

Line Listing Report

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EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-10010419893	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash erythematous (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010419896	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Orchitis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010419949	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Asthenia (4d - Recovered/Resolved -), Injection site hypoaesthesia (4d - Recovered/Resolved -), Motor dysfunction (4d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010420014	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oral herpes (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010420018	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010420020	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Recovered/Resolved -), Heavy menstrual bleeding (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010420051	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010420144	25/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Presyncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010420207	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010420326	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010420381	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	ICSR

											1{DF} - Intramuscular])			
EU-EC-10010420388	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Tonsillitis (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010420389	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epistaxis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010420406	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (21d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010420839	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Headache (2d - Recovered/Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (1d - Recovered/Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-10010420896	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010420908	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (14d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010421457	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaemia (n/a - Recovering/Resolving -), Heavy menstrual bleeding (19d - Recovered/Resolved -), Intermenstrual bleeding (n/a - Recovered/Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - Arrhythmia - Dose not changed - [n/a - 1{DF} - n/a])	ICSR	
EU-EC-10010421741	25/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Fall (n/a - Recovering/Resolving - Other Medically Important Condition), Heart rate decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Hyperventilation (n/a - Recovered/Resolved -), Nervousness (n/a - Recovering/Resolving -), Presyncope (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR	

										Seizure (n/a - Recovered/Resolved - Other Medically Important Condition), Shock (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10010422595	25/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (2d - Recovered/Resolved - Other Medically Important Condition), Headache (3d - Recovered/Resolved - Other Medically Important Condition), Lethargy (2d - Recovered/Resolved - Other Medically Important Condition), Pain (3d - Recovered/Resolved - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ETHINYLESTRADIOL, NORGESTIMATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010422617	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Unknown -), Headache (1d - Unknown -), Vomiting (1d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010422944	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -), Rash (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010422945	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010423014	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010423198	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010423207	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovering/Resolving -), Fatigue (3d - Recovering/Resolving -), Headache (4d - Recovering/Resolving -), Nausea (1d - Recovering/Resolving -), Vomiting (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010423661	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010424162	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010424172	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (2d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010424308	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S -)	Not reported	ICSR

											Immunisation - n/a - [n/a - n/a - n/a]		
EU-EC-10010424396	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (0d - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010424474	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -), Nausea (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010424789	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010424837	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Odynophagia (n/a - Unknown -), Pyrexia (n/a - Unknown -), Rhinorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010424863	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Unknown -), Headache (n/a - Unknown -), Pyrexia (n/a - Unknown -), Vaccination site inflammation (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010424870	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Ageusia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Anosmia (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-10010424872	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovering/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010424880	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010424981	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epilepsy (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-10010425036	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10010425049	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR

										Lymphadenopathy (n/a - Recovered/Resolved -), Nasal congestion (n/a - Recovered/Resolved -), Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved -)			
EU-EC-10010425062	25/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010425847	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (2d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Lymphadenopathy (1d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010426094	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010427828	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye swelling (3d - Recovered/Resolved -), Haematoma (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010427846	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (30min - Recovered/Resolved -), Menstruation delayed (8wk - Recovered/Resolved -), Myalgia (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010427990	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving -), Headache (n/a - 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-10010428942	25/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anal sphincter atony (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Bladder sphincter atony (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myelitis transverse (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Other Medically Important Condition), Paraesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10010429402	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (3d - Recovered/Resolved -), Dizziness (4d - Recovering/Resolving -), Fatigue (4d - Recovering/Resolving -), Influenza (3d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -), Malaise (3d - Recovered/Resolved -), Nausea (3d - Recovering/Resolving -), Pyrexia (4d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010430183	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cytokine increased (42d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hepatic failure (42d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Multisystem inflammatory syndrome in children (42d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Polyserositis (42d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (42d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Renal failure (42d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010432592	25/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Not Recovered/Not Resolved -), Feeling hot (2d - Recovering/Resolving -), Pyrexia (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010411008	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010411158	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving -), Asthenia (1d - Recovered/Resolved -), Chest pain (4d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Chills (2d - Recovered/Resolved -), Dyspnoea (3d - Recovered/Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Malaise (5d - Recovered/Resolved -), Myalgia (n/a - Recovering/Resolving -), Palpitations (n/a - Recovering/Resolving -)			
EU-EC-10010411168	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Chills (1d - Recovered/Resolved -), Fatigue (5d - Recovered/Resolved -), Injection site haematoma (1d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010411228	24/10/2021	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-10010411459	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye pain (11d - Recovered/Resolved -), Eye pruritus (11d - Recovered/Resolved -), Eye swelling (11d - Recovered/Resolved -), Rash (11d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[FUSIDIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010411476	24/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Unknown -), Hypersomnia (n/a - Unknown -), Lethargy (n/a - Recovering/Resolving -), Lymph node pain (n/a - Unknown -), Pharyngitis streptococcal (n/a - Unknown -), Swelling face (n/a - Unknown - Other Medically Important Condition), Vomiting (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-10010411508	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthmatic crisis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Atelectasis (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Hospitalisation), Respiratory tract infection (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10010411523	24/10/2021	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), Hypoaesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Presyncope (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CIRCADIN [MELATONIN] (C - Poor quality sleep - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010411531	24/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010411605	24/10/2021	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-10010411621	24/10/2021	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])	[DERMATOPHAGOIDES FARINAE (504), DERMATOPHAGOIDES PTERONYSSINUS (503), ALUMINIUM HYDROXIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010411632	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site erythema (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Menstruation irregular (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 AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [ATOMOXETINE] (C - n/a - n/a - [n/a - n/a - n/a]), [METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010411697	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (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-10010411724	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -), Nausea (n/a - 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-10010411799	24/10/2021	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-10010411806	24/10/2021	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-10010411807	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010411809	24/10/2021	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-10010411811	24/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[LISDEXAMFETAMINE DIMESYLATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010408228	23/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010408723	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyskinesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010408789	23/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010408795	23/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenitis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010408805	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bell's palsy (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010408837	23/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injury (n/a - Recovering/Resolving -), Lip swelling (n/a - Recovering/Resolving -), Pruritus (n/a - Recovering/Resolving -), Swelling (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010408853	23/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Stevens-Johnson syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]), [SULFASALAZINE] (S - Colitis ulcerative - Not applicable - [n/a - 3000mg - Oral])	AZATHIOPRINE [AZATHIOPRINE] (C - Colitis ulcerative - n/a - [n/a - 150mg - Oral]), [MESALAZINE] (C - Colitis ulcerative - n/a - [n/a - 3200mg - Oral])	ICSR
EU-EC-10010409050	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [ETHINYLESTRADIOL, ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

													- n/a)], [THIAMINE HYDROCHLORIDE, RETINOL] (C - n/a - n/a - [n/a - n/a - n/a])		
EU-EC-10010409062	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (2mo - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported		ICSR	
EU-EC-10010409101	23/10/2021	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-10010409180	23/10/2021	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-10010409221	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	ANTICONCEPTIEPIL [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])		ICSR	
EU-EC-10010409289	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported		ICSR	
EU-EC-10010409305	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])		ICSR	
EU-EC-10010409306	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported		ICSR	
EU-EC-10010409322	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hyperpyrexia (n/a - Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported		ICSR	
EU-EC-10010409344	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Fatigue (n/a -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported		ICSR	

