

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])	IF
EU-EC-10013341605	26/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Extensive swelling of vaccinated limb (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site reaction (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (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 -), Pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	I F
EU-EC-10013341880	26/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving -), Amnesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Arthralgia (n/a - Recovering/Resolving -), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving -), Hypertension (n/a - Unknown -), Loss of consciousness (0d - Recovered/Resolved -), Muscle spasms (n/a - Recovering/Resolving -), Psychogenic seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tremor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY 30 MICROGRAMS/DOSE [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	I
EU-EC-10013341984	26/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	I
EU-EC-	26/08/2022	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Male	No	Headache (5d -	COMIRNATY	Not reported	I

10013342597			Professional	Economic Area		Years				Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}] - Intramuscular use))	
EU-EC-10013342664	26/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (3d - Recovered/Resolved -), Headache (2h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF}] - Intramuscular use))	Not reported
EU-EC-10013343025	26/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Ventricular tachycardia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a] - n/a)	Not reported
EU-EC-10013343043	26/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use))	Not reported
EU-EC-10013344421	26/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Vulval ulceration (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular use))	Not reported
EU-EC-10013344592	26/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Pyrexia (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -), Vulval ulceration (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular use))	Not reported
EU-EC-10013346666	26/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Condition aggravated (n/a - Not Recovered/Not Resolved - Disabling), Headache (n/a - Not Recovered/Not Resolved -), Hypoaacusis (n/a - Not Recovered/Not Resolved -), Tinnitus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF}] - Intramuscular use))	Not reported
EU-EC-10013346686	26/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Polymenorrhoea (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF}] - Intramuscular use))	Not reported
EU-EC-10013346884	26/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF}] - Intramuscular use))	Not reported
EU-EC-10013346901	26/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF}] - Intramuscular use))	Not reported
EU-EC-10013346923	26/08/2022	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 - [21d - 1{DF}] - Intramuscular use))	Not reported
EU-EC-10013346946	26/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site erythema (8d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -)	Not reported

EU-EC-10013348077	26/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angioedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chronic spontaneous urticaria (n/a - Not Recovered/Not Resolved -)	[1d - 1{DF} - Intramuscular use) COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]), [INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013349777	26/08/2022	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 - [1d - 1{DF} - n/a])	Not reported	I
EU-EC-10013328147	25/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disease recurrence (2d - Recovered/Resolved - Other Medically Important Condition), Seizure (2d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[LAMOTRIGINE] (C - Epilepsy - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - n/a]), [SODIUM VALPROATE] (C - Epilepsy - n/a - [n/a - n/a - n/a])	I
EU-EC-10013328189	25/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epilepsy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Generalised tonic-clonic seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tonic convulsion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013328628	25/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Granuloma (n/a - Not Recovered/Not Resolved -)	COMIRNATY 30 MICROGRAMS/DOSE [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013329460	25/08/2022	Spontaneous	Non Healthcare Professional	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 - n/a])	Not reported	I
EU-EC-10013329548	25/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Unknown - Other Medically Important Condition), Disturbance in attention (n/a - Recovered/Resolved -), Loss of personal independence in daily activities (n/a - Unknown -), Pyrexia (n/a - Recovering/Resolving -), Splenomegaly (n/a - Unknown -), Stress (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013330028	25/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Administration site pain (3d - Recovered/Resolved -), Body temperature increased (1d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I

EU-EC-10013330423	25/08/2022	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 use])	Not reported	i
EU-EC-10013332074	25/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Hyperacusis (n/a - Recovering/Resolving - Other Medically Important Condition), Illness (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (1d - Recovered/Resolved - Other Medically Important Condition), Photophobia (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i
EU-EC-10013333409	25/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pallor (n/a - Unknown -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	i
EU-EC-10013333533	25/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dehydration (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Glomerulonephritis chronic (n/a - Unknown - Other Medically Important Condition), Haematuria (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypertension (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Paraesthesia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Proteinuria (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Renal disorder (n/a - Unknown -), Vomiting (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	i
EU-EC-10013334087	25/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes simplex reactivation (25d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	i
EU-EC-10013334091	25/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tinnitus (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	i
EU-EC-10013337485	25/08/2022	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S -	Not reported	i

				Area										
												Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]	
EU-EC-10013337506	25/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	I	
EU-EC-10013316250	24/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Eldokla, A.. Postural orthostatic tachycardia syndrome after mRNA COVID-19 vaccine. Clinical autonomic research, 2022;1-5, doi:10.1007/s10286-022-00880-3 Eldokla, A.. Postural orthostatic tachycardia syndrome after mRNA COVID-19 vaccine. Clinical autonomic research, 2022;32(4):307- 311, doi:10.1007/s10286-022-00880-3	12-17 Years	Not Specified	Female	No	Postural orthostatic tachycardia syndrome (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	I	
EU-EC-10013316620	24/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Gokay, S.. Urticaria as a rare side effect of polyethylene Glycol-3350 in a child: case report, Acta Clin Croat, 2018;57:187-189, doi:10.20471/acc,2018,57,01.26	12-17 Years	Not Specified	Not Specified	No	Urticaria (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	I	
EU-EC-10013316979	24/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Administration site erythema (1d - Recovered/Resolved -), Administration site oedema (2d - Recovered/Resolved -), Administration site pain (4d - Recovered/Resolved -), Diarrhoea (0d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Lymphadenitis (n/a - Recovered/Resolved -), Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I	
EU-EC-10013317049	24/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Recovered/Resolved -), Syncope (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	I	
EU-EC-10013317113	24/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Unknown -), Rash macular (n/a - Unknown -), Vaccination site oedema (n/a - Unknown -), Vaccination site pain (n/a - Unknown -), Vaccination site reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported	I	
EU-EC-10013317949	24/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition), Migraine (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I	

										Important Condition), Pain in extremity (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Somnolence (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10013318218	24/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013318274	24/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	No adverse event (2d - Recovered/Resolved - Other Medically Important Condition), No adverse event (3d - Recovered/Resolved - Other Medically Important Condition)	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (S - Pain - Unknown - [n/a - n/a - n/a]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [PARACETAMOL] (S - Pain - Unknown - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013318303	24/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (3d - Recovered/Resolved - Other Medically Important Condition), Gait disturbance (3d - Recovered/Resolved - Other Medically Important Condition), Headache (2d - Recovered/Resolved - Other Medically Important Condition), Malaise (3d - Recovered/Resolved - Other Medically Important Condition)	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (S - Pain - Unknown - [n/a - n/a - n/a]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [PARACETAMOL] (S - Pain - Unknown - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013318604	24/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013318710	24/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pericardial effusion (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pericarditis (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013319942	24/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myocarditis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I

										Condition), Pulmonary oedema (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10013320260	24/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013320279	24/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (3d - Recovered/Resolved - Other Medically Important Condition), Headache (1d - Recovered/Resolved - Other Medically Important Condition), Menstruation delayed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Somnolence (2d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013321322	24/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dacryoadenitis acquired (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Eye swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown -), Myopia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Ocular hyperaemia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013321354	24/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ocular hyperaemia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013321587	24/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Conduction disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular use]), [FLUOXETINE HYDROCHLORIDE] (S - Depression - Drug withdrawn - [n/a - 20mg - Oral use])	Not reported	I
EU-EC-10013321617	24/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Disabling), Tachycardia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	I

