

## 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 I (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10014103815	25/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intravenous use])	Not reported
EU-EC-10014105618	25/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Contusion (n/a - Recovering/Resolving - ), Lymphadenopathy (4d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014106315	25/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	SARS-CoV-2 test positive (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-10014107308	25/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Extrasystoles (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	[MEQUITAZINE] (C n/a - n/a - [n/a - n/a])
EU-EC-10014108616	25/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - ), Dyspnoea (n/a - Unknown - ), Inappropriate schedule of product administration (n/a - Unknown - ), Myocarditis (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Recovering/Resolving - ), Pericarditis (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), IBUPROFEN, IBUPROFEN SODIUM (S - n/a - Unknown - [n/a - 200mg - n/a - More in ICSR])	Not reported
EU-EC-10014108617	25/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood urine present (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014093789	24/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (2d - Recovered/Resolved - ), Feeling abnormal (3d - Recovered/Resolved - ), Pain (3d - Recovered/Resolved - ), Pain in extremity (3d - Recovered/Resolved - ), Paraesthesia (3d - Recovered/Resolved - ), Vaccination site pain (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014093828	24/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (2d - Recovered/Resolved - ), Body temperature increased (1d - Recovered/Resolved - ), Headache (7d - Recovered/Resolved - ), Myalgia (2d - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported

											Recovered/Resolved - ), Vertigo (7d - Recovered/Resolved - ), Visual impairment (2d - Recovered/Resolved - )		
EU-EC-10014094347	24/11/2022	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 - Intramuscular use - More in ICSR])	Not reported	
EU-EC-10014094510	24/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema multiforme (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Product use issue (n/a - Unknown - ), Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - Immunisation - Not applicable - [1d - n/a - n/a])	[AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - r - n/a - [n/a - n/a - n/a])	
EU-EC-10014094728	24/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anti-GAD antibody positive (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood glucose increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Glycosylated haemoglobin increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Polydipsia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Type 1 diabetes mellitus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	
EU-EC-10014094850	24/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (1d - Recovered/Resolved - ), Body temperature increased (2d - Recovered/Resolved - ), Myalgia (1d - Recovered/Resolved - ), Nausea (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	[PARACETAMOL, PHENYLEPHRINE HYDROCHLORIDE, PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral use])	
EU-EC-10014095653	24/11/2022	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	
EU-EC-10014095790	24/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10014097290	24/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (2d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Nausea (2d - Recovered/Resolved - ), Pruritus (2d - Recovered/Resolved - ), Rash (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	

											), Renal pain (2d - Recovered/Resolved - ), Spinal pain (2d - Recovered/Resolved - )		
EU-EC-10014097302	24/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014097332	24/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Chills (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - ), Epistaxis (n/a - Recovering/Resolving - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Lip pain (n/a - Unknown - ), Lip swelling (1d - Recovered/Resolved - ), Lymph node pain (n/a - Unknown - ), 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 - Unknown - ), Pyrexia (n/a - Recovering/Resolving - ), Vaccination site pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014097648	24/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Injection site pain (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[CEFALEXIN] (C - n/ Not applicable - [n/i n/a - n/a]), [PHENPROCOUMON (C - n/a - Not applicable - [n/a - n - n/a])	
EU-EC-10014097940	24/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Not Recovered/Not Resolved - ), Paraesthesia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014097979	24/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Unknown - Other Medically Important Condition), Dyspepsia (n/a - Unknown - Other Medically Important Condition), Infection susceptibility	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported	

										increased (n/a - Unknown - Other Medically Important Condition), Upper respiratory tract infection (n/a - Unknown - Other Medically Important Condition), Urinary tract infection (n/a - Unknown - Other Medically Important Condition)		
EU-EC-10014098022	24/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (0d - Recovered/Resolved - ), Headache (n/a - Unknown - ), Malaise (0d - Recovered/Resolved - ), Nausea (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[PARACETAMOL] (C n/a - n/a - [n/a - n/a - Oral use])
EU-EC-10014099236	24/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	General physical health deterioration (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10014099246	24/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Complement factor increased (50d - Recovered/Resolved - Disabling, Other Medically Important Condition), Electrocardiogram ST segment abnormal (n/a - Not Recovered/Not Resolved - Disabling), Electrocardiogram ST segment elevation (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Electrocardiogram abnormal (n/a - Not Recovered/Not Resolved - Disabling), Hypoaesthesia (n/a - Not Recovered/Not Resolved - Disabling), Lymphocyte count decreased (50d - Recovered/Resolved - Disabling, Other Medically Important Condition), Pain (174d - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Paraesthesia (n/a - Unknown - ), Poor quality sleep (n/a - Not Recovered/Not Resolved - Disabling), Sinus bradycardia (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10014099766	24/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Thammathiwat, T., Multiple Venous and Pulmonary Artery Thrombosis as the Presenting Features of Spontaneously Reversible Nephrotic Syndrome after Exposure to SARS-CoV-2 Virus (Pfizer/BioNTech BNT162b2) Vaccination. Vaccines. 2022;10 (11):1888. doi:10.3390/vaccines10111888	12-17 Years	Not Specified	Male	No	Nephrotic syndrome (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary artery thrombosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pulmonary venous thrombosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014100598	24/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site pain (n/a - Not	COMIRNATY [TOZINAMERAN] (S -	Not reported