										Recovering/Resolving -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (3d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	applicable - [n/a - 1{DF} - n/a]		
EU-EC-10010409371	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (0d - Recovered/Resolved -), Dyspnoea (8d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Malaise (8d - Recovered/Resolved -), Pyrexia (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PREDNISONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010409384	23/10/2021	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-10010409952	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010409955	23/10/2021	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-10010410039	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010410041	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (6h - Recovered/Resolved -), Headache (24h - Recovered/Resolved -), Myalgia (12h - Recovered/Resolved -), Pyrexia (6h - Recovered/Resolved -), Syncope (30min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-	23/10/2021	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Amenorrhoea (n/a -	COMIRNATY	Not reported	ICSR

10010410149			Healthcare Professional	Economic Area		Years	Specified			Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC-10010410162	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal distension (n/a - Not Recovered/Not Resolved -), Breast pain (n/a - Not Recovered/Not Resolved -), Breast swelling (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[MICONAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010410363	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (3d - Recovered/Resolved -), Malaise (3d - Recovered/Resolved -), Myalgia (3d - Recovered/Resolved -), Pain in extremity (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010410490	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (21d - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010410585	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Fatigue (2d - Recovered/Resolved -), Headache (n/a - Recovering/Resolving -), Malaise (3d - Recovered/Resolved -), Myalgia (2d - 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-10010410588	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Menstruation delayed (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-10010410837	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (1d - Recovered/Resolved -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [NOT AVAILABLE] (S - Rheumatic disorder - Dose not changed - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010410877	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (288h - Recovered/Resolved -), Headache (288h - Recovered/Resolved -), Malaise (96h - Recovered/Resolved -), Myalgia (36h -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

EU-EC-10010410891	23/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovered/Resolved -) Amenorrhoea (n/a - Not Recovered/Not Resolved -), Chills (5d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Myalgia (5d - Recovered/Resolved -), Pyrexia (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010396068	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Aphthous ulcer (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010396101	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010396269	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Musculoskeletal discomfort (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010396343	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (3d - Recovered/Resolved -), Fatigue (3d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -), Vertigo (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010396581	22/10/2021	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), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010396598	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved -), Chills (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	22/10/2021	Spontaneous	Non	European	Not available	12-17	Not	Male	No	Chills (n/a - Not	COMIRNATY	Not reported	ICSR

10010396620			Healthcare Professional	Economic Area		Years	Specified			Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC-10010396672	22/10/2021	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-10010397037	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (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-10010397118	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyskinesia (n/a - Not Recovered/Not Resolved -), Tic (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010397169	22/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mydriasis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010398019	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (2d - Recovered/Resolved - Other Medically Important Condition), Feeling abnormal (1d - Recovered/Resolved - Other Medically Important Condition), Headache (2d - Recovered/Resolved - Other Medically Important Condition), Malaise (2d - Recovered/Resolved - Other Medically Important Condition), Muscular weakness (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										- Other Medically Important Condition), Nausea (2d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10010398093	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010398479	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown -), Hypoaesthesia (n/a - Unknown -), Hypoaesthesia oral (n/a - Unknown -), Nausea (n/a - Unknown -), Paraesthesia (n/a - Unknown -), Photophobia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010398647	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain lower (n/a - Recovering/Resolving -), Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010398653	22/10/2021	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-10010398744	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (48h - Recovered/Resolved -), Menstrual disorder (72h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010398854	22/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved With Sequelae - Life Threatening), Dizziness (n/a - Recovered/Resolved With Sequelae - Life Threatening), Dyspnoea (n/a - Recovered/Resolved With Sequelae - Life Threatening)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TOPIRAMATE] (C - n/a - n/a - [n/a - n/a - n/a])	[FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [QUETIAPINE, QUETIAPINE FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TOPIRAMATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010398897	22/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Recovered/Resolved - Other Medically Important Condition), Eye pruritus (n/a - Recovered/Resolved - Other Medically Important Condition), Seasonal allergy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sneezing (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-10010399561	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [1d - n/a - n/a])	Not reported	ICSR

											Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10010399590	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovered/Resolved With Sequelae - Disabling), Ageusia (n/a - Recovered/Resolved With Sequelae - Disabling), Amenorrhoea (n/a - Recovered/Resolved With Sequelae - Disabling), Asthenia (n/a - Recovered/Resolved With Sequelae - Disabling), Balance disorder (n/a - Recovered/Resolved With Sequelae - Disabling), Cough (n/a - Recovered/Resolved With Sequelae - Disabling), Decreased appetite (n/a - Recovered/Resolved With Sequelae - Disabling), Dizziness (n/a - Recovered/Resolved With Sequelae - Disabling), Dyspnoea (n/a - Recovered/Resolved With Sequelae - Disabling), Fall (n/a - Recovered/Resolved With Sequelae - Disabling), Fatigue (n/a - Recovered/Resolved With Sequelae - Disabling), Headache (n/a - Recovered/Resolved With Sequelae - Disabling), Hypoacusis (n/a - Recovered/Resolved With Sequelae - Disabling), Hypoesthesia (n/a - Recovered/Resolved With Sequelae - Disabling), Hypothermia (n/a - Recovered/Resolved With Sequelae - Disabling), Irritability (n/a - Recovered/Resolved With Sequelae - Disabling), Listless (n/a - Recovered/Resolved With Sequelae - Disabling), Lymphadenopathy (n/a - Recovered/Resolved With Sequelae - Disabling), Malaise (n/a - Recovered/Resolved With Sequelae - Disabling), Muscular weakness (n/a - Recovered/Resolved With Sequelae - Disabling), Myalgia (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [56d - n/a - n/a])	Not reported	ICSR	

										With Sequelae - Disabling), Oedema peripheral (n/a - Recovered/Resolved With Sequelae - Disabling), Oropharyngeal pain (n/a - Recovered/Resolved With Sequelae - Disabling), Oxygen saturation decreased (n/a - Recovered/Resolved With Sequelae - Disabling), Pain in extremity (n/a - Recovered/Resolved With Sequelae - Disabling), Poor peripheral circulation (n/a - Recovered/Resolved With Sequelae - Disabling), Pulmonary pain (n/a - Recovered/Resolved With Sequelae - Disabling), Pyrexia (n/a - Recovered/Resolved With Sequelae - Disabling), Rhinitis (n/a - Recovered/Resolved With Sequelae - Disabling), Vaccination site pain (n/a - Recovered/Resolved With Sequelae - Disabling), Visual impairment (n/a - Recovered/Resolved With Sequelae - Disabling)			
EU-EC-10010399896	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Myalgia (1d - Recovered/Resolved -), Vaccination site reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010400098	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Polymenorrhoea (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-10010400101	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (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-10010400130	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Abdominal pain (n/a - Recovering/Resolving -), Dysmenorrhoea (n/a - Unknown -), Heavy menstrual bleeding (n/a - Recovering/Resolving -), Localised oedema (n/a - Recovering/Resolving -), Ovarian cyst (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010400456	22/10/2021	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-10010400849	22/10/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