EU-EC-10013321813	24/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Not Recovered/Not Resolved - Disabling) Erythema (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported	i
EU-EC-10013321836	24/08/2022	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 - n/a - [1d - 1{DF} - Intramuscular use])	Not reported	i
EU-EC-10013321900	24/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -), Influenza like illness (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported	i
EU-EC-10013321913	24/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ear infection (8d - Not Recovered/Not Resolved -), Influenza like illness (n/a - Not Recovered/Not Resolved -), Lacrimation increased (8d - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -), Tonsillitis (8d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported	i
EU-EC-10013321924	24/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported	i
EU-EC-10013322816	24/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Suspected COVID-19 (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	i
EU-EC-10013322841	24/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Antinuclear antibody positive (n/a - Unknown -), Asthenia (n/a - Not Recovered/Not Resolved -), Autoimmune disorder (n/a - Unknown - Other Medically Important Condition), Balance disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Bedridden (n/a - Unknown -), Blood alkaline phosphatase decreased (n/a - Unknown -), Blood copper decreased (n/a - Unknown -), Blood creatinine decreased (n/a - Unknown -), Blood urea decreased (n/a - Unknown -), Bradycardia (n/a - Unknown - Other Medically Important Condition), CSF glucose increased (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[ASCORBIC ACID] (C - n/a - n/a - [n/a - n/a - n/a]), [CALCIUM PANTOTHENATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CYANOCOBALAMIN] (C - n/a - n/a - [n/a - n/a - n/a]), [CYPROHEPTADINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUNARIZINE] (C - n/a - n/a - [n/a - n/a - n/a]), [INOSITOL] (C - n/a - n/a - [n/a - n/a - n/a]), [LYSINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [NICOTINAMIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [RIBOFLAVIN] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	i

										<p>Medically Important Condition),</p> <p>CSF protein decreased (n/a - Unknown -),</p> <p>Drooling (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Dyskinesia (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),</p> <p>Fear of disease (n/a - Unknown -),</p> <p>Gait disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Headache (n/a - Recovered/Resolved - Other Medically Important Condition),</p> <p>Hypotension (n/a - Unknown -),</p> <p>Left ventricular dysfunction (n/a - Unknown -),</p> <p>Loss of personal independence in daily activities (n/a - Unknown -),</p> <p>Lymphadenopathy (n/a - Unknown -),</p> <p>Mean cell haemoglobin concentration increased (n/a - Unknown -),</p> <p>Migraine (n/a - Not Recovered/Not Resolved -),</p> <p>Muscular weakness (n/a - Unknown -),</p> <p>Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition),</p> <p>Pain (n/a - Unknown -),</p> <p>Pharyngitis (n/a - Unknown -),</p> <p>Pyrexia (n/a - Unknown -),</p> <p>Scoliosis (n/a - Unknown -),</p> <p>Sinus tachycardia (n/a - Unknown -),</p> <p>Supraventricular extrasystoles (n/a - Unknown -),</p> <p>Tachycardia (n/a - Unknown -),</p> <p>Tremor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),</p> <p>Urine output increased (n/a - Unknown -)</p>			
EU-EC-10013323782	24/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	<p>Chills (n/a - Recovered/Resolved - Other Medically Important Condition),</p> <p>Dizziness (2d - Recovered/Resolved - Other Medically Important Condition),</p> <p>Dysphagia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p>	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	

										Ear pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), Pain in jaw (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pharyngeal swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10013324925	24/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013305117	23/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Decreased appetite (7d - Recovered/Resolved -), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), Lethargy (7d - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	[METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - Oral use])	I
EU-EC-10013306108	23/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Administration site pain (1d - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013306472	23/08/2022	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), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013306476	23/08/2022	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), Dizziness (n/a - Unknown - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Pain - n/a - [2d - n/a - n/a])	I

										Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Tremor (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10013306846	23/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Influenza like illness (n/a - Unknown -), Sleep disorder (n/a - Unknown -), Syncope (n/a - Unknown -)	COMIRNATY 30 MICROGRAMS/DOSE [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013306925	23/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Alopecia totalis (n/a - Not Recovered/Not Resolved -), Cyanosis (n/a - Not Recovered/Not Resolved -), Neurodermatitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013307272	23/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (3d - Recovered/Resolved -), Pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013308927	23/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (172h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (172h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (172h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (172h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (172h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Loss of personal independence in daily activities (172h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (172h - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013309963	23/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (2h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (2h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013310045	23/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB (n/a - Recovering/Resolving -), Blood creatine phosphokinase increased (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Troponin I increased (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I

										-), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10013310226	23/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Palpitations (n/a - Recovering/Resolving -), Pupil dilation procedure (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013310547	23/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heart rate (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DIPHENHYDRAMINE HYDROCHLORIDE] (C - n/a - n/a - [1d - n/a - n/a])	I
EU-EC-10013310552	23/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition), Hot flush (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Pain (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [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])	I
EU-EC-10013310579	23/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (2d - Recovered/Resolved - Other Medically Important Condition), Hypoaesthesia (1d - Recovered/Resolved - Other Medically Important Condition), Monoparesis (2d - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (2d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL] (C - Dysmenorrhoea - n/a - [1d - n/a - n/a])	I
EU-EC-10013310679	23/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - Other Medically Important Condition), Dry throat (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), Nausea (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I

										Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10013310681	23/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	METHOTREXATE [METHOTREXATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DIHYDROCODEINE TARTRATE, PARACETAMOL BP, DIHYDROCODEINE TARTRATE BP, PARACETAMOL, DIHYDROCODEINE TARTRATE BP] (C - n/a - n/a - [n/a - n/a - n/a]), [ONDANSETRON] (C - n/a - n/a - [n/a - n/a - n/a])	I
EU-EC-10013310690	23/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Neck pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013310739	23/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (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	I
EU-EC-10013311227	23/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Confusional state (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Tendonitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013311248	23/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Hypotension (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	[TRANEXAMIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	I
EU-EC-10013311328	23/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved -), Uterine pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013311336	23/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oligomenorrhoea (n/a - Not Recovered/Not Resolved -), Uterine pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013312640	23/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013313061	23/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (30min - Recovered/Resolved -), Expired product administered (30min - Recovered/Resolved -), Immunisation (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I

										Off label use (n/a - Unknown - Other Medically Important Condition), Syncope (30min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10013313531	23/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013313589	23/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Insomnia (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013313721	23/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site pain (34d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013314204	23/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site lymphadenopathy (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])	Not reported	I
EU-EC-10013314236	23/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -), Vomiting (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013314276	23/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013314279	23/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013314340	23/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (3d - Recovered/Resolved -), Malaise (3d - Recovered/Resolved -), Vaccination site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])	Not reported	I
EU-EC-10013314844	23/08/2022	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	I
EU-EC-10013315062	23/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Farinazzo, E.. Cutaneous adverse reactions after m-RNA COVID-19 vaccine: early reports from Northeast Italy. J Eur Acad Dermatol Venereol. 2021;35:e548-e551. doi:10.1111/jdv.17343	12-17 Years	Not Specified	Not Specified	No	Multisystem inflammatory syndrome (n/a - Unknown - Life Threatening, Other Medically Important Condition), Rash maculo-papular (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	I
EU-EC-10013294869	22/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Kirpalani, A.. Thrombotic thrombocytopenic purpura temporally associated with BNT162b2 vaccination in an adolescent successfully treated with caplacizumab. British Journal of Haematology, 2022;196 (1):e11-e14. doi:10.1111/bjh.17782 Kirpalani, A.. Thrombotic thrombocytopenic purpura temporally associated with BNT162b2 vaccination in an adolescent successfully treated with caplacizumab. British Journal of Haematology, 2021;10.1111/bjh.17782. doi:10.1111/bjh.17782	12-17 Years	Not Specified	Female	No	Thrombotic thrombocytopenic purpura (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	I
EU-EC-10013294873	22/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (11480min - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (11480min - Recovered/Resolved - Other Medically Important)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I

										Condition), Electrocardiogram ST segment elevation (11480min - Recovered/Resolved - Other Medically Important Condition), Headache (244h - Recovered/Resolved -), Hypoaesthesia (11480min - Recovered/Resolved - Other Medically Important Condition), Inflammation (7d - Recovered/Resolved -), Myocarditis (11480min - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving -), Troponin I increased (11480min - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10013295479	22/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Recovering/Resolving -), Diarrhoea (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Hypoaesthesia (n/a - Recovering/Resolving -), Oropharyngeal pain (n/a - Recovering/Resolving -), Pain (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Rhinitis (n/a - Recovering/Resolving -), Vaccination site discolouration (n/a - Recovering/Resolving -), Vision blurred (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	1
EU-EC-10013295770	22/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Menstruation delayed (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Painful respiration (n/a - Unknown - Other Medically Important Condition), Pulmonary pain (n/a -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	1