EU-EC-10014101240	24/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Not Resolved - ) Feeding intolerance (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Vomiting (n/a - Unknown - )	n/a - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	COVID-19 MRNA VACCINE MODERNA (CX-024414) [ELASOMERAN] (C - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])
EU-EC-10014082660	23/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Pallor (n/a - Recovering/Resolving - ), Seizure (n/a - Recovering/Resolving - Other Medically Important Condition), Shock (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10014083425	23/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10014084475	23/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10014084529	23/11/2022	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 - ), Headache (1d - Recovered/Resolved - ), Vomiting (1d - Recovered/Resolved - )	COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10014086177	23/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (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-10014086439	23/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Unknown - ), Menstrual disorder (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014086727	23/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - ), Insomnia (n/a - Unknown - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Recovering/Resolving - ), Pain (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Recovering/Resolving - ), Vaccination site swelling (n/a - Recovering/Resolving - ), Vomiting (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014086815	23/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (30d - Recovered/Resolved - ), Discomfort (n/a - Unknown - ), Dyspnoea (30d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014086892	23/11/2022	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Male	No	Flank pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - )	Not reported

			Professional	Area							Resolved - )	n/a - n/a - [n/a - n/a - n/a]	
EU-EC-10014087065	23/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Rash (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	AERIUS [DESLORATADINE] (C - r - n/a - n/a - [n/a - r - Oral use])
EU-EC-10014087394	23/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Epistaxis (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Recovering/Resolving - ), Malaise (n/a - Unknown - ), Myalgia (n/a - Recovering/Resolving - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014087848	23/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Fatigue (2d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved - ), Malaise (1d - Recovered/Resolved - ), Vaccination site pain (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	INTUNIV [GUANFACINE] (C - r - n/a - n/a - [n/a - n/a - Oral use]), [LISDEXAMFETAMIN DIMESYLATE] (C - r - n/a - n/a - [n/a - n/a - (use)]), [MELATONIN] (C - r - n/a - n/a - [n/a - n/a - (use)])
EU-EC-10014087969	23/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No		Parosmia (n/a - Not Recovered/Not Resolved - ), Taste disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014088475	23/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Arthralgia (1d - Recovered/Resolved - ), Fatigue (1d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved - ), Malaise (1d - Recovered/Resolved - ), Pain in extremity (1d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10014088608	23/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No		Immunisation reaction (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10014088730	23/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No		Haematemesis (1a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Haemoptysis (1a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Menstruation irregular (1a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Muscle spasms (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Rectal haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10014088846	23/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No		Dehydration (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	[ANHYDROUS AZITHROMYCIN] (C Large intestine infection - Unknown [6d - n/a - Intramuscular use])

										Hospitalisation), Kidney enlargement (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)		
EU-EC-10014089100	23/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Sensory disturbance (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
EU-EC-10014089104	23/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Diplopia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Strabismus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Wheelchair user (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10014089118	23/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014089560	23/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Lee, J. A Suspected Case of Multisystem Inflammatory Disease in Children Following COVID-19 Vaccination: A Case Report and Systematic Literature Review. Pediatric Infectious Disease Journal. 2022;41(11):E456-E460. doi:10.1097/INF.0000000000003674	12-17 Years	Not Specified	Female	No	Multisystem inflammatory syndrome in children (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10014089576	23/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Giray, D.. Acute myocarditis following COVID-19 mRNA vaccination: a paediatric case. Cardiology in the Young. 2022;1-3. doi:10.1017/S1047951121004698 Giray, D.. Acute myocarditis following COVID-19 mRNA vaccination: a paediatric case. Cardiology in the Young. 2022;32(7):1178-1180. doi:10.1017/S1047951121004698	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014089577	23/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Morita, Y. Acute Perimyocarditis in an Adolescent Japanese Male after a Booster Dose of the BNT162b2 COVID-19 Vaccine. The Tohoku journal of experimental medicine. 2022;258(3):177-182. doi:10.1620/tjem.2022.J068	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014090173	23/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown - ), Lymphadenopathy (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	[ALDER POLLEN, CORYLIUS AVELLAN/ POLLEN, ALLERGEN ALNUS, ARTEMISIA VULGARIS, ARTEMI: VULGARIS POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMER/ POLLEN, ARTEMISIA VULGARIS POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS

POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMERATA POLLE BETULA, BETULA POLLEN, HORDEUM VULGARE POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, TRITICUM AESTIVUM POLLEN, CULTIVATED OAT POLLEN, DACTYLIS GLOMERATA POLLEN, BETULA POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMERATA POLLEI BETULA POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMERATA POLLEI CORYLUS AVELLANA POLLEN, HORDEUM VULGARE POLLEN, ARTEMISIA VULGARIS POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, TRITICUM AESTIVUM POLLEN, CULTIVATED OAT POLLEN, DACTYLIS GLOMERATA POLLEI HORDEUM VULGARIS POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, TRITICUM AESTIVUM POLLEN, CULTIVATED OAT POLLEN, DACTYLIS GLOMERATA POLLEI PLANTAGO LANCEOLATA POLLE PARIETARIA OFFICINALIS POLLE PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMERATA POLLEI PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMERATA POLLEI PLANTAGO LANCEOLATA POLLE PLANTAGO LANCEOLATA POLLE SECALE CEREALE POLLEN] (C - Immunisation - n/a [1d - .1mL - Subcutaneous use])

[DERMATOPHAGOID PTERONYSSINUS, DERMATOPHAGOID

EU-EC-10014090182	23/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site erythema (n/a - Recovering/Resolving - ), Injection site swelling (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]), [ALDER POLLEN, CORYLUS AVELLANA POLLEN, ALLERGENS, ALNUS, ARTEMISIA VULGARIS, ARTEMISIA VULGARIS POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMERATA POLLEN, ARTEMISIA VULGARIS POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMERATA POLLEN, PLANTAGO LANCEOLATA POLLEN, BETULA, BETULA POLLEN, HORDEUM VULGARE POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, TRITICUM AESTIVUM POLLEN, CULTIVATED OAT POLLEN, DACTYLIS GLOMERATA POLLEN, BETULA POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMERATA POLLEN, BETULA POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMERATA POLLEN, PLANTAGO LANCEOLATA POLLEN, CORYLUS AVELLANA POLLEN, HORDEUM VULGARE POLLEN, ARTEMISIA VULGARIS POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, TRITICUM AESTIVUM POLLEN, CULTIVATED OAT POLLEN, DACTYLIS GLOMERATA POLLEN, HORDEUM VULGARE POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, TRITICUM AESTIVUM POLLEN, CULTIVATED OAT POLLEN, DACTYLIS GLOMERATA POLLEN, PLANTAGO LANCEOLATA POLLEN, PARIETARIA OFFICINALIS POLLEN, PHLEUM PRATENSE	FARINAE] (C - Immunisation - n/a [1d - .1mL - Subcutaneous use]) Not reported
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											<p>POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMERATA POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMERATA POLLEN, PLANTAGO LANCEOLATA POLLEN, PLANTAGO LANCEOLATA POLLEN, SECALE CEREALE POLLEN] (S - Immunisation - Dose not changed - [n/a - .1mL - Subcutaneous use]),</p> <p>[DERMATOPHAGOIDES PTERONYSSINUS, DERMATOPHAGOIDES FARINAE] (S - Immunisation - Dose not changed - [n/a - n/a - Subcutaneous use])</p>	
EU-EC-10014090365	23/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	<p>Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Electric shock sensation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Feeling abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Impaired quality of life (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Loss of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other</p>	<p>COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])</p> <p>Not reported</p>	