			Professional	Area							Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]		
EU-EC-10010400964	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR	
EU-EC-10010401135	22/10/2021	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-10010401229	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Malaise (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010401460	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Pharyngitis (n/a - Not Recovered/Not Resolved -), Swelling of eyelid (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-10010401471	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypomenorrhoea (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-10010401472	22/10/2021	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 - [n/a - 1{DF} - n/a]	Not reported	ICSR	
EU-EC-10010401490	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]	Not reported	ICSR	
EU-EC-10010401577	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asymptomatic 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 - [1d - n/a - n/a]	Not reported	ICSR	
EU-EC-10010401578	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Conjunctival haemorrhage (n/a - Unknown - Other Medically Important Condition), Conjunctivitis (n/a - Unknown -), Dizziness (n/a - Recovering/Resolving -), Fall (n/a - Unknown -), Fatigue (n/a - Unknown -), Feeling of body	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[CLONAZEPAM] (C - Anxiety, Autism spectrum disorder - n/a - [n/a - .5mg - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Anxiety, Autism spectrum disorder - n/a - [n/a - 40mg - n/a]), [LORAZEPAM] (C - n/a - n/a - [n/a - n/a - Oral]), [QUETIAPINE, QUETIAPINE	ICSR	

										temperature change (n/a - Unknown -), Gait disturbance (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Headache (n/a - Recovering/Resolving -), Hyperhidrosis (n/a - Unknown -), Muscular weakness (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved -), Pallor (n/a - Unknown -), Presyncope (n/a - Unknown -), Pyrexia (n/a - Recovered/Resolved -), Stress (n/a - Unknown -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Vertigo (n/a - Unknown -), Vision blurred (n/a - Unknown -), Vomiting (n/a - Recovered/Resolved -)	FUMARATE] (C - Insomnia - n/a - [n/a - 75mg - n/a])		
EU-EC-10010401635	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Collagen disorder (n/a - Unknown - Other Medically Important Condition), Platelet count decreased (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), White blood cell count decreased (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-10010401637	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[NAPROXEN, NAPROXEN SODIUM] (C - Heavy menstrual bleeding - n/a - [1d - n/a - n/a]), [TRANEXAMIC ACID] (C - Heavy menstrual bleeding - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10010401934	22/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010401943	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (9d - Recovered/Resolved -), Vaccination failure (9d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010402176	22/10/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (6d -	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

				Area						Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (6d - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COVID-19 - n/a - [n/a - n/a - n/a]		
EU-EC-10010402340	22/10/2021	Spontaneous	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-10010402356	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovering/Resolving -), Malaise (11d - Recovered/Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	MENQUADFI SOLUTION FOR INJECTION [TETANUS TOXOID, N. MENINGITIDIS GROUP C (STRAIN C11) POLYSACCHARIDE (DE-O-ACETYLATED) CONJUGATED TO TETANUS TOXOID, NEISSERIA MENINGITIDIS GROUP A POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN, NEISSERIA MENINGITIDIS GROUP W-135 POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN, NEISSERIA MENINGITIDIS GROUP Y POLYSACCHARIDE CONJUGATED TO TETANUS TOXOID CARRIER PROTEIN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010402733	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Seizure (0d - Recovered/Resolved - Other Medically Important Condition), Seizure (20min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010403020	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Condition aggravated (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Head titubation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tremor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010403049	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	Yes	Blindness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR

										Pyrexia (48h - Recovered/Resolved -)	1{DF} - Intramuscular])		
EU-EC-10010403095	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010403099	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site erythema (1d - Recovered/Resolved - Other Medically Important Condition), Lip oedema (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010403235	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010403264	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Migraine (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010403331	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010403427	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010403445	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site urticaria (2wk - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010403449	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010403523	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010403534	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010403535	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010403734	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010403803	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010403809	22/10/2021	Spontaneous	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 - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010403861	22/10/2021	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	Not reported	ICSR

										Injection site pain (2d - Recovered/Resolved -), Rash (n/a - Not Recovered/Not Resolved -)	applicable - [1d - 1{DF} - Intramuscular])		
EU-EC-10010403943	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010403950	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (8d - Recovered/Resolved -), Pain in extremity (8d - Recovered/Resolved -), Swelling (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010403954	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010404106	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Body temperature decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Chills (n/a - Recovered/Resolved - Other Medically Important Condition), Confusional state (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Life Threatening), Fear (n/a - Recovered/Resolved - Other Medically Important Condition), Hyperventilation (n/a - Recovered/Resolved - Other Medically Important Condition), Musculoskeletal stiffness (n/a - Recovered/Resolved - Other Medically Important Condition), Panic attack (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010404511	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epididymitis (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-10010404758	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Dysgeusia (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Recovered/Not Resolved -), Injection site warmth (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Parosmia (n/a - Not Recovered/Not Resolved -)			
EU-EC-10010405069	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010405500	22/10/2021	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-10010405660	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site discomfort (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010405820	22/10/2021	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-10010406135	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -), Vaccination site swelling (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ALGELDRATE, PHEUM PRATENSE POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, ARRHENATHERUM ELATIUS POLLEN, HOLCUS LANATUS POLLEN, ANTHOXANTHUM ODORATUM POLLEN, AGROSTIS STOLONIFERA POLLEN, DACTYLIS GLOMERATA POLLEN, FESTUCA RUBRA POLLEN, ALNUS GLUTINOSA POLLEN, BETULA VERRUCOSA POLLEN, CORYLUS AVELLANA POLLEN, BETULA VERRUCOSA POLLEN, DERMATOPHAGOIDES FARINAE, DERMATOPHAGOIDES PTERONYSSINUS, PHEUM PRATENSE POLLEN, POA	ICSR

