskeletal chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - Immunisation - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10011040228	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovering/Resolving - Other Medically Important Condition), Rash (n/a - Unknown - Other Medically Important Condition), Urticaria (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011040237	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Electrocardiogram ST segment elevation (n/a - Recovering/Resolving - Other Medically Important Condition), Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011040241	22/12/2021	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-10011040248	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011040266	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (2h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011040281	22/12/2021	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011040293	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011040297	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Syncope (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 - Intramuscular])	Not reported	ICSR
EU-EC-10011040445	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 immunisation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Heart rate variability increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoesthesia (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-10011040456	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovered/Resolved - Other Medically Important Condition), Decreased appetite (n/a - Recovered/Resolved - Other Medically Important Condition), Dysphagia (n/a - Recovered/Resolved - Other Medically Important Condition), Flank pain (n/a - Recovered/Resolved - Other Medically Important Condition), Nasopharyngitis (n/a -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR

										Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), SARS-CoV-2 test negative (n/a - Recovered/Resolved - Other Medically Important Condition), Sensation of foreign body (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10011040788	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Essential tremor (n/a - Not Recovered/Not Resolved -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011040793	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arrhythmia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Hyperpyrexia (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011040890	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (2d - Recovered/Resolved -), Influenza like illness (3d - Recovered/Resolved -), Syncope (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011041316	22/12/2021	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-10011041623	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (50d - Recovering/Resolving - Other Medically Important Condition), Lymphoma (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011042043	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011042542	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (3d - Recovered/Resolved -), Malaise (3d - Recovered/Resolved -), Myalgia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011042592	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Tinnitus (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011042607	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - .3mL - n/a])	Not reported	ICSR

EU-EC-10011042993	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypotension (n/a - Unknown - Disabling), Loss of personal independence in daily activities (n/a - Unknown - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011043040	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Muscle twitching (n/a - Not Recovered/Not Resolved -), Nervous system disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011043063	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (4d - Recovered/Resolved -), Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-10011043284	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011043367	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (6d - Recovered/Resolved -), Headache (6d - Recovered/Resolved -), Injection site pain (6d - Recovered/Resolved -), Pyrexia (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC-10011043458	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase increased (5d - Recovered/Resolved -), Disease recurrence (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Pharyngeal erythema (n/a - Not Recovered/Not Resolved -), Productive cough (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Rhinorrhoea (n/a - Not Recovered/Not Resolved -), Upper respiratory tract infection (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[CARBOCISTEINE] (C - Upper respiratory tract inflammation - n/a - [6d - n/a - Oral]), [CEFDITOREN PIVOXIL] (C - Upper respiratory tract inflammation - n/a - [6d - n/a - Oral]), [PARACETAMOL] (C - Upper respiratory tract inflammation - n/a - [6d - n/a - Oral])	ICSR
EU-EC-10011043603	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal discomfort (0d - Recovered/Resolved -), Abdominal pain (1d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR

										Recovered/Resolved - Caused/Prolonged Hospitalisation), Body temperature increased (0d - Recovered/Resolved -), Diarrhoea (0d - Recovered/Resolved -), Fatigue (7d - Recovered/Resolved -), Headache (5d - Recovered/Resolved -), Lip oedema (6d - Recovered/Resolved -), Multisystem inflammatory syndrome in children (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (4d - Recovered/Resolved -), Rash (6d - Recovered/Resolved -), Syncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10011043663	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Recovered/Resolved -), Chills (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011043816	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Encephalitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011043845	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (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-10011043850	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Unknown - Other Medically Important Condition), Haemoptysis (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011043870	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angioedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Face oedema (n/a - Unknown - Caused/Prolonged Hospitalisation), Flushing (n/a -	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

										Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Visual impairment (n/a - Unknown - Caused/Prolonged Hospitalisation)			
EU-EC-10011044055	22/12/2021	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-10011044105	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination failure (12d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011044306	22/12/2021	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 -), Chills (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Echocardiogram (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), Nausea (n/a - Not Recovered/Not Resolved -), Pain in jaw (n/a - Not Recovered/Not Resolved -), Troponin increased (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011044314	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Dyspnoea (n/a - Unknown -), 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-10011044317	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Generalised tonic-clonic seizure (n/a - Recovering/Resolving - Other Medically Important Condition), Urinary incontinence (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011044329	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Electrocardiogram ST segment elevation	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										(n/a - Recovered/Resolved - Other Medically Important Condition), Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved -)			
EU-EC-10011044337	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Pericarditis (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-10011044387	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Syncope (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-10011044392	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), 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-10011044465	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination failure (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011044631	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Somnolence (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011044692	22/12/2021	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])	[DESOGESTREL] (C - Contraception, Dysmenorrhoea - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011044698	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011045120	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Unknown -), Chills (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011045367	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Ataxia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diabetes mellitus inadequate control (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-10011045426	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypoaacusis (n/a - Recovering/Resolving - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -)	Not reported	ICSR

										Vestibular neuritis (n/a - Recovering/Resolved - Caused/Prolonged Hospitalisation)	Not applicable - [1d - .3mL - Intramuscular]		
EU-EC-10011045483	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Ischaemic stroke (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011045838	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Somnolence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011045863	22/12/2021	Spontaneous	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 - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011046042	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011046146	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Palpitations (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011046214	22/12/2021	Spontaneous	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 - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011046216	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Ageusia (n/a - Not Recovered/Not Resolved -), Anosmia (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Influenza like illness (n/a - Not Recovered/Not Resolved -), Injection site discomfort (2d - Recovered/Resolved -), Insomnia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Somnolence (n/a - Not Recovered/Not Resolved -), Vaccination site pain (3d - Recovered/Resolved -), Vaccination site rash (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011046268	22/12/2021	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-10011046334	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (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