EU-EC-10013296059	22/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Resolved - Other Medically Important Condition) 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 - Intramuscular use])	Not reported	I
EU-EC-10013296681	22/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Blood pressure increased (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Fear of injection (n/a - Not Recovered/Not Resolved -), Hyperhidrosis (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Muscle twitching (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	I
EU-EC-10013296958	22/08/2022	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), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Suspected COVID-19 (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013297269	22/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenitis (10d - Recovered/Resolved -), Lymphadenopathy (10d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013297703	22/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Swelling (n/a - Not Recovered/Not Resolved - Disabling), Vaccination site erythema (n/a - Unknown - Disabling), Vaccination site pain (n/a - Unknown - Disabling), Vaccination site swelling (n/a - Unknown - Disabling), Vaccination site warmth (n/a - Unknown - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-	22/08/2022	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Nausea (n/a -	COMIRNATY	Not reported	I

10013297900			Healthcare Professional	Economic Area		Years	Specified			Unknown -), Pyrexia (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10013298613	22/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Acute hepatic failure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Budd-Chiari syndrome (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013299347	22/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Not Recovered/Not Resolved -), Chest pain (n/a - Not Recovered/Not Resolved -), Dizziness postural (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Electrocardiogram ST segment depression (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Electrocardiogram T wave inversion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza A virus test positive (n/a - Not Recovered/Not Resolved -), Microcytosis (n/a - Not Recovered/Not Resolved -), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin increased (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013299475	22/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaemia (n/a - Recovered/Resolved -), Arthralgia (n/a - Recovered/Resolved -), Chest discomfort (n/a - Recovered/Resolved -), Chest pain (n/a - Recovered/Resolved -), Neutropenia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013300517	22/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown -), Chest pain (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Menstrual disorder (n/a - Unknown -), Pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013301099	22/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Neuralgic amyotrophy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported

EU-EC-10013301353	22/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (14d - Recovered/Resolved -), Heavy menstrual bleeding (21d - Recovered/Resolved -)	1{DF} - Intramuscular use)) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [2d - 1{DF} - Intramuscular use))	Not reported	I
EU-EC-10013301388	22/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenitis (16d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use))	Not reported	I
EU-EC-10013301483	22/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (1a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use))	Not reported	I
EU-EC-10013302322	22/08/2022	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), Cough (n/a - Unknown -), Nasal congestion (n/a - Unknown -), Nausea (n/a - Unknown -), Pyrexia (n/a - Unknown -), Rhinorrhoea (n/a - Unknown -), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use))	Not reported	I
EU-EC-10013302467	22/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epileptic encephalopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Status epilepticus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) BRIVARACETAM [BRIVARACETAM] (C - Lennox-Gastaut syndrome - n/a - [n/a - n/a - n/a]), CANNABIDIOL [CANNABIDIOL] (C - Lennox-Gastaut syndrome - n/a - [n/a - n/a - n/a]), PERAMPANEL [PERAMPANEL] (C - Lennox-Gastaut syndrome - n/a - [n/a - n/a - n/a]), [CLOBAZAM] (C - Lennox-Gastaut syndrome - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013303236	22/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	I
EU-EC-10013303258	22/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])	Not reported	I
EU-EC-10013303331	22/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site lymphadenopathy (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])	Not reported	I
EU-EC-10013303389	22/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (0d - Recovered/Resolved -), Fatigue (0d - Recovered/Resolved -), Nausea (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])	Not reported	I
EU-EC-10013303392	22/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug	Not reported	I

										Pyrexia (n/a - Not Recovered/Not Resolved -)	withdrawn - [n/a - n/a - Intramuscular use]		
EU-EC-10013292066	20/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovering/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013283109	19/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea exertional (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Lymphoma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013283856	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (106d - Recovered/Resolved -), Fatigue (n/a - Unknown -), Myalgia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013284229	19/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Drug ineffective (6d - Recovered/Resolved - Other Medically Important Condition), Suspected COVID-19 (6d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013285242	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anosmia (7d - Recovered/Resolved -), Bone pain (7d - Recovered/Resolved -), Chills (7d - Recovered/Resolved -), Cough (7d - Recovered/Resolved -), Decreased appetite (7d - Recovered/Resolved -), Dizziness (7d - Recovered/Resolved -), Dyspnoea (7d - Recovered/Resolved -), Insomnia (7d - Recovered/Resolved -), Myalgia (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30(DF) - n/a])	Not reported	I
EU-EC-10013285385	19/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypotension (5min - Recovered/Resolved -), Malaise (5min - Recovered/Resolved -), Syncope (5min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013285417	19/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypotension (5min - Recovered/Resolved -), Malaise (n/a - Unknown -), Myalgia (10min - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I

											Syncope (5min - Recovered/Resolved - Other Medically Important Condition)		
EU-EC-10013285676	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown -), Chills (n/a - Recovering/Resolving -), Dizziness (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[DROSPIRENONE, LACTOSE, LACTOSE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral use])	I
EU-EC-10013285718	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Inflammation (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30{DF} - n/a])	Not reported	I
EU-EC-10013286466	19/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Facial paralysis (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013286897	19/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	Yes	Circulatory collapse (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Febrile convulsion (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (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	I
EU-EC-10013286908	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (33d - Recovered/Resolved -), Fatigue (33d - Recovered/Resolved -), Groin pain (33d - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -), Pain (33d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013287264	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site reaction (1d - Recovered/Resolved -), Pruritus (1d - Recovered/Resolved -), Rash (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013287751	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Menstruation irregular (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013287798	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), Oligomenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013287873	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysphagia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	I

										Menstruation irregular (n/a - Not Recovered/Not Resolved -)	immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])		
EU-EC-10013287948	19/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epistaxis (3d - Recovered/Resolved -), Immunisation reaction (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013287998	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013288244	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Depressed mood (20d - Recovering/Resolving -), Heavy menstrual bleeding (20d - Recovering/Resolving -), Hypovitaminosis (20d - Recovering/Resolving -), Injection site reaction (20d - Recovering/Resolving -), Menstruation irregular (20d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013289224	19/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Alopecia (n/a - Not Recovered/Not Resolved -), Arthralgia (n/a - Not Recovered/Not Resolved -), Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Confusional state (n/a - Unknown -), Cough (n/a - Unknown -), Disturbance in attention (n/a - Unknown -), Ear inflammation (n/a - Unknown -), Ear pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ear tube insertion (n/a - Unknown - Caused/Prolonged Hospitalisation), Emotional disorder (n/a - Unknown -), Eye pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Not Recovered/Not Resolved -), Fibromyalgia (n/a - Unknown -), Gait disturbance (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypersensitivity (n/a - Not Recovered/Not Resolved -), Hypoaesthesia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I

										Resolved -), Inappropriate schedule of product administration (n/a - Unknown -), Inflammation (n/a - Unknown - Caused/Prolonged Hospitalisation), Inflammatory marker increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Insomnia (n/a - Not Recovered/Not Resolved -), Iron deficiency (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Movement disorder (n/a - Unknown -), Multisystem inflammatory syndrome in children (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Rheumatoid arthritis (n/a - Unknown - Other Medically Important Condition), Taste disorder (n/a - Unknown -), Vitamin D decreased (n/a - Not Recovered/Not Resolved -)			
EU-EC-10013289659	19/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fall (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Neck pain (n/a - Not Recovered/Not Resolved -), Pain (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	I
EU-EC-10013290715	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (4d - Recovered/Resolved -), Headache (4d - Recovered/Resolved -), Malaise (4d - Recovered/Resolved -), Pyrexia (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013290716	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013290717	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site lymphadenopathy (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19	[AMOXICILLIN] (C - Pharyngitis - Drug withdrawn - [8d - n/a -	I