PRATENSIS POLLEN,
LOLIUM PERENNE
POLLEN, SECALE
CEREALE POLLEN,
ALNUS GLUTINOSA
POLLEN,
ARRHENATHERUM
ELATIUS POLLEN,
HOLCUS LANATUS
POLLEN,
ANTHOXANTHUM
ODORATUM POLLEN,
AGROSTIS
STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA
POLLEN, BETULA
VERRUCOSA POLLEN,
CORYLUS AVELLANA
POLLEN, PHEUM
PRATENSE POLLEN,
POA PRATENSIS
POLLEN, LOLIUM
PERENNE POLLEN,
SECALE CEREALE
POLLEN,
ARRHENATHERUM
ELATIUS POLLEN,
HOLCUS LANATUS
POLLEN,
ANTHOXANTHUM
ODORATUM POLLEN,
AGROSTIS
STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA
POLLEN, PHEUM
PRATENSE POLLEN,
POA PRATENSIS
POLLEN, LOLIUM
PERENNE POLLEN,
SECALE CEREALE
POLLEN,
ARRHENATHERUM
ELATIUS POLLEN,
HOLCUS LANATUS
POLLEN,
ANTHOXANTHUM
ODORATUM POLLEN,
AGROSTIS
STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA
POLLEN, BETULA
VERRUCOSA POLLEN,
PHEUM PRATENSE
POLLEN, POA
PRATENSIS POLLEN,
LOLIUM PERENNE
POLLEN, SECALE
CEREALE POLLEN,
ARRHENATHERUM
ELATIUS POLLEN,
HOLCUS LANATUS
POLLEN, TRITICUM
AESTIVUM POLLEN,
ANTHOXANTHUM
ODORATUM POLLEN,
AGROSTIS
STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA
POLLEN, TRITICUM
AESTIVUM, PHEUM
PRATENSE POLLEN,
POA PRATENSIS
POLLEN, LOLIUM
PERENNE POLLEN,
SECALE CEREALE
POLLEN,
ARRHENATHERUM
ELATIUS POLLEN,
HOLCUS LANATUS
POLLEN,
ANTHOXANTHUM
ODORATUM POLLEN,
AGROSTIS
STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA
POLLEN] (C - n/a - n/a
- [1d - n/a - n/a - More
in ICSR]),
[ALGELDRATE,
PHEUM PRATENSE
POLLEN, POA
PRATENSIS POLLEN,
LOLIUM PERENNE
POLLEN, SECALE
CEREALE POLLEN,
ARRHENATHERUM
ELATIUS POLLEN,
HOLCUS LANATUS
POLLEN,
ANTHOXANTHUM
ODORATUM POLLEN,
AGROSTIS

STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA
POLLEN, ALNUS
GLUTINOSA POLLEN,
BETULA VERRUCOSA
POLLEN, CORYLUS
AVELLANA POLLEN,
BETULA VERRUCOSA
POLLEN,
DERMATOPHAGOIDES
FARINAE,
DERMATOPHAGOIDES
PTERONYSSINUS,
PHLEUM PRATENSE
POLLEN, POA
PRATENSIS POLLEN,
LOLIUM PERENNE
POLLEN, SECALE
CEREALE POLLEN,
ALNUS GLUTINOSA
POLLEN,
ARRHENATHERUM
ELATIUS POLLEN,
HOLCUS LANATUS
POLLEN,
ANTHOXANTHUM
ODORATUM POLLEN,
AGROSTIS
STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA
POLLEN, BETULA
VERRUCOSA POLLEN,
CORYLUS AVELLANA
POLLEN, PHLEUM
PRATENSE POLLEN,
POA PRATENSIS
POLLEN, LOLIUM
PERENNE POLLEN,
SECALE CEREALE
POLLEN,
ARRHENATHERUM
ELATIUS POLLEN,
HOLCUS LANATUS
POLLEN,
ANTHOXANTHUM
ODORATUM POLLEN,
AGROSTIS
STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA
POLLEN, PHLEUM
PRATENSE POLLEN,
POA PRATENSIS
POLLEN, LOLIUM
PERENNE POLLEN,
SECALE CEREALE
POLLEN,
ARRHENATHERUM
ELATIUS POLLEN,
HOLCUS LANATUS
POLLEN,
ANTHOXANTHUM
ODORATUM POLLEN,
AGROSTIS
STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA
POLLEN, BETULA
VERRUCOSA POLLEN,
PHLEUM PRATENSE
POLLEN, POA
PRATENSIS POLLEN,
LOLIUM PERENNE
POLLEN, SECALE
CEREALE POLLEN,
ARRHENATHERUM
ELATIUS POLLEN,
HOLCUS LANATUS
POLLEN, TRITICUM
AESTIVUM POLLEN,
ANTHOXANTHUM
ODORATUM POLLEN,
AGROSTIS
STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA
POLLEN, TRITICUM
AESTIVUM, PHLEUM
PRATENSE POLLEN,
POA PRATENSIS
POLLEN, LOLIUM
PERENNE POLLEN,
SECALE CEREALE
POLLEN,
ARRHENATHERUM
ELATIUS POLLEN,
HOLCUS LANATUS
POLLEN,
ANTHOXANTHUM
ODORATUM POLLEN,
AGROSTIS
STOLONIFERA
POLLEN, DACTYLIS
GLOMERATA POLLEN,
FESTUCA RUBRA
POLLEN]

(C - n/a - n/a

												- [1d - n/a - n/a]), [DESLORATADINE] (C - n/a - n/a - [n/a - n/a - n/a]), [MONTELUKAST, MONTELUKAST SODIUM] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10010406143	22/10/2021	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-10010406388	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nausea (0d - Recovered/Resolved - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010406380	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ISOTRETINOIN] (C - Acne - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010406381	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (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-10010406510	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010406523	22/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypotonia (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tachycardia (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010406566	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myalgia (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a])	Not reported	ICSR
EU-EC-10010406634	22/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Aphthous ulcer (6d - Recovered/Resolved - Other Medically Important Condition), Genital lesion (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-10010406855	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperthermia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010407002	22/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ACICLOVIR, ACICLOVIR SODIUM] (C - Antiemetic supportive care - n/a - [n/a - n/a - n/a]),	ICSR

										Condition), Confusional state (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoaesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)		[ANTI-D IMMUNOGLOBULIN] (C - Antiemetic supportive care - n/a - [n/a - n/a - n/a])	
EU-EC-10010407306	22/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain in jaw (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010382447	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (15d - Recovered/Resolved - Other Medically Important Condition), Hyperpyrexia (15d - Recovered/Resolved - Other Medically Important Condition), Pruritus (15d - Recovered/Resolved - Other Medically Important Condition), Rash (15d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010382588	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovered/Resolved -), Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010382948	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyshidrotic eczema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010383058	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Aphthous ulcer (7d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

											Headache (3d - Recovered/Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - n/a]		
EU-EC-10010383555	21/10/2021	Spontaneous	Healthcare Professional	Non 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)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010383566	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tremor (3h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	ENBREL [ETANERCEPT] (C - Psoriasis - n/a - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - Oral])	ICSR	
EU-EC-10010383610	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010383612	21/10/2021	Spontaneous	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), Malaise (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-10010383620	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown - Other Medically Important Condition), Nasopharyngitis (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010383866	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness exertional (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown -), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[DOCONEXENT, ICOSAPENT, FISH OIL, ICOSAPENT ETHYL, DOCOSAHEXAENOIC ACID ETHYL ESTER, OMEGA-3-ACID ETHYL ESTERS 90, OMEGA-3-ACID ETHYL ESTERS 90, DOCOSAHEXAENOIC ACID ETHYL ESTER] (C - n/a - n/a -), [VITAMINS NOS] (C - n/a - n/a -)	ICSR	
EU-EC-10010384378	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved - Other Medically Important Condition), Fatigue (3d - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	