										Dizziness (n/a - Unknown - Other Medically Important Condition), Mobility decreased (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10011046342	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Headache (n/a - Not Recovered/Not Resolved - Disabling), Nausea (n/a - Not Recovered/Not Resolved - Disabling), Pain (n/a - Recovering/Resolving - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011046375	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (13d - Recovered/Resolved - Other Medically Important Condition), Chest pain (4d - Recovered/Resolved - Other Medically Important Condition), Chills (2d - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Nausea (5d - Recovered/Resolved - Other Medically Important Condition), Oropharyngeal pain (6d - Recovered/Resolved - Other Medically Important Condition), Pain (6d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - Immunisation - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10011046428	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Cold sweat (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Myocarditis (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10011046434	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (1d - Recovered/Resolved - Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Immunisation (n/a - Unknown - Other Medically Important Condition), Lethargy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	ADALIMUMAB [ADALIMUMAB] (C - Crohn's disease - n/a - [n/a - n/a - n/a]), AZATHIOPRINE [AZATHIOPRINE] (C - Crohn's disease - n/a - [332d - n/a - n/a]), [INFLUENZA VIRUS] (C - Immunisation - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10011046455	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011046594	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown - Other Medically Important Condition), Arthralgia (n/a - Unknown - Other Medically Important Condition), Injection site reaction (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - Other Medically Important Condition), Oedema peripheral (n/a - Unknown - Other Medically Important Condition), Rash morbilliform (n/a - Unknown - Other Medically Important Condition), Urticaria (n/a - Unknown - Other Medically Important Condition)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011047305	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pruritus (n/a - Recovering/Resolving -), Rash pruritic (n/a - Recovering/Resolving -), Syncope (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-10011047306	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	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-10011047310	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Appendicitis (n/a - Recovering/Resolving - 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-10011047311	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (2min - Recovered/Resolved - Other Medically Important Condition), Vision blurred (2min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011047313	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (15min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011047314	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Acute kidney injury (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nephrotic syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Oedema peripheral (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Periorbital oedema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Swelling face (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-10011047317	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (10min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011047322	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nasopharyngitis (n/a - Recovered/Resolved -), 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-10011047328	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (5min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011047338	22/12/2021	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-10011047339	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown -), Headache (n/a - Unknown -), Nausea (n/a - Unknown -), Pyrexia (n/a - Recovered/Resolved -), Syncope (n/a - Unknown - Other Medically Important Condition), Vaccination site hypoaesthesia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	22/12/2021	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	Chills (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011047340			Healthcare Professional	European Economic Area		Years	Specified			Recovered/Resolved - Caused/Prolonged Hospitalisation), Dehydration (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Feeling of body temperature change (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Lethargy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC-10011047358	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bradycardia (8min - Recovered/Resolved - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved -), Pallor (8min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011047364	22/12/2021	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 - n/a])	Not reported	ICSR
EU-EC-10011047366	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (10min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011047371	22/12/2021	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 - Intramuscular])	Not reported	ICSR
EU-EC-10011047373	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ischaemic stroke (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Transient ischaemic attack (n/a - 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-10011047376	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Appendicitis (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-10011047379	22/12/2021	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-10011047388	22/12/2021	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 - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011047451	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Disabling), Eye irritation (n/a - Not Recovered/Not Resolved - Disabling), Eye pain (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - n/a - n/a]), [ZOLPIDEM, ZOLPIDEM TARTRATE] (C - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Lymphadenopathy (n/a - Not Recovered/Not Resolved - Disabling), Migraine (n/a - Not Recovered/Not Resolved - Disabling), Myalgia (n/a - Not Recovered/Not Resolved - Disabling), Pyrexia (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC-10011047462	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	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-10011047493	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Grip strength decreased (n/a - Not Recovered/Not Resolved -), Illusion (n/a - Not Recovered/Not Resolved -), Limb discomfort (n/a - Not Recovered/Not Resolved -), Movement disorder (n/a - Not Recovered/Not Resolved -), Neuropathy peripheral (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-10011047519	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Seizure (n/a - Recovering/Resolving - 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-10011047521	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Electrocardiogram normal (n/a - Recovered/Resolved -), Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Troponin increased (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011047551	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nasopharyngitis (n/a - Recovered/Resolved -), Overdose (n/a - Unknown -), Product preparation error (n/a - Unknown -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011047608	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [FISH OIL] (C - n/a - n/a - [n/a - n/a - n/a]), [GUANFACINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [LAMOTRIGINE] (C - Depression - n/a - [n/a - 25mg - n/a]),	ICSR

										Recovering/Resolving - Other Medically Important Condition), Feeding disorder (n/a - Recovering/Resolving - Other Medically Important Condition), Hypertension (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition), Weight decreased (n/a - Recovering/Resolving - Other Medically Important Condition)	[NICOTINAMIDE, RIBOFLAVIN, THIAMINE NITRATE, PYRIDOXINE HYDROCHLORIDE, THIAMINE HYDROCHLORIDE, NICOTINAMIDE, RIBOFLAVIN, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - 100mg - Oral]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])		
EU-EC-10011047637	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved -), Heart rate increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY MAGNESIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [FERROUS BISGLYCINATE] (C - n/a - n/a - [n/a - n/a - n/a]), [LEVOMEFOLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [MECOBALAMIN] (C - n/a - n/a - [n/a - n/a - n/a]), [PYRIDOXAL PHOSPHATE] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011047718	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ageusia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Anosmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011047742	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011047780	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Acute disseminated encephalomyelitis (n/a - Unknown - Other Medically Important Condition), Aphasia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Gait inability (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Neurological decompensation (n/a - Not Recovered/Not Resolved - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Condition), Psychomotor skills impaired (n/a - Not Recovered/Not Resolved -), Wheelchair user (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10011047801	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	C-reactive protein increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Colitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	CYMBALTA [DULOXETINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - Oral]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Gastroesophageal reflux disease - n/a - [n/a - n/a - Oral]), [AMLODIPINE, AMLODIPINE BESILATE, AMLODIPINE MALEATE, AMLODIPINE MESILATE] (C - Hypertension - n/a - [n/a - n/a - Oral]), [METOPROLOL, METOPROLOL TARTRATE] (C - Hypertension - n/a - [n/a - n/a - Oral]), [VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011047836	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 immunisation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011047867	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain in extremity (n/a - Recovering/Resolving -), Pyrexia (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 - n/a])	Not reported	ICSR
EU-EC-10011047968	22/12/2021	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 - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011048061	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Recovered/Resolved -), Ageusia (n/a - Recovered/Resolved -), Chills (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Lymphadenopathy (n/a - Unknown -), Nausea (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011048210	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Immunisation reaction (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