EU-EC-10014090377	23/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Medically Important Condition) Fatigue (2d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved - ), Pain in extremity (n/a - Unknown - ), Pyrexia (1d - Recovered/Resolved - ), Urticaria (n/a - Unknown - ), Vaccination site pain (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014090660	23/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown - ), Illness (n/a - Unknown - ), Immunisation (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10014091156	23/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Collignon, C.. [Internet] Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 30 August - 2 september 2021 COVID-19 vaccines: EMA reviewing cases of multisystem inflammatory syndrome. European Medicines Agency, 2022;29:620-623, doi:10.1016/j.arpced.2022.08.018	12-17 Years	Not Specified	Male	No	Multisystem inflammatory syndrome in children (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014091788	23/11/2022	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), 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
EU-EC-10014070391	22/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10014070680	22/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - ), Dyspnoea exertional (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Hypokalaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - ), Tachycardia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014073009	22/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Listless (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10014073346	22/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ), Dysmenorrhoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014073375	22/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (3d - Recovered/Resolved - ), Fatigue (n/a - Unknown - ), Pain in extremity (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

EU-EC-10014073760	22/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Unknown - ), Eye paraesthesia (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Hypoaesthesia (n/a - Unknown - ), Hypoaesthesia eye (n/a - Unknown - ), Hypoaesthesia oral (n/a - Unknown - ), Paraesthesia (n/a - Unknown - ), Paraesthesia oral (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014074007	22/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014074059	22/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymph node pain (n/a - Unknown - ), Lymphadenopathy (4d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014076089	22/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood potassium decreased (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10014076674	22/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angina pectoris (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Arrhythmia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (346d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Headache (446d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Neuralgia (336d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Palpitations (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014076773	22/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (14h - Recovered/Resolved - ), Vomiting (14h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10014077726	22/11/2022	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), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Hypertension (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - n/a])	Not reported
EU-EC-10014078022	22/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported



										Chills (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	applicable - [1d - n/a - Intramuscular use])	
EU-EC-10014078370	22/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10014080000	22/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Petruzzi, M.. Oral erythema multiforme after Pfizer-BioNTech COVID-19 vaccination: a report of four cases, BMC Oral Health. 2022;22(1):90. doi:doi/10.1186/s12903-022-02124-2	12-17 Years	Not Specified	Male	No	Erythema multiforme (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014080750	22/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspepsia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014060810	21/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Collignon, C.. Two pediatric cases of multisystem inflammatory-like syndrome following COVID-19 vaccination. Archives de pediatrie. 2022;29:620-623. doi:10.1016/j.arcped.2022.08.018	12-17 Years	Not Specified	Male	No	Multisystem inflammatory syndrome (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10014060826	21/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Pareek, M.. Myopericarditis after Covid-19 Vaccination - a Case Series, Social Science Research Network. 2021 Pareek, M.. Short-Term Outcomes After Myopericarditis Related to COVID-19 Vaccination. JACC: Cardiovascular Imaging. 2022;15(11):2002-2005. doi:10.1016/j.jcmg.2022.03.026	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014060854	21/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Pareek, M.. Myopericarditis after Covid-19 Vaccination - A Case Series, Social Science Research Network. 2021 Pareek, M.. Short-Term Outcomes After Myopericarditis Related to COVID-19 Vaccination. JACC: Cardiovascular Imaging. 2022;15(11):2002-2005. doi:10.1016/j.jcmg.2022.03.026	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014060937	21/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	[FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE] (C - Asthma - n/a - [n/a - n/a - n/a])
EU-EC-10014060962	21/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Cardiac failure (n/a - Unknown - Other Medically Important Condition), Depressed mood (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Exercise tolerance increased (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

										Muscular weakness (n/a - Unknown - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Somatic symptom disorder (n/a - Unknown - )		
EU-EC-10014061959	21/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Muscle twitching (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014062149	21/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), Pruritus (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10014062895	21/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - ), Headache (n/a - Unknown - ), Injected limb mobility decreased (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pyrexia (n/a - Recovered/Resolved - ), Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10014062975	21/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Chills (1d - Recovered/Resolved - ), Dizziness (1d - Recovered/Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (1d - Recovered/Resolved - ), Increased tendency to bruise (1d - Recovered/Resolved - ), Malaise (n/a - Recovering/Resolving - ), Myalgia (n/a - Recovering/Resolving - ), Pyrexia (1d - Recovered/Resolved - ), Rash (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014063047	21/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Gait disturbance (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
EU-EC-10014063252	21/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Unknown - ), Intermenstrual bleeding (n/a - Unknown - ), Menstrual disorder (6mo - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[PARACETAMOL] (C Headache - n/a - [n - n/a - n/a])