										Important Condition), Pain (3d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10010384397	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dehydration (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hypophagia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (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 - n/a])	Not reported	ICSR
EU-EC-10010384403	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Intentional overdose (n/a - Unknown -), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [DIAZEPAM] (S - n/a - Unknown - [n/a - n/a - n/a]), [LORAZEPAM] (S - n/a - Unknown - [n/a - n/a - n/a]), [VENLAFAXINE HYDROCHLORIDE] (S - n/a - Unknown - [n/a - 20g - n/a]), [ZOPICLONE] (S - n/a - Unknown - [n/a - 60mg - n/a])	Not reported	ICSR
EU-EC-10010384431	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ageusia (n/a - Not Recovered/Not Resolved -), Anosmia (n/a - Not Recovered/Not Resolved -), Dysgeusia (n/a - Not Recovered/Not Resolved -), Weight decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010385143	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (46d - Recovering/Resolving - Life Threatening), Fatigue (46d - Recovering/Resolving - Life Threatening), Headache (46d - Recovering/Resolving - Life Threatening), Malaise (46d - Recovering/Resolving - Life Threatening), Myalgia (46d - Recovering/Resolving - Life Threatening), Nausea (46d - Recovering/Resolving - Life Threatening), Pericarditis (46d - Recovering/Resolving - Life Threatening, Other Medically Important Condition), Pyrexia (46d - Recovering/Resolving - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	21/10/2021	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Female	No	Granuloma annulare	COMIRNATY	Not reported	ICSR

10010385289			Professional	Economic Area		Years				(n/a - Unknown -)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC-10010385416	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (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-10010385428	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypomenorrhoea (n/a - Not Recovered/Not Resolved -), Menstruation delayed (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010385688	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (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-10010385713	21/10/2021	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010385727	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010385728	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown - Other Medically Important Condition), Nausea (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)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010385765	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Behaviour disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Personality change (n/a - Unknown - Caused/Prolonged Hospitalisation), Psychotic disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010385807	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dysstasia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Neuropathy peripheral (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10010385871	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Loss of consciousness (1d - Recovered/Resolved - Other Medically Important Condition), Tinnitus (n/a - Unknown -), Visual impairment (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010385878	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain in extremity (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010385885	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Altered state of consciousness (30h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyskinesia (30h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Feeling abnormal (30h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myoclonus (30h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Presyncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Somnolence (30h - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010385919	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010386187	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (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-10010386514	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Recovering/Resolving -), Asthenia (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR

										Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Pain (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)			
EU-EC-10010386698	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paresis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Meningitis (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-10010387210	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010387997	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site haematoma (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010388159	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010388201	21/10/2021	Spontaneous	Non 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 - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[THIAMINE HYDROCHLORIDE, RETINOL] (C - n/a - n/a -)	ICSR
EU-EC-10010389040	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

EU-EC-10010389061	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (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-10010389068	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition), Cold sweat (n/a - Recovered/Resolved -), Dizziness (1d - Recovered/Resolved -), Feeling hot (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Pallor (1d - Recovered/Resolved -), Pruritus (n/a - Recovered/Resolved -), Urticaria (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010389077	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010389122	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature abnormal (2d - Recovered/Resolved - Other Medically Important Condition), Chest pain (2d - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Illness (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Somnolence (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010389137	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disease recurrence (n/a - Recovering/Resolving - Other Medically Important Condition), Epilepsy (n/a - Recovering/Resolving - Other Medically Important Condition), Eye disorder (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

											Feeling abnormal (n/a - Recovering/Resolving -), Hypoaesthesia (n/a - Recovering/Resolving -), Vision blurred (n/a - Recovering/Resolving -)			
EU-EC-10010389256	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bradycardia (n/a - Recovering/Resolving - Other Medically Important Condition), Fall (n/a - Recovering/Resolving -), Presyncope (n/a - Recovering/Resolving -), Seizure (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-10010389350	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Conjunctival hyperaemia (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Feeling abnormal (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 - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010389351	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Herpes ophthalmic (n/a - Unknown - Other Medically Important Condition), Herpes virus infection (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -), Pruritus (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010389372	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal distension (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR	
EU-EC-10010389416	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Mobility decreased (1d - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR	

										Paralysis (0d - Recovered/Resolved - Other Medically Important Condition)	applicable - [1d - n/a - n/a]		
EU-EC-10010389440	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Petechiae (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010389444	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Petechiae (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular - More in ICSR])	Not reported	ICSR
EU-EC-10010389452	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Petechiae (7d - Recovered/Resolved -), Vaccination site pain (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010389713	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Feeling of body temperature change (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Injection site warmth (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010389724	21/10/2021	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-10010389726	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (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-10010389782	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Polymenorrhoea (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-10010389843	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Photophobia (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-10010389851	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bell's palsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010389964	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

										- Caused/Prolonged Hospitalisation)	n/a - n/a - [n/a - n/a - n/a]		
EU-EC-10010390130	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Pyrexia (n/a - Unknown -), Rhinorrhoea (n/a - Unknown -), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR
EU-EC-10010390189	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash macular (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-10010390421	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness postural (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-10010390539	21/10/2021	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 - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010390613	21/10/2021	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-10010390619	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (1wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010390736	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Alopecia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010390869	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Breast pain (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Palpitations (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010390900	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (6d - Not Recovered/Not Resolved -), Influenza (6d - Not Recovered/Not Resolved -), Influenza like illness (6d - Not Recovered/Not Resolved -), Nausea (6d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010390921	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition), Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Cold sweat (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Feeling abnormal (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved - Other Medically Important Condition), Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition), Throat irritation (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10010390923	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - Disabling), Dizziness (n/a - Not Recovered/Not Resolved - Disabling), Headache (n/a - Not Recovered/Not Resolved - Disabling), Nausea (n/a - Recovering/Resolving - Disabling), Pyrexia (n/a - Not Recovered/Not Resolved - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010390928	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Feeding disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gamma-glutamyltransferase decreased (n/a - Unknown -), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition), Tongue disorder (15d - 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-10010390931	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Hypersomnia (n/a - Unknown -), Hypoesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (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-10010391094	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Musculoskeletal chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin increased (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

										Resolved - Other Medically Important Condition)			
EU-EC-10010391161	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pulmonary embolism (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]), [ETHINYLESTRADIOL, LEVONORGESTREL] (S - Contraception - Drug withdrawn - [n/a - 21{DF} - Oral])	Not reported	ICSR
EU-EC-10010391262	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010391273	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010391279	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010391284	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved -), Vertigo (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010391291	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010391372	21/10/2021	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-10010391384	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010391399	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	[CODEINE HYDROCHLORIDE, PARACETAMOL, ACETYLSALICYLIC ACID, CODEINE HYDROCHLORIDE, PARACETAMOL, ACETYLSALICYLIC ACID, PARACETAMOL DC 96 %] (C - n/a - n/a - [n/a - n/a - n/a]), [ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010391401	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dermatitis bullous (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]), [PARACETAMOL] (S - Antipyresis - Drug withdrawn - [2d - n/a - Oral])	Not reported	ICSR
EU-EC-10010391414	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010391439	21/10/2021	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	Not reported	ICSR

											immunisation - Not applicable - [1d - .3mL - Intramuscular])		
EU-EC-10010391446	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010391447	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (1d - Recovered/Resolved -), Influenza like illness (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010391449	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010391592	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010391593	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pruritus (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-10010391605	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Liver disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[GINGER, HANGKOBOKUTO] (C - n/a - n/a - [n/a - n/a - n/a]), [MAGNOLIA BARK] (C - n/a - n/a - [n/a - n/a - n/a]), [PERILLA FRUTESCENS VAR. CRISPA] (C - n/a - n/a - [n/a - n/a - n/a]), [PINELLIA TERNATA] (C - n/a - n/a - [n/a - n/a - n/a]), [PORIAE COCOS SCLEROTIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [ZINGIBER OFFICINALE RHIZOME] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010391676	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010391683	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (8h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010391684	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010391729	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (49d - Recovered/Resolved -), Dizziness (1mo - Recovered/Resolved -), Dysmenorrhoea (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR

											Headache (1mo - Recovered/Resolved -)			
EU-EC-10010391737	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Immunisation reaction (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010391774	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovering/Resolving -), Influenza like illness (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010391804	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (1h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010391865	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010391968	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010392352	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic shock (n/a - Recovered/Resolved - Other Medically Important Condition), Blood pressure decreased (n/a - Recovered/Resolved -), Bradycardia (n/a - Unknown - Other Medically Important Condition), Cold sweat (n/a - Recovered/Resolved -), Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Dry skin (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Feeling abnormal (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR	

										Heart rate decreased (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Pallor (n/a - Recovered/Resolved -)			
EU-EC-10010392716	21/10/2021	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 - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010392884	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovering/Resolving -), Troponin increased (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010392914	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site inflammation (4d - Recovered/Resolved -), Injection site pain (4d - Recovered/Resolved -), Injection site swelling (4d - Recovered/Resolved -), Menstruation delayed (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010392914	21/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (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-10010393319	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Recovered/Resolved - Other Medically Important Condition), Cough (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-10010393348	21/10/2021	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-10010393813	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Diarrhoea (2d - Recovered/Resolved -), Fatigue (4d - Recovered/Resolved -), Hyperpyrexia (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovered/Resolved -), Malaise (n/a - Recovering/Resolving -), Oropharyngeal pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010393872	21/10/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Asthma (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR

			Professional	Area						-), Cough (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -)	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]		
EU-EC-10010394077	21/10/2021	Spontaneous	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 - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10010394316	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010394336	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash maculo-papular (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-10010394402	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10010394405	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010394502	21/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angioedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash (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-10010394556	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Decreased appetite (2d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010394672	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010394857	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Presyncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (0d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10010394892	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Foster CE, Penella ADV, Davis AL, Arrington AS, Campbell J, Palazzi DL. Varicella-Zoster virus reactivation following SARS-CoV-2 immunization in two patients with leukemia. <i>Pediatr Blood-Cancer</i> 2021;68(10):e29191.	12-17 Years	Adolescent	Female	No	Herpes zoster disseminated (n/a - Unknown - Caused/Prolonged Hospitalisation), Infection reactivation (n/a - Unknown - Caused/Prolonged Hospitalisation), Varicella zoster virus infection (n/a - Unknown - Caused/Prolonged Hospitalisation)	MERCAPTOPYRINE [MERCAPTOPYRINE] (S - Acute lymphocytic leukaemia - Unknown - [n/a - n/a - Unknown]), METHOTREXATE [METHOTREXATE] (S - Acute lymphocytic leukaemia - Unknown - [n/a - n/a - Unknown]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10010395458	21/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010395498	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Injection site erythema (n/a - Recovering/Resolving -), Injection site inflammation (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Injection site pruritus (n/a - Recovering/Resolving -), Injection site swelling (n/a - Recovering/Resolving -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010395683	21/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010368961	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site warmth (1h - Recovered/Resolved -), Presyncope (1h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010369147	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010369165	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain in extremity (1d - Recovered/Resolved - Other Medically Important Condition), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10010369193	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	SARS-CoV-2 test positive (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

											Recovering/Resolving -)	immunisation - Not applicable - [n/a - .3mL - Intramuscular])		
EU-EC-10010369322	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No		Abdominal pain (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10010369375	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Asthenia (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10010369421	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Arthralgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hench-Schonlein purpura (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010369651	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Headache (n/a - Recovering/Resolving -), Insomnia (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010369734	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010369736	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No		Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TERBUTALINE SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010369893	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		Feeling abnormal (n/a - Recovered/Resolved -), Heart rate decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010369955	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Sinus arrhythmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10010370176	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010370302	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (6min - Recovered/Resolved - Other Medically Important Condition), Anaemia (n/a - Recovered/Resolved - Other Medically Important Condition), Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition), Cold sweat (n/a - Recovered/Resolved - Other Medically Important Condition), Heart rate decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (44min - Recovered/Resolved - Other Medically Important Condition), Peripheral coldness (n/a - Recovered/Resolved - Other Medically Important Condition), Peripheral pulse decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Tetany (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-10010370345	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaemia (n/a - Recovering/Resolving -), Bradycardia (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling abnormal (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010370399	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (n/a - Unknown - Other Medically Important Condition), Dermatitis bullous (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Important Condition), Skin exfoliation (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10010371428	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (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-10010371558	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Axillary mass (n/a - Recovering/Resolving - Other Medically Important Condition), Axillary pain (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010371561	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Axillary pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010371598	20/10/2021	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-10010371692	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Atrial septal defect (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Transient ischaemic attack (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010371729	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Lymphadenopathy (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010371879	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling hot (6d - Recovered/Resolved - Other Medically Important Condition), Increased upper airway secretion (6d - Recovered/Resolved - Other Medically Important Condition), Lethargy (6d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (6d - Recovered/Resolved - Other Medically Important Condition), Suspected COVID-19 (6d - Recovered/Resolved - Other Medically Important Condition), Vaccine breakthrough infection (6d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010371881	20/10/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S -)	Not reported	ICSR

				Area								COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]		
EU-EC-10010372276	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (1d - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010372309	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown -), Nausea (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010372366	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Ear discomfort (n/a - Unknown -), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010372382	20/10/2021	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), Costochondritis (n/a - Unknown - Other Medically Important Condition), Hyperaesthesia (n/a - Unknown - Other Medically Important Condition), Inflammation (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-10010372445	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Throat tightness (n/a - Unknown - Disabling, Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010372471	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Liver function test increased (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010372479	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (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-10010372489	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaemia (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	

										Condition), Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	applicable - [n/a - n/a - n/a]		
EU-EC-10010372491	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010372494	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye pain (n/a - Unknown - Disabling, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Metamorphopsia (n/a - Unknown - Disabling, Other Medically Important Condition), Photophobia (n/a - Unknown - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010372505	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving -), Skin reaction (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010372788	20/10/2021	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-10010372893	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Muscular weakness (n/a - Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10010372906	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Polymenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaginal haemorrhage (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-10010372950	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Axillary pain (n/a - Unknown - Other Medically Important Condition), Headache (1d - Recovered/Resolved - Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site erythema (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination site swelling (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010372959	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	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 - Intramuscular])	Not reported	ICSR
EU-EC-10010373440	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (3d - Not Recovered/Not Resolved -), Malaise (3d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010374356	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - Disabling), Migraine (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010375027	20/10/2021	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-10010375594	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (6d - Recovering/Resolving -), Headache (6d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Recovering/Resolving -), Nausea (6d - Recovering/Resolving -)			
EU-EC-10010376008	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Shock (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010376012	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -), Headache (n/a - Unknown -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010376039	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - 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)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010376117	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericardial effusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010376118	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Brain herniation (n/a - Unknown - Other Medically Important Condition), Brain oedema (n/a - Unknown - Other Medically Important Condition), Circulatory collapse (n/a - Fatal - Results in Death, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