											(n/a - Unknown - Other Medically Important Condition)			
EU-EC-10011048227	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (555min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10011048389	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (1wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10011048457	22/12/2021	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-10011048487	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown -), Headache (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), INFLECTRA [INFLIXIMAB] (S - Juvenile idiopathic arthritis - Unknown - [n/a - 250mg - n/a])	ARAVA [LEFLUNOMIDE] (C - Juvenile idiopathic arthritis - n/a - [n/a - 20mg - n/a])	ICSR	
EU-EC-10011048508	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Pericarditis (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-10011048510	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Chua, G.. Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination, 2021	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myopericarditis (n/a - 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-10011048726	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (9d - 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-10011048796	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Immunisation (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	ELLAONE [LULIPRISTAL ACETATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-10011049004	22/12/2021	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-10011049427	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -)	Not reported	ICSR	

				Economic Area						Recovered/Resolved - Other Medically Important Condition)	Not applicable - [1d - n/a - Intramuscular])		
EU-EC-10011049624	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	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-10011049901	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (57d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011050013	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anaemia (n/a - Recovering/Resolving -), Heavy menstrual bleeding (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011050059	22/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (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-10011050144	22/12/2021	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 - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10011050148	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (n/a - Unknown -), Pyrexia (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10011050156	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Condition aggravated (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Post viral fatigue syndrome (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sleep disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011050160	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (63d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011050162	22/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epididymitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Testicular pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Testicular swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011050447	22/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011050556	22/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Balance disorder (n/a - Unknown -), Dizziness (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Multiple sclerosis (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), INFLECTRA [INFLIXIMAB] (S - Juvenile idiopathic arthritis - Drug withdrawn - [1107d - 250mg - n/a])	ARAVA [LEFLUNOMIDE] (C - Juvenile idiopathic arthritis - n/a - [n/a - 20mg - n/a])	ICSR

										Hospitalisation, Other Medically Important Condition), Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Quadripareisis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)			
EU-EC-10011019548	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (1d - Recovered/Resolved -), Mydriasis (1d - Recovered/Resolved -), Somnolence (1d - Recovered/Resolved -), Visual impairment (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011019662	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Immunisation reaction (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011019663	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011020000	21/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Polymenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011020159	21/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Rash (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011020229	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (9d - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (9d - Recovered/Resolved - Other Medically Important Condition), Pain in extremity (9d - Recovered/Resolved - Other Medically Important Condition), Paraesthesia (9d - Recovered/Resolved - Other Medically Important Condition), Seizure (9d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011020234	21/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dermatitis atopic (n/a - Not Recovered/Not Resolved - Congenital Anomaly)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011020260	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (4d - Recovered/Resolved -), Headache (4d - Recovered/Resolved -), Pyrexia (4d - Recovered/Resolved -), Rash (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011020282	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (4d - Recovered/Resolved -), Feeling cold (4d - Recovered/Resolved -), Pain in extremity (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011020359	21/12/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

				Area						-), Headache (n/a - Recovered/Resolved -)	n/a - [n/a - 1{DF} - Intramuscular:]		
EU-EC-10011020413	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular:])	Not reported	ICSR
EU-EC-10011020536	21/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved -), Bone pain (n/a - Recovered/Resolved -), Peripheral swelling (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular:])	Not reported	ICSR

 Rows 501 - 1000

[Return](#) - [Refresh](#) - [Print](#) - [Export](#)