EU-EC-10014063580	21/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Adrenal insufficiency (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014063794	21/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved - ), Oral mucosal blistering (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014064745	21/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Pareek, M.. Short-Term Outcomes After Myopericarditis Related to COVID-19 Vaccination. JACC: Cardiovascular Imaging. 2022;15 (11):2002-2005. doi:10.1016/j.jcmg.2022.03.026	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014064762	21/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (2d - Recovered/Resolved - ), Administration site erythema (5d - Recovered/Resolved - ), Fatigue (2d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Nausea (1d - Recovered/Resolved - ), Vertigo (1d - Recovered/Resolved - )	COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10014064930	21/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Atrioventricular block first degree (n/a - Unknown - ), Electroencephalogram abnormal (n/a - Unknown - ), Epilepsy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (1040min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (1040min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10014065181	21/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (2d - Recovered/Resolved - ), Influenza like illness (2d - Recovered/Resolved - ), Pain (2d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular use])	Not reported
EU-EC-10014065199	21/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site erythema (n/a - Not Recovered/Not Resolved - ), Vaccination site pruritus (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014065246	21/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Pain (n/a - Unknown - ), Rash pruritic (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014066048	21/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperthermia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	[LOMERIZINE HYDROCHLORIDE] - Migraine - n/a - [n/a - n/a - Oral use])

										Caused/Prolonged Hospitalisation), Sjogren's syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC-10014066427	21/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014066684	21/11/2022	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), Heavy menstrual 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
EU-EC-10014066729	21/11/2022	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use - More in ICSR])	Not reported
EU-EC-10014066740	21/11/2022	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), Menstruation delayed (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use - More in ICSR])	Not reported
EU-EC-10014067026	21/11/2022	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 - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10014067649	21/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - ), Atrioventricular septal defect (n/a - Unknown - Other Medically Important Condition), Bladder disorder (n/a - Recovering/Resolving - ), Gait disturbance (n/a - Recovering/Resolving - ), Guillain-Barre syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Leukopenia (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neuropathy peripheral (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - ), Paraesthesia (n/a - Recovering/Resolving - ), Paralysis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paraparesis (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	[HEPARIN, HEPARIN SODIUM] (C - Cardiac disorder - n/a - [n/a n/a - n/a]), [PHENPROCOUMON (C - Cardiac disorder n/a - [n/a - n/a - n/a]), [PHENPROCOUMON (C - Heart disease congenital - n/a - [n/a - n/a - Oral use]), [RAMIPRIL] (C - Heart disease congenital - n/a - [n/a - n/a - Oral use])

										Performance status decreased (n/a - Not Recovered/Not Resolved - ), Peroneal nerve injury (n/a - Recovering/Resolving - Other Medically Important Condition), Somnolence (n/a - Unknown - ), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition)		
EU-EC-10014067655	21/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Collignon, C.. Two pediatric cases of multisystem inflammatory-like syndrome following COVID-19 vaccination. Archives de pediatrie, 2022;29:620-623. doi:10.1016/j.arcped.2022.08.018	12-17 Years	Not Specified	Male	No	Multisystem inflammatory syndrome (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10014067670	21/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Ahmed, H.. A Case Series of Myocarditis Related to the COVID-19 Vaccine. Cureus, 2022;14(10):10.7759/cureus.29892. doi:10.7759/cureus.29892	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014068485	21/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chronic fatigue syndrome (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Muscle discomfort (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myositis (n/a - Unknown - Other Medically Important Condition), Performance status decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Post viral fatigue syndrome (n/a - Not Recovered/Not Resolved - ), White blood cell count decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - Intramuscular use])	[FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE] (C - Asthma - n/a - [n/a n/a - Inhalation use]  [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthr - n/a - [n/a - n/a - Inhalation use])
EU-EC-10014068751	21/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Tanaka, A.. A case of coronary spastic angina as post-COVID-19 vaccination myocarditis. The 516th Fukuoka Regional Meeting of the Japan Pediatric Society, 2022;516th:21 Tanaka, A.. A case of coronary spastic angina-associated myocarditis occurred after COVID-19 vaccination. The 58th Annual Meeting of Japanese Society of Pediatric Cardiology and Cardiac, 2022;58th Tanaka, A.. A case of coronary spastic angina-associated myocarditis occurred after COVID-19 vaccination. The 54th Annual Meeting of Japanese Society of Pediatric Infectious disease, 2022;54th:184	12-17 Years	Not Specified	Male	No	Atrioventricular block complete (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electrocardiogram ST segment elevation (n/a - Unknown - Other Medically Important Condition), Ischaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Prinzmetal angina (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular use])	Not reported