											Gastric disorder (n/a - Unknown -), Gastric ulcer (n/a - Unknown - Other Medically Important Condition), Gastritis erosive (n/a - Unknown - Other Medically Important Condition), Myocardial bridging (n/a - Unknown - Other Medically Important Condition), Myocardial infarction (n/a - Fatal - Results in Death, Other Medically Important Condition), Pulmonary congestion (n/a - Unknown - Other Medically Important Condition), Pulmonary oedema (n/a - Unknown - Other Medically Important Condition), Respiratory failure (n/a - Fatal - Results in Death, Other Medically Important Condition)			
EU-EC-10010376134	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urticaria (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-10010376188	20/10/2021	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-10010376855	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved -), Fall (n/a - Recovered/Resolved -), Heart rate decreased (n/a - Recovered/Resolved -), Loose tooth (n/a - Recovered/Resolved -), Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Presyncope (n/a - Recovered/Resolved -), Tooth socket haemorrhage (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010376887	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bell's palsy (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-10010376916	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Eating disorder (9d - Recovered/Resolved -), Fatigue (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR	

										Gastroesophageal reflux disease (n/a - Unknown -), Headache (n/a - Unknown -), Pain in extremity (16h - Recovered/Resolved -), Productive cough (n/a - Unknown -), Rhinitis allergic (n/a - Unknown -), Somnolence (n/a - Unknown -), Wheezing (n/a - Unknown -)			
EU-EC-10010376925	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cyanosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia aspiration (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010376939	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Recovering/Resolving - Other Medically Important Condition), Pain (n/a - Unknown -), Pallor (n/a - Unknown -), Vision blurred (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010377122	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysphonia (n/a - Not Recovered/Not Resolved -), Nasal congestion (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Respiratory symptom (n/a - Not Recovered/Not Resolved -), Rhinitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010377541	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blindness (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Hypoesthesia oral (n/a - Unknown - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Important Condition), Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vision blurred (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10010377608	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angina pectoris (n/a - Recovering/Resolving -), Aspartate aminotransferase increased (n/a - Recovering/Resolving -), Blood creatine phosphokinase increased (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Peripheral vascular disorder (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010377642	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angina pectoris (n/a - Recovering/Resolving -), Aspartate aminotransferase increased (n/a - Recovering/Resolving -), Blood creatine phosphokinase increased (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Peripheral vascular disorder (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010377766	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Arthralgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Back pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Fall (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) [BUDESONIDE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]), [NAPROXEN, NAPROXEN SODIUM] (C - Pain - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)])		ICSR

											Gait disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Muscle tightness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Musculoskeletal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10010378316	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010378346	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Inappropriate schedule of product administration (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR	
EU-EC-10010378366	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fall (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR	
EU-EC-10010378432	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Haemorrhagic ovarian cyst (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010378561	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (n/a - Recovered/Resolved -), Influenza like illness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010378578	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010378605	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (4d - Recovered/Resolved -), Papule (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	

										Rash macular (n/a - Recovered/Resolved -)			
EU-EC-10010378700	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010378709	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Eye pruritus (24h - Recovering/Resolving -), Eyelid oedema (24h - Recovering/Resolving -), Ocular hyperaemia (24h - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010378782	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fall (n/a - Recovered/Resolved -), Hypotension (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010378854	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010378879	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [42d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010378888	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010378912	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010378913	20/10/2021	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 - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010378931	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash vesicular (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010378932	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (2wk - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010378960	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Paraesthesia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010378978	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Recovering/Resolving -), Seizure (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010378996	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Influenza like illness (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010378997	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Influenza like illness (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010379086	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hyperhidrosis (1d - Recovered/Resolved -), Vision blurred (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR

EU-EC-10010379088	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010379145	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Acquired phimosis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010379146	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010379147	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [ETHINYLESTRADIOL, LEVONORGESTREL] (S - n/a - Drug withdrawn - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010379156	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010379184	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (2d - Recovered/Resolved -), Chills (2d - Recovered/Resolved -), Fatigue (5d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010379249	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intraventricular haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Subarachnoid haemorrhage (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010379253	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest discomfort (n/a - Unknown -), Dyspnoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010379302	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Loss of personal independence in daily activities (4d - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	20/10/2021	Spontaneous	Healthcare	Non	Not available	12-17	Not	Female	No	Syncope (n/a -)	TOZINAMERAN	Not reported	ICSR

10010379338			Professional	European Economic Area		Years	Specified			Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC-10010379345	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (1d - Recovered/Resolved -), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Immunisation (n/a - Unknown -), Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Off label use (n/a - Unknown -), Respiration abnormal (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010379353	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (0d - Recovered/Resolved - Other Medically Important Condition), Dizziness (0d - Recovered/Resolved - Other Medically Important Condition), Hypoaesthesia (0d - Recovered/Resolved - Other Medically Important Condition), Nausea (0d - Recovered/Resolved - Other Medically Important Condition), Pallor (0d - Recovered/Resolved - Other Medically Important Condition), Presyncope (0d - Recovered/Resolved - Other Medically Important Condition), Vomiting (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010380176	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	C-reactive protein increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Erythema multiforme (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Urine ketone body	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

											present (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10010380189	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Allergy to vaccine (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Anaphylactic reaction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Erythema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ocular hyperaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Photophobia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Visual impairment (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010380210	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site swelling (n/a - Recovered/Resolved -), Polymenorrhoea (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-10010380230	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual discomfort (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-10010380474	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR	
EU-EC-10010381144	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010381477	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR	
EU-EC-	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea	COMIRNATY	Not reported	ICSR	

10010381569			Professional	Economic Area		Years				(37d - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])		
EU-EC-10010381645	20/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (34d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010381773	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tachycardia (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-10010381797	20/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -), Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010381831	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Altered state of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010381898	20/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic shock (n/a - Unknown - Other Medically Important Condition), Asphyxia (n/a - Unknown - Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Dyslalia (n/a - Unknown -), Dysstasia (n/a - Unknown -), Fall (n/a - Unknown -), Nausea (n/a - Unknown -), Rash macular (n/a - Unknown -), Vaccination site pruritus (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010382190	20/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

											applicable - [n/a - 1{DF} - n/a])		
EU-EC-10010355490	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010356560	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010356646	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (1d - Recovered/Resolved -), Chills (1d - Recovered/Resolved -), Dyspnoea (1d - Recovered/Resolved -), Erythema (2d - Recovered/Resolved -), Eye swelling (3d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (2d - Recovered/Resolved -), Influenza like illness (2d - Recovered/Resolved -), Lip swelling (3d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Nausea (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-10010356652	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovering/Resolving -), Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Musculoskeletal chest pain (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (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-	19/10/2021	Spontaneous	Non	European	Not available	12-17	Not	Male	No	Pyrexia (n/a -	COMIRNATY	Not reported	ICSR