										Recovered/Not Resolved -)	immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])	n/a)], [IBUPROFEN, IBUPROFEN ARGININE] (C - Oropharyngeal pain - Drug withdrawn - [3d - n/a - n/a]), [PARACETAMOL] (C - Headache - Drug withdrawn - [2d - n/a - n/a])	
EU-EC-10013290719	19/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovering/Resolved -), Malaise (n/a - Recovering/Resolved -), Pyrexia (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	i
EU-EC-10013290925	19/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (n/a - Recovering/Resolved -), Pyrexia (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	i
EU-EC-10013290952	19/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	i
EU-EC-10013271378	18/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dysentery (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Leukaemia (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 - 1{DF} - Intramuscular use])	Not reported	i
EU-EC-10013272008	18/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	i
EU-EC-10013273224	18/08/2022	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 use])	Not reported	i
EU-EC-10013273341	18/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	Yes	Herpes virus infection (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - .3mL - Intramuscular use])	Not reported	i
EU-EC-10013273583	18/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angina pectoris (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a])	Not reported	i
EU-EC-10013273683	18/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (137d - Recovered/Resolved -), Headache (137d - Recovered/Resolved -), Visual impairment (137d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	i
EU-EC-10013273913	18/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Bedridden (309d - Not Recovered/Not Resolved -), Depression (309d - Not Recovered/Not Resolved -), Fatigue (309d - Not Recovered/Not Resolved -), Oropharyngeal pain	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	i

										(309d - Not Recovered/Not Resolved -), Pyrexia (309d - Not Recovered/Not Resolved -)			
EU-EC-10013274277	18/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Lymph node pain (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -), Neoplasm (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	i
EU-EC-10013274841	18/08/2022	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 use])	Not reported	i
EU-EC-10013275487	18/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Alopecia areata (n/a - Not Recovered/Not Resolved - Disabling), Alopecia totalis (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	i
EU-EC-10013275750	18/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Wound (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	i
EU-EC-10013276047	18/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	Yes	Asthenia (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i
EU-EC-10013278125	18/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiac dysfunction (n/a - Unknown - Other Medically Important Condition), Cardiac failure (n/a - Fatal - Results in Death, Other Medically Important Condition), Chest pain (n/a - Unknown -), Dyspepsia (n/a - Unknown -), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Myocardial injury (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (n/a - Unknown -), Pulmonary function	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i

											test decreased (n/a - Unknown -), Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Unknown -)		
EU-EC-10013278341	18/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovered/Resolved - Other Medically Important Condition), Erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Erythema (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling hot (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Joint swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Other Medically Important Condition), Swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i
EU-EC-10013278572	18/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Heavy menstrual bleeding (n/a - Recovering/Resolving -), Immunisation reaction (n/a - Recovered/Resolved -), Polymenorrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	i
EU-EC-10013279951	18/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Amnesia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Folate deficiency (n/a - Unknown - Disabling, Other Medically Important Condition), Haematochezia (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i

											Headache (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Lymphadenopathy (n/a - Unknown - Disabling, Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Pain (n/a - Unknown - Disabling, Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Disabling, Other Medically Important Condition), Vaccination site pain (n/a - Unknown - Disabling, Other Medically Important Condition)		
EU-EC-10013279957	18/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i
EU-EC-10013280077	18/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyskinesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sleep disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DROSPIRENONE, ETHINYLESTRADIOL] (C - Polycystic ovaries - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a])	i
EU-EC-10013280919	18/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site erythema (n/a - Unknown -), Vaccination site induration (n/a - Unknown -), Vaccination site reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	i
EU-EC-10013280937	18/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular use])	Not reported	i
EU-EC-10013280941	18/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	i

EU-EC-10013280949	18/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])	Not reported	I
EU-EC-10013281156	18/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site urticaria (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013281163	18/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013281193	18/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [4d - n/a - Intramuscular use - More in ICSR])	Not reported	I
EU-EC-10013281196	18/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013281222	18/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])	Not reported	I
EU-EC-10013281224	18/08/2022	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 - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013281245	18/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])	Not reported	I
EU-EC-10013259128	17/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013259410	17/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition), Influenza like illness (n/a - Recovered/Resolved - Other Medically Important Condition), Micturition urgency (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013260258	17/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition), Rash pruritic (n/a - Recovering/Resolving - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I

										Condition), Vaccination site erythema (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - Other Medically Important Condition), Vaccination site pruritus (n/a - Unknown - Other Medically Important Condition), Vaccination site swelling (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10013260290	17/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injury (n/a - Unknown -), Nausea (n/a - Unknown -), Syncope (3min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013260379	17/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013260484	17/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (2d - Recovered/Resolved - Other Medically Important Condition), Chills (1d - Recovered/Resolved - Other Medically Important Condition), Fatigue (2d - Recovered/Resolved - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Painful respiration (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013260577	17/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Headache (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use - More in ICSR])	Not reported	I
EU-EC-10013262267	17/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Allergy to vaccine (n/a - Unknown -), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013262268	17/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013262758	17/08/2022	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), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013262841	17/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -), Balance disorder (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	I

										Dizziness (n/a - Unknown -), Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Presyncope (0d - Recovered/Resolved -)	1{DF} - Intramuscular use))	
EU-EC-10013263615	17/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (7h - Recovered/Resolved -), Headache (7h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013265022	17/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013266212	17/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menometrorrhagia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menstruation delayed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use))	Not reported
EU-EC-10013266300	17/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Guillain-Barre syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Motor dysfunction (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use))	Not reported
EU-EC-10013266369	17/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Mydriasis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use))	Not reported
EU-EC-10013266499	17/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (140d - Recovered/Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use))	Not reported
EU-EC-10013266606	17/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diplopia (n/a - Not Recovered/Not Resolved - Disabling), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use))	Not reported
EU-EC-10013266745	17/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (12d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use))	Not reported
EU-EC-10013267086	17/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Tension headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013268127	17/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Palpitations (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013268167	17/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Pain in extremity (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use))	Not reported

EU-EC-10013268770	17/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	I
EU-EC-10013268975	17/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013268978	17/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Unknown -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])	Not reported	I
EU-EC-10013269750	17/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Vaccination site inflammation (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])	PROTOPIC 0,03% POMADA [TACROLIMUS] (C - Pruritus - n/a - [14d - n/a - n/a])	I
EU-EC-10013269753	17/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013269754	17/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013269756	17/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain (n/a - Recovering/Resolving -), Pyrexia (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013269862	17/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Glossitis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	I
EU-EC-10013269903	17/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovering/Resolving -), Presyncope (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013269914	17/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness postural (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013243613	16/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hyperhidrosis (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013244277	16/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DESOGESTREL, ETHINYLESTRADIOL] (C - Oral contraception - n/a - [n/a - n/a - n/a])	I
EU-EC-10013244387	16/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Haemorrhage (n/a - Unknown - Other Medically Important Condition), Menstruation irregular (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	I
EU-EC-10013245777	16/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pallor (n/a - Unknown -), Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013245834	16/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	I
EU-EC-10013246043	16/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving -), Fatigue (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	I

										Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	applicable - [n/a - n/a - n/a])		
EU-EC-10013246500	16/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Haematemesis (n/a - Recovered/Resolved - Other Medically Important Condition), Malaise (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013246501	16/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lip swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013246563	16/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pseudoallergic reaction (n/a - Recovered/Resolved -), Rash macular (n/a - Recovered/Resolved -), Urticaria (n/a - Recovered/Resolved -), Viral rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013247076	16/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013247152	16/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013247442	16/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013247471	16/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Orthostatic hypotension (n/a - Unknown -), Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013247731	16/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Somnolence (30min - Recovered/Resolved -), Syncope (30min - Recovered/Resolved -), Vomiting (30min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013247741	16/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Head discomfort (n/a - Unknown -), Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013248143	16/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heart rate increased (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Pyrexia (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I