10010356896			Healthcare Professional	Economic Area		Years	Specified			Recovering/Resolving -), Tremor (n/a - Recovering/Resolving -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC-10010356904	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Phlebitis superficial (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010357002	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Tinnitus (22d - Recovered/Resolved -), Vertigo (22d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010357027	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site pain (n/a - Not Recovered/Not Resolved -), Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010357143	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010357216	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010357219	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010357404	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Migraine (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010357427	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010357430	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010357433	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010357596	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menometrorrhagia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [LYNESTRENOL] (S - n/a - Drug withdrawn - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010357773	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epilepsy (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown]), [SODIUM VALPROATE, VALPROIC ACID] (S - Epilepsy - Unknown -)	Not reported	ICSR

EU-EC-10010358277	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition aggravated (n/a - Not Recovered/Not Resolved - Disabling), Infectious mononucleosis (n/a - Not Recovered/Not Resolved - Disabling)	[n/a - n/a - Unknown]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010358282	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash erythematous (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [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-10010358434	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Unknown - Caused/Prolonged Hospitalisation), Altered state of consciousness (42h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (42h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Clonic convulsion (42h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Depressed level of consciousness (42h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (n/a - Unknown - Caused/Prolonged Hospitalisation), Encephalopathy (402h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (42h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010358500	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Interchange of vaccine products (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown - More in ICSR]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10010358950	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (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-10010358995	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bell's palsy (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

										Medically Important Condition)	applicable - [n/a - n/a - n/a]		
EU-EC-10010358997	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Lethargy (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010359028	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	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-10010359401	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Heart rate increased (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Syncope (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-10010359814	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (5s - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC-10010359872	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (n/a - Recovered/Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010359939	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (3d - Recovered/Resolved -), Headache (12h - Recovered/Resolved -), Pain in extremity (2d - Recovered/Resolved -), Pain in extremity (3d - Recovered/Resolved -), Puncture site oedema (2d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010359980	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Axillary pain (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (1min - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [21d - .3mL - Intramuscular])	Not reported	ICSR

EU-EC-10010360127	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010360356	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pulmonary oedema (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010360607	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blister (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain of skin (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Skin discolouration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Skin exfoliation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Skin lesion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Skin reaction (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-10010360695	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Puncture site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010360936	19/10/2021	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-10010361003	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vomiting (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-10010361110	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010361150	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved -), Swelling of eyelid (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010361193	19/10/2021	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 - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010361436	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S -	Not reported	ICSR

											Lymph node pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	n/a - n/a - [n/a - .3mL - Intramuscular])		
EU-EC-10010361860	19/10/2021	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-10010362271	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blindness (n/a - Recovered/Resolved - Other Medically Important Condition), Chills (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Hyperhidrosis (n/a - Recovered/Resolved -), Muscular weakness (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010362275	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	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-10010362302	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Petit mal epilepsy (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-10010362304	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR	
EU-EC-10010362322	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010362325	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010362347	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	C-reactive protein increased (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR	

											Mycarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin increased (n/a - Not Recovered/Not Resolved -)	applicable - [n/a - n/a - n/a]		
EU-EC-10010362352	19/10/2021	Spontaneous	Healthcare Professional	Non 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)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010362392	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (n/a - Unknown - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urticaria (1d - Recovered/Resolved - Other Medically Important Condition), Urticaria (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-10010362393	19/10/2021	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), Tachycardia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010362405	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Analgesic drug level (n/a - Unknown - Other Medically Important Condition), Dizziness postural (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pharyngeal swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Photopsia (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [AMYL METACRESOL, 2,4 DICHLOROBENZYL ALCOHOL, LIDOCAINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 1500mg - n/a]), [BENZYDAMINE HYDROCHLORIDE, BENZYDAMINE HYDROCHLORIDE, BENZOCAINE] (C - n/a - n/a - n/a - n/a), [PARACETAMOL] (C - n/a - n/a - [n/a - 1500mg - n/a])	[AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - n/a - n/a - 500mg - n/a),	ICSR	
EU-EC-10010362428	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Mycarditis (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-10010362432	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Mycarditis (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-	19/10/2021	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	Abdominal pain (n/a)	TOZINAMERAN	[CHLORPHENAMINE	ICSR	

10010362443			Healthcare Professional	European Economic Area		Years	Specified			- Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Dehydration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved -), Ear disorder (n/a - Not Recovered/Not Resolved -), Ear pain (n/a - Not Recovered/Not Resolved -), Eating disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved -), Lethargy (n/a - Not Recovered/Not Resolved -), Ocular hyperaemia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Rash (2d - Recovered/Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	MALEATE, PSEUDOEPHEDRINE HYDROCHLORIDE, IBUPROFEN, IBUPROFEN] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])		
EU-EC-10010362449	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin I increased (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010362450	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Compartment syndrome (n/a - Unknown - Other Medically Important Condition), Haematoma (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010362741	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Chills (n/a - Recovered/Resolved -), Hallucination (n/a - Recovered/Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Lacrimation increased (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10010362976	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	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-10010362981	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (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-10010363072	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaesthesia (1d - Recovered/Resolved -), Muscular weakness (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010363218	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Injection site reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010363493	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (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-10010363509	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved - Other Medically Important Condition), Discomfort (n/a - Recovered/Resolved -), Electrocardiogram abnormal (n/a - Unknown -), Infection (n/a - Recovering/Resolving -), Malaise (n/a - Unknown -), Musculoskeletal stiffness (n/a - Recovered/Resolved -), Painful respiration (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010363523	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010363527	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	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 - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010363530	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved -), Pneumothorax (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010363536	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010363767	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010363770	19/10/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved)	COMIRNATY [TOZINAMERAN] (S - COVID-19)	Not reported	ICSR

				Economic Area						- Other Medically Important Condition)	immunisation - Not applicable - [n/a - n/a - n/a]		
EU-EC-10010363784	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Acute disseminated encephalomyelitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), CSF cell count increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), CSF immunoglobulin increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), CSF protein increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Central nervous system lesion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Magnetic resonance imaging head abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), White matter lesion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010363813	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Lymphadenopathy (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-10010364197	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010364244	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Recovered/Resolved -), Monoparesis (3d - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Resolved -), Paraesthesia (3d - Not Recovered/Not Resolved -)			
EU-EC-10010364526	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	[ETHINYLESTRADIOL, GESTODENE] (C - n/a - Unknown - [n/a - n/a])	ICSR
EU-EC-10010364671	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010364925	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	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-10010364942	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010364967	19/10/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Other Medically Important Condition), Dysgeusia (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypersomnia (n/a - Unknown - Other Medically Important Condition), Oropharyngeal pain (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010364982	19/10/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (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-10010365047	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Recovered/Resolved -), Influenza like illness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010365058	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010365069	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (2h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010365113	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Recovering/Resolving -), Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR

EU-EC-10010365177	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovering/Resolving -) Ageusia (n/a - Recovering/Resolving -), Anosmia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010365201	19/10/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovering/Resolving -), Back pain (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Immunisation reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010365207	19/10/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (21d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR

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