EU-EC-10013248202	16/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Other Medically Important Condition) Axillary pain (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i
EU-EC-10013248258	16/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i
EU-EC-10013249036	16/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site 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	i
EU-EC-10013249128	16/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hot flush (2d - Recovered/Resolved - Other Medically Important Condition), Pain (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination site bruising (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i
EU-EC-10013249132	16/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i
EU-EC-10013249488	16/08/2022	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 use])	Not reported	i
EU-EC-10013249694	16/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (6d - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (6d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i
EU-EC-10013249727	16/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown -), Poor quality sleep (n/a - Unknown -), Pulse abnormal (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	i
EU-EC-10013250096	16/08/2022	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN] (S -	[OXCARBAZEPINE] (C - Epilepsy - n/a - [n/a - n/a	i

			Professional	Economic Area						-), Focal dyscognitive seizures (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination site swelling (3d - Recovered/Resolved -)	COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	- Oral use))	
EU-EC-10013250427	16/08/2022	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013250715	16/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [COVID-19 VACCINE] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013250755	16/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013251199	16/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hyperthermia (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013251440	16/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Henoch-Schönlein purpura (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [15d - 1{DF} - Intramuscular use]), [ISOTRETINOIN] (S - Acne - Drug withdrawn - [n/a - 35mg - Oral use])	Not reported	I
EU-EC-10013251807	16/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (3mo - Recovered/Resolved - Other Medically Important Condition), Heavy menstrual bleeding (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 30ug - Intramuscular use])	Not reported	I
EU-EC-10013252340	16/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (20s - Recovered/Resolved -), Seizure (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013252373	16/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013253167	16/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (276d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Influenza like illness (276d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013253888	16/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (162d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Decreased appetite	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	I

										(162d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Inflammation (162d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pleural effusion (162d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pyrexia (162d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)			
EU-EC-10013254254	16/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymph node pain (n/a - Unknown - Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	AVAMYS [FLUTICASON FUROATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DROSPIRENONE, ETHINYLESTRADIOL] (C - n/a - n/a - [n/a - n/a - n/a]), [FEXOFENADINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [ISOTRETINOIN] (C - n/a - n/a - [n/a - n/a - n/a])	I
EU-EC-10013254291	16/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (276d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Influenza like illness (276d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013254621	16/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (185d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013257549	16/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blepharospasm (n/a - Unknown -), Confusional state (n/a - Not Recovered/Not Resolved -), Disorientation (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Unknown -), Hypoaesthesia (n/a - Unknown -), Illness (n/a - Unknown -), Malaise (n/a - Not Recovered/Not Resolved -), Panic reaction (n/a - Not Recovered/Not Resolved -), Seizure (n/a - Unknown - Other Medically Important Condition), Stress (n/a - Unknown -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013257738	16/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ataxia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Disturbance in attention (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	I

										Memory impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sensory level abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10013236462	15/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Guillain-Barre syndrome (n/a - Recovering/Resolving - Other Medically Important Condition), Muscular weakness (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013237190	15/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013237529	15/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013237994	15/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013238568	15/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013238714	15/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013239084	15/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Novak, B., Vulvar Ulcerations in Adolescents Following Both COVID-19 Infection and Vaccination. Journal of Pediatric and Adolescent Gynecology, 2022;35(2):225-226. doi:10.1016/j.jpog.2022.01.087	12-17 Years	Not Specified	Female	No	Dysuria (n/a - Recovered/Resolved - Other Medically Important Condition), Vaginal discharge (n/a - Recovered/Resolved - Other Medically Important Condition), Vulval ulceration (n/a - Recovered/Resolved - Other Medically Important Condition), Vulvovaginal pruritus (n/a - Recovered/Resolved - Other Medically Important Condition), Vulvovaginal swelling (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013239548	15/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013239578	15/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chills (8d - Recovered/Resolved)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I

										- Caused/Prolonged Hospitalisation), Headache (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10013240067	15/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Arthralgia (n/a - Unknown -), Chills (n/a - Unknown -), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	i
EU-EC-10013240251	15/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lennox-Gastaut syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	BRIVARACETAM [BRIVARACETAM] (C - Toxicity to various agents - n/a - [n/a - n/a - n/a]), CANNABIDIOL [CANNABIDIOL] (C - n/a - n/a - [n/a - n/a - n/a]), PERAMPANEL [PERAMPANEL] (C - n/a - n/a - [n/a - n/a - n/a]), [CLOBAZAM] (C - Toxicity to various agents - n/a - [n/a - n/a - n/a]), [HYOSCINE] (C - n/a - n/a - [n/a - n/a - n/a]), [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a - n/a])	i
EU-EC-10013240330	15/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (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	i
EU-EC-10013240443	15/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (7d - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (7d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i
EU-EC-10013241504	15/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	i
EU-EC-10013241728	15/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i

										Recovered/Not Resolved - Other Medically Important Condition), Tension headache (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Urticaria (n/a - Recovering/Resolved - Other Medically Important Condition)			
EU-EC-10013241922	15/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lip swelling (n/a - Recovered/Resolved -), Rash (n/a - Recovered/Resolved -), Urticaria (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013241952	15/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013242104	15/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013242164	15/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013242409	15/08/2022	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), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013225254	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site erythema (n/a - Unknown -), Vaccination site oedema (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013225918	12/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eye swelling (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), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013226328	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (46d - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013226871	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anti-neutrophil cytoplasmic antibody positive vasculitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthma exercise induced (n/a - Recovering/Resolving -), Back pain (n/a - Unknown - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I

										<p>Hospitalisation),</p> <p>Blood incompatibility haemolytic anaemia of newborn (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),</p> <p>Dyspnoea (n/a - Unknown -),</p> <p>Glomerulonephritis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Headache (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Hyperparathyroidism secondary (n/a - Unknown -),</p> <p>Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Performance status decreased (n/a - Unknown -),</p> <p>Proteinuria (n/a - Not Recovered/Not Resolved -),</p> <p>Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Renal failure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)</p>			
EU-EC-10013227158	12/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	<p>Chills (4d - Recovered/Resolved -),</p> <p>Fatigue (4d - Recovered/Resolved -),</p> <p>Headache (4d - Recovered/Resolved -),</p> <p>Lymphadenopathy (4d - Recovered/Resolved -),</p> <p>Pyrexia (4d - Recovered/Resolved -)</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	I
EU-EC-10013227560	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	<p>Malaise (n/a - Unknown -),</p> <p>Pain (n/a - Unknown -),</p> <p>Pain in extremity (n/a - Unknown -),</p> <p>Skin plaque (n/a - Unknown -),</p> <p>Vaccination site erythema (n/a - Unknown -),</p> <p>Vaccination site oedema (n/a - Unknown -),</p> <p>Vaccination site pain (n/a - Unknown -)</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013227605	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	<p>Nausea (n/a - Unknown -),</p> <p>Pyrexia (n/a - Unknown -),</p> <p>Rash (n/a - Unknown -),</p> <p>Vomiting (n/a - Unknown -)</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013227809	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	<p>Nausea (n/a - Unknown -),</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	I

										Pyrexia (n/a - Unknown -)	applicable - [n/a - 1{DF} - Intramuscular use])		
EU-EC-10013229030	12/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013229705	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013229732	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Crohn's disease (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Oral use])	[ETHINYLESTRADIOL, LEVONORGESTREL, PLACEBO] (C - Hormonal contraception - Dose not changed - [n/a - n/a - n/a])	I
EU-EC-10013229851	12/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angina pectoris (n/a - Recovered/Resolved - Other Medically Important Condition), Pelvic pain (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013229871	12/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Recovering/Resolving - Other Medically Important Condition), Amenorrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013229951	12/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (3wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013229952	12/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epistaxis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013229965	12/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	[PARACETAMOL] (C - n/a - Unknown - [n/a - n/a - n/a])	I
EU-EC-10013230651	12/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (n/a - Unknown -), Weight decreased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013230713	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pityriasis rosea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013230873	12/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I

										Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved -), Presyncope (n/a - Not Recovered/Not Resolved -)			
EU-EC-10013231013	12/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eating disorder (n/a - Unknown -), Illness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	I
EU-EC-10013232777	12/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (4d - Fatal - Results in Death), Myalgia (4d - Fatal - Results in Death), Pyrexia (4d - Fatal - Results in Death), Septic shock (4d - Fatal - Results in Death, Other Medically Important Condition), Vomiting (4d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013232775	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (46d - Recovered/Resolved -), Paraesthesia (46d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - n/a])	Not reported	I
EU-EC-10013233543	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	I
EU-EC-10013233555	12/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ageusia (n/a - Recovering/Resolving -), Anosmia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013233604	12/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epistaxis (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013233637	12/08/2022	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 - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013233638	12/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013233689	12/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Axillary pain (n/a - Recovering/Resolving -), Diarrhoea (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013233720	12/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Parotitis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013233724	12/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Decreased appetite (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013215888	11/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Marziali, E.. Acute Rejection Following COVID-19 Vaccination in Penetrating Keratoplasty in a Young Male - A Case Report and Review of Literature, Ocular Immunology and Inflammation, 2022;1-4, doi:10.1080/09273948.2022.2106248	12-17 Years	Not Specified	Male	No	Corneal graft rejection (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	I
EU-EC-10013217298	11/08/2022	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Male	No	Autoantibody positive (n/a -	COMIRNATY [TOZINAMERAN] (S -	Not reported	I

			Professional	Area						Unknown -), Chronic fatigue syndrome (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Migraine (n/a - Not Recovered/Not Resolved -)	COVID-19 immunisation - n/a - [n/a - 2{DF} - n/a])	
EU-EC-10013217393	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (48d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013217499	11/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Constipation (n/a - Not Recovered/Not Resolved -), Dyspepsia (n/a - Unknown -), Flatulence (n/a - Unknown -), Lymphadenitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013218259	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013218428	11/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown -), Vaccination site erythema (n/a - Unknown -), Vaccination site oedema (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013218444	11/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pallor (n/a - Unknown -), Presyncope (n/a - Unknown -), Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013219620	11/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysuria (n/a - Unknown -), Gait disturbance (n/a - Unknown -), Immune system disorder (n/a - Unknown -), Oedema genital (n/a - Unknown -), Pain (n/a - Unknown - Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved -), Vaginal ulceration (n/a - Recovering/Resolving -), Vulval disorder (n/a - Unknown -), Vulval ulceration (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported

EU-EC-10013219764	11/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Other Medically Important Condition) Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013219981	11/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site erythema (n/a - Unknown -), Vaccination site oedema (n/a - Unknown -), Vaccination site pain (n/a - Unknown -), Vaccination site pruritus (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013220248	11/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013220267	11/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown -), Syncope (n/a - Unknown -), Vertigo (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013220376	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rheumatoid arthritis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013220391	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chronic fatigue syndrome (n/a - Not Recovered/Not Resolved - Disabling), Disturbance in attention (18d - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Headache (18d - Not Recovered/Not Resolved -), Hyperacusis (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013220584	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular use])	Not reported	I
EU-EC-10013220821	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013221580	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013221610	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (2d - Recovered/Resolved - Other Medically Important Condition), Discomfort (3d - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (2d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) [ESCITALOPRAM] (C - n/a - n/a - [n/a - n/a - Oral use]), [METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - Oral use])		I

											Nausea (1d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)		
EU-EC-10013221630	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epilepsy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013222099	11/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013222429	11/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PROPANTHELINE BROMIDE] (C - Hyperhidrosis - n/a - [n/a - n/a - n/a])	I
EU-EC-10013222563	11/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	I
EU-EC-10013222614	11/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Unknown -), Myalgia (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	I
EU-EC-10013222971	11/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Takase, B.. Delayed Vasovagal Reaction with Reflex Syncope Following COVID-19 Vaccination. Internal Medicine. 2022;61(14):2167-2170. doi:10.2169/internalmedicine.9318-21	12-17 Years	Not Specified	Female	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	I
EU-EC-10013222997	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])	Not reported	I
EU-EC-10013223018	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013223044	11/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Recovering/Resolving -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013223209	11/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013205466	10/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013205515	10/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (10d - Recovered/Resolved -), Asthmatic crisis (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest discomfort (11d - Recovered/Resolved -), Cyanosis (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a - .3mL - Intramuscular use])	Not reported	I

										Dyspnoea (11d - Recovered/Resolved -), Fatigue (10d - Recovered/Resolved -), Hyperpyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Hyperventilation (11d - Recovered/Resolved -), Paraesthesia (1d - Recovered/Resolved -), Pharyngotonsillitis (n/a - Recovered/Resolved -), Tachycardia (10d - Recovered/Resolved -)			
EU-EC-10013205621	10/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved -), Hyperhidrosis (n/a - Not Recovered/Not Resolved -), Loss of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Not Recovered/Not Resolved -), Pericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 300uL - Intramuscular use])	Not reported	I
EU-EC-10013207036	10/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Facial paralysis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013207328	10/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013207858	10/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013207936	10/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperhidrosis (n/a - Unknown -), Hypotension (n/a - Unknown -), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013207941	10/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013208139	10/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013208883	10/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Headache (1d - Recovered/Resolved -), Inappropriate schedule of product administration (n/a -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I

										Unknown -), Pyrexia (2d - Recovered/Resolved -)			
EU-EC-10013208890	10/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiac dysfunction (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiomegaly (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown -), Electrocardiogram ST segment elevation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemodynamic instability (n/a - Unknown - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Unknown -), Myocardial necrosis marker increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown -), Paraesthesia (n/a - Unknown -), Pyrexia (1d - Recovered/Resolved -), Ventricular hypokinesia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013209298	10/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Noninfective sialoadenitis (n/a - Unknown -), Pyrexia (48h - Recovered/Resolved -), Swelling face (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported	I
EU-EC-10013209727	10/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eyelid oedema (n/a - Unknown -), Hypersensitivity (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013209817	10/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I

										Pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10013210788	10/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthmatic crisis (1d - Recovered/Resolved - Other Medically Important Condition), Heavy menstrual bleeding (5wk - Recovered/Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular use])	Not reported	I
EU-EC-10013210790	10/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013210844	10/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (65d - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Oligomenorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Uterine pain (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013210973	10/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013211006	10/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013211078	10/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Ear discomfort (n/a - Not Recovered/Not Resolved -), Ear pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013211643	10/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Bloise, S.. Adenomesenteritis following SARS-CoV-2. Vaccination in Children: A Case Report and Review of The Literature. Children. 2022;9 (7):993. doi:10.3390/children9070993	12-17 Years	Not Specified	Female	No	Lymphadenitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013211768	10/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Unknown -), Malaise (n/a - Unknown -), Pallor (n/a - Unknown -), Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013211818	10/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Unknown -), Malaise (n/a - Unknown -), Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013212372	10/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013212726	10/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	I

										Drug ineffective (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC-10013214100	10/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[WARFARIN, WARFARIN SODIUM] (C - n/a - n/a - n/a)
EU-EC-10013195915	09/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (5d - Recovered/Resolved - 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
EU-EC-10013195974	09/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dehydration (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Drug ineffective (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Gastritis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013196215	09/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Systemic viral infection (n/a - Unknown - Other Medically Important Condition), Urinary tract infection (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013196817	09/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown -), Bell's palsy (n/a - Unknown - Other Medically Important Condition), Facial discomfort (n/a - Unknown -), Headache (n/a - Unknown -), Hypoaesthesia (n/a - Unknown -), Myalgia (n/a - Unknown -), Neck pain (n/a - Unknown -), Sluggishness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013197078	09/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dehydration (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Gastritis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013197182	09/08/2022	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Asthenia (2min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported

				Area						-), Dizziness (2min - Recovered/Resolved -), Syncope (2min - Recovered/Resolved -)	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	
EU-EC-10013197191	09/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Unknown -), Heart rate abnormal (n/a - Unknown -), Oxygen saturation (n/a - Unknown -), Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013197293	09/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013197316	09/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (10d - Recovered/Resolved - Disabling), Muscular weakness (10d - Recovered/Resolved - Disabling), Pyrexia (3d - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013197320	09/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (5min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013197359	09/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypertension (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013197527	09/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013197598	09/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pyrexia (0d - Recovered/Resolved -), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013198718	09/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013200026	09/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Unknown -), Dizziness (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Pallor (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013200429	09/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site erythema (n/a - Unknown -), Vaccination site oedema (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported

EU-EC-10013200664	09/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arrhythmia (n/a - Recovered/Resolved - Other Medically Important Condition), Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition), Left ventricular hypertrophy (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i
EU-EC-10013200681	09/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (35d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (31d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (31d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (35d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oropharyngeal pain (35d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Viral infection (30d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	i
EU-EC-10013200726	09/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vertigo (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	i
EU-EC-10013201417	09/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -), Neck pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	i
EU-EC-10013201421	09/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eyelid oedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lip swelling (n/a - Recovering/Resolving - Other Medically Important Condition), Oedema (n/a - Unknown - Other Medically Important Condition), Swelling of eyelid (n/a - Unknown - Other Medically Important Condition), Swollen tongue (n/a - Unknown - Other Medically Important Condition), Throat tightness (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i
EU-EC-10013201488	09/08/2022	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),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -	Not reported	i

										Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	,3mL - Intramuscular use)		
EU-EC-10013201491	09/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Tanaka, A.. A case of female child developing acute perimyocarditis after COVID-19 vaccination, The 58th Annual Meeting of Japanese Society of Pediatric Cardiology and Cardiac, 2022;58th	12-17 Years	Not Specified	Female	No	Chest pain (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Electrocardiogram ST segment elevation (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (107h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Troponin I increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Troponin T increased (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	I
EU-EC-10013202742	09/08/2022	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 - Intramuscular use - More in ICSR])	Not reported	I
EU-EC-10013204459	09/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Paraesthesia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013204469	09/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013204571	09/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	I
EU-EC-10013204601	09/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013204657	09/08/2022	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S -	Not reported	I

			Professional	Area						-), Vaccination site pain (n/a - Unknown -)	COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	
EU-EC-10013204661	09/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Eye pain (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Parosmia (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Rash macular (n/a - Recovering/Resolving -), Taste disorder (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a])	Not reported
EU-EC-10013185465	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Eye swelling (n/a - Recovered/Resolved - Other Medically Important Condition), Hyperhidrosis (n/a - Recovered/Resolved - Other Medically Important Condition), Lip swelling (n/a - Recovered/Resolved - Other Medically Important Condition), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition), Pruritus (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013185521	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Cough (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Urticaria (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013185559	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013185608	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013185713	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site erythema (n/a - Unknown -), Vaccination site oedema (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013186510	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site erythema (n/a - Unknown -), Vaccination site oedema (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported

EU-EC-10013187237	08/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site pain (n/a - Unknown -), Fatigue (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site reaction (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013187284	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013187398	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heart rate abnormal (n/a - Unknown -), Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013187402	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Vaccination site reaction (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported	I
EU-EC-10013187431	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Lymph node pain (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported	I
EU-EC-10013187553	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013187798	08/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (30min - Recovered/Resolved -), Deafness (15min - Recovered/Resolved -), Fatigue (0d - Recovered/Resolved -), Injection site warmth (15min - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -), Pallor (15min - Recovered/Resolved -), Visual impairment (15min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	I
EU-EC-10013187933	08/08/2022	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 use])	Not reported	I
EU-EC-10013187944	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dengue virus test positive (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I

										Headache (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10013188152	08/08/2022	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 use])	Not reported	I
EU-EC-10013188431	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013188505	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Psychogenic seizure (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013188725	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site erythema (n/a - Unknown -), Vaccination site oedema (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013188733	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013188783	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site erythema (n/a - Unknown -), Vaccination site oedema (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013188786	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site erythema (n/a - Unknown -), Vaccination site oedema (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013188856	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013189209	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Monoparesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported	I
EU-EC-10013189443	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013189461	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), 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 - [n/a - .3mL - Intramuscular use])	Not reported	I

EU-EC-10013189665	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Other Medically Important Condition) Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013189680	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Unknown -), Heart rate increased (n/a - Unknown -), Oxygen saturation normal (n/a - Unknown -), Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013189835	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Konno, A.. Cardiac MRI performed for myocarditis after COVID-19 vaccination : A report of 3 pediatric cases. The 58th Annual Meeting of Japanese Society of Pediatric Cardiology and Cardiac. 2022;58th	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Ejection fraction decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Electrocardiogram ST segment elevation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electrocardiogram T wave inversion (n/a - Unknown - Other Medically Important Condition), Heart rate increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocardial necrosis marker increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial oedema (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myoglobin blood increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Respiratory rate increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Troponin I increased (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) [AMBROXOL, AMBROXOL HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [CARBOCISTEINE] (C - n/a - n/a - [n/a - n/a - n/a]), [CLINDAMYCIN PHOSPHATE] (C - n/a - n/a - [n/a - n/a - n/a]), [HYDROXYZINE, HYDROXYZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [MOMETASONE] (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]), [NADIFLOXACIN] (C - n/a - n/a - [n/a - n/a - n/a]), [RUPATADINE, RUPATADINE FUMARATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SUPLATAST TOSILATE] (C - n/a - n/a - [n/a - n/a - n/a]), [TIPEPIDINE HIBENZATE] (C - n/a - n/a - [n/a - n/a - n/a])		I

EU-EC-10013190743	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Arthralgia (6d - Recovered/Resolved -), Headache (6d - Recovered/Resolved -), Malaise (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013190891	08/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), COVID-19 (n/a - Unknown - Disabling, Other Medically Important Condition), Drug ineffective (n/a - Unknown - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013191065	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Urinary tract infection (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013191238	08/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oligomenorrhoea (77d - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013191255	08/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	I
EU-EC-10013191321	08/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (122d - Recovered/Resolved -), Diarrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013191613	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Doman, K., A case of mild encephalitis/encephalopathy with a reversible splenic lesion (MERS) after SARS CoV-2 vaccination, The 6th Chugoku/Shikoku Branch Congress of the Japanese Society of Intensive, 2022;6th:46	12-17 Years	Not Specified	Male	No	Altered state of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cytotoxic lesions of corpus callosum (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalitis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	[IVERMECTIN] (C - Product used for unknown indication - n/a - [2d - n/a - Oral use])	I

										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Incontinence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Magnetic resonance imaging abnormal (n/a - Unknown -), Meningitis aseptic (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Middle East respiratory syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Speech disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Visual impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10013191709	08/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	i
EU-EC-10013192050	08/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving - Other Medically Important Condition), Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	i
EU-EC-10013192078	08/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	i

										Dyspnoea (n/a - Not Recovered/Not Resolved -), Exercise tolerance decreased (n/a - Not Recovered/Not Resolved -), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved -)			
EU-EC-10013192474	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013192776	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Konno, A.. Cardiac MRI performed for myocarditis after COVID-19 vaccination : A report of 3 pediatric cases. The 58th Annual Meeting of Japanese Society of Pediatric Cardiology and Cardiac. 2022;58th	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Blood pressure increased (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), C-reactive protein increased (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest discomfort (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Electrocardiogram ST segment elevation (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electrocardiogram T wave inversion (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fibrin D dimer increased (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Heart rate increased (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocardial necrosis marker increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I

										Hospitalisation), Troponin I increased (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10013193018	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abnormal behaviour (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling hot (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Hemiparesis (n/a - Recovering/Resolving - Other Medically Important Condition), Hypophagia (n/a - Recovering/Resolving - Other Medically Important Condition), Lethargy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	i
EU-EC-10013193546	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain lower (n/a - Recovering/Resolving - Other Medically Important Condition), Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Haematuria (n/a - Recovering/Resolving - Other Medically Important Condition), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	i
EU-EC-10013193626	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pneumonia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary tuberculosis (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	i
EU-EC-10013194125	08/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	i
EU-EC-10013194288	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	i
EU-EC-10013194355	08/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	i
EU-EC-10013194403	08/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported	i
EU-EC-	08/08/2022	Spontaneous	Non	European	Not available	12-17	Adolescent	Male	No	Pyrexia (n/a -	COMIRNATY	Not reported	i

10013194409			Healthcare Professional	Economic Area		Years				Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	[TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])		
EU-EC-10013173337	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovering/Resolving -), Gastroenteritis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oropharyngeal pain (n/a - Recovering/Resolving -), Pyrexia (3d - Recovered/Resolved -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013173444	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Leukopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013173601	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bell's palsy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013173667	05/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Arthralgia (n/a - Unknown -), Asthenia (n/a - Unknown -), Chest pain (n/a - Unknown -), Headache (n/a - Unknown -), Injection site reaction (n/a - Unknown -), Myalgia (n/a - Unknown -), Pyrexia (24h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported	I
EU-EC-10013174474	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Pleuritic pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013174813	05/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperthyroidism (n/a - Recovering/Resolving - Other Medically Important Condition), Irritability (n/a - Recovering/Resolving -), Palpitations (n/a - Recovering/Resolving -), Temperature intolerance (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013175131	05/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013175279	05/08/2022	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 - Intramuscular use])	Not reported	I

EU-EC-10013175631	05/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Basal ganglia haemorrhage (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013175643	05/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Injection site reaction (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	I
EU-EC-10013175723	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	I
EU-EC-10013175829	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Sanada, H., Two Cases of Pericarditis Following COVID-19 Vaccination, The 58th Annual Meeting of Japanese Society of Pediatric Cardiology and Cardiac, 2022;58th	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocardial necrosis marker increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Orthostatic intolerance (n/a - Not Recovered/Not Resolved -), Pericardial effusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Troponin I increased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013176337	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Psychogenic seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013176725	05/08/2022	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 - Intramuscular use])	Not reported	I
EU-EC-10013177443	05/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported	I
EU-EC-10013177984	05/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	[BECLOMETASONE DIPROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DEXMETHYLPHENIDATE, DEXMETHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	I
EU-EC-10013178126	05/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not	COMIRNATY 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE	Not reported	I

										Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])	
EU-EC-10013178412	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Psychogenic seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013179112	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013180849	05/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypomenorrhoea (n/a - Not Recovered/Not Resolved -), Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	[KETOPROFENE] (C - Migraine - n/a - [n/a - n/a - Oral use]), [KETOPROFEN] (C - Migraine - n/a - [n/a - n/a - Oral use]), [PARACETAMOL] (C - Migraine - n/a - [n/a - n/a - Oral use])
EU-EC-10013180967	05/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Condition aggravated (78d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rheumatoid arthritis (78d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	ENBREL [ETANERCEPT] (C - Juvenile idiopathic arthritis - Not applicable - [n/a - 25mg - Subcutaneous use])
EU-EC-10013181202	05/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Deafness (26d - Recovered/Resolved -), Headache (26d - Recovered/Resolved -), Hypotension (26d - Recovered/Resolved -), Paraesthesia (26d - Recovered/Resolved -), Vision blurred (26d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013182065	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiac dysfunction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown -), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	[FLUTICASON PROPRIONATE, SALMETEROL XINAFOATE] (C - Asthma - n/a - [n/a - n/a - Inhalation use]), [FLUTICASON PROPRIONATE] (C - Asthma - n/a - [n/a - n/a - Inhalation use]), [MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma, Rhinitis allergic - n/a - [n/a - n/a - Oral use]), [OLOPATADINE HYDROCHLORIDE] (C - Asthma, Rhinitis allergic - n/a - [n/a - n/a - Oral use])

										Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10013182682	05/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (9d - Recovered/Resolved -), COVID-19 (3d - Recovered/Resolved - Other Medically Important Condition), Cough (9d - Recovered/Resolved -), Nasopharyngitis (9d - Recovered/Resolved -), Vaccination failure (3d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	i
EU-EC-10013163908	04/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pyrexia (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	i
EU-EC-10013164288	04/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Conversion disorder (n/a - Recovering/Resolving -), Disturbance in attention (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Hallucination, auditory (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	i
EU-EC-10013164635	04/08/2022	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 use])	Not reported	i
EU-EC-10013164960	04/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pyrexia (24h - Recovered/Resolved -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	i
EU-EC-10013165235	04/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Neoplasm malignant (n/a - Unknown - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - n/a])	Not reported	i
EU-EC-10013165295	04/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown -), Herpes dermatitis (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Unknown -), Pruritus (n/a - Unknown -), Rash (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	i

										Resolved -), Rash (n/a - Unknown -)			
EU-EC-10013165302	04/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dysphagia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013165358	04/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Unknown -), Pyrexia (12h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013165380	04/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Vaccination site erythema (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013167212	04/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Administration site pain (2d - Recovered/Resolved -), Body temperature increased (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013167259	04/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epilepsy (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved -), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	I
EU-EC-10013168209	04/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013168245	04/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013168364	04/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Acne (n/a - Recovering/Resolving -), Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menometrorrhagia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [25d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013168865	04/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	ENBREL [ETANERCEPT] (C - Juvenile idiopathic arthritis - n/a - [n/a - 50mg - Subcutaneous use])	I
EU-EC-10013169672	04/08/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013169730	04/08/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved -), Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	I

										Recovered/Resolved -), Intussusception (n/a - Recovered/Resolved - Other Medically Important Condition), Lethargy (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Myalgia (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vaccination site reaction (n/a - Recovered/Resolved -)	applicable - [1d - n/a - n/a])		
EU-EC-10013170450	04/08/2022	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 - n/a - n/a])	Not reported	I
EU-EC-10013171053	04/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013171791	04/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	I
EU-EC-10013171818	04/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Unknown -), Malaise (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	I
EU-EC-10013152349	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Breakthrough COVID-19 (10d - Recovered/Resolved -), Cough (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Hyperpyrexia (3d - Recovered/Resolved - Other Medically Important Condition), Oropharyngeal pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported	I
EU-EC-10013154438	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chronic fatigue syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tremor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013154741	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dysphagia (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -), Rash erythematous (2wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013154744	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (n/a - Unknown -), Pain in extremity (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	I

EU-EC-10013154747	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiovascular disorder (n/a - Unknown -), Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Unknown -)	applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013155355	03/08/2022	Spontaneous	Non 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 - n/a - [n/a - 2{DF} - n/a])	Not reported	I
EU-EC-10013156240	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013156243	03/08/2022	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 -), Pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013157248	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood immunoglobulin E increased (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Recovering/Resolving -), Eosinophil count increased (n/a - Recovering/Resolving -), Palpitations (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	I
EU-EC-10013157664	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Body temperature increased (2d - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013157783	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved With Sequelae -), Flatulence (n/a - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013157848	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	Yes	Ecema nummular (n/a - Not Recovered/Not Resolved -), Parapsoriasis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013157954	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (4d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013158600	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Nausea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013158942	03/08/2022	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 - n/a - n/a])	Not reported	I
EU-EC-10013158948	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown -), Chills (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I

										Pyrexia (n/a - Recovering/Resolving -)			
EU-EC-10013159052	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013159073	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest discomfort (n/a - Recovered/Resolving -), Dyspnoea (n/a - Recovered/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovered/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013159096	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gastrointestinal disorder (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013159217	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovered/Resolving - Other Medically Important Condition), Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013159316	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Heavy menstrual bleeding (n/a - Recovered/Resolving - Other Medically Important Condition), Iron deficiency anaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013159332	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Antinuclear antibody (n/a - Unknown -), COVID-19 (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	I
EU-EC-10013159391	03/08/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Recovered/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013159503	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Recovered/Resolving -), Injection site erythema (n/a - Recovered/Resolving -), Pain (n/a - Recovered/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013159504	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site swelling (n/a - Recovered/Resolving -), Skin reaction (n/a - Recovered/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	I
EU-EC-10013159581	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I
EU-EC-10013159592	03/08/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown -), Fatigue (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	I