											Pyrexia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Wall motion score index abnormal (n/a - Unknown - )		
EU-EC-10014068842	21/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Reshef, E., Orbital Inflammation Following COVID-19 Vaccination, Ophthalmic plastic and reconstructive surgery. 2022;38(3):e67-e70. doi:10.1097/IOP.0000000000002161	12-17 Years	Not Specified	Male	No	Disease recurrence (n/a - Recovered/Resolved - ), Erythema (n/a - Recovered/Resolved - ), Erythema of eyelid (n/a - Recovered/Resolved - ), Exophthalmos (n/a - Recovered/Resolved - Other Medically Important Condition), Eye movement disorder (n/a - Recovered/Resolved - ), Eyelid oedema (n/a - Recovered/Resolved - ), Lacrimal gland enlargement (n/a - Recovered/Resolved - ), Parophthalmia (n/a - Recovered/Resolved - ), Periorbital fat herniation (n/a - Recovered/Resolved - ), Periorbital oedema (n/a - Recovered/Resolved - ), Periorbital pain (n/a - Recovered/Resolved - ), Periorbital swelling (n/a - Recovered/Resolved - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	
EU-EC-10014068906	21/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Vorster, L., COVID-19 vaccine (mRNA BNT162b2) and COVID-19 infection-induced thrombotic thrombocytopenic purpura in adolescents. Pediatric Blood and Cancer. 2022;69(6):e29681. doi:10.1002/pbc.29681	12-17 Years	Not Specified	Female	No	Thrombotic thrombocytopenic purpura (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - n/a - n/a])	Not reported	
EU-EC-10014069683	21/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	
EU-EC-10014039774	18/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Appendicitis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014040044	18/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014041557	18/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypokinesia (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Paraesthesia (n/a - Not Recovered/Not Resolved - ), Pruritus (n/a - Not Recovered/Not Resolved - ), Vaccination site erythema (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	

											Resolved - ), Vaccination site rash (n/a - Not Recovered/Not Resolved - )		
EU-EC-10014042096	18/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Administration site pain (2d - Recovered/Resolved - ), Chills (2d - Recovered/Resolved - ), Headache (n/a - Unknown - ), Pyrexia (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	
EU-EC-10014042339	18/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (20d - Recovered/Resolved - ), Chest pain (19d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspepsia (20d - Recovered/Resolved - ), Myocarditis (20d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (20d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10014043061	18/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (5d - Recovered/Resolved - ), Body temperature increased (1d - Recovered/Resolved - ), Myalgia (5d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	
EU-EC-10014043166	18/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (5d - Recovered/Resolved - ), Body temperature increased (1d - Recovered/Resolved - ), Myalgia (5d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	
EU-EC-10014043777	18/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Oligomenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014043936	18/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Recovering/Resolving - ), Myalgia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014044065	18/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014044229	18/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Balance disorder (n/a - Recovering/Resolving - ), Feeling abnormal (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - ), Photosensitivity reaction (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	

											Vision blurred (n/a - Recovering/Resolving - )		
EU-EC-10014044246	18/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 immunisation (n/a - Not Recovered/Not Resolved - ), Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014045079	18/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014046734	18/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014049313	18/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Pallor (n/a - Unknown - ), Pulmonary function test decreased (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[BUDESONIDE] (C - n/a - n/a - [n/a - n/a - Oral use])	
EU-EC-10014049516	18/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site erythema (n/a - Recovering/Resolving - ), Vaccination site induration (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ), Vaccination site swelling (n/a - Recovering/Resolving - ), Vaccination site warmth (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014049538	18/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown - ), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ), Ovarian cyst (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014049545	18/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dry skin (n/a - Recovering/Resolving - ), Eczema (0d - Recovering/Resolving - ), Rash (n/a - Recovering/Resolving - ), Skin burning sensation (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014049582	18/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown - ), Headache (n/a - Recovering/Resolving - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014050855	18/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Burning sensation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Demyelination (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypoesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	
EU-EC-10014050909	18/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chronic tonsillitis (305d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	



											Infectious mononucleosis (283d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Urticaria (n/a - Unknown - Caused/Prolonged Hospitalisation)		
EU-EC-10014051084	18/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Blindness unilateral (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Keratoconus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1Ci - n/a])	Not reported	
EU-EC-10014051086	18/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Unknown - ), Headache (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	
EU-EC-10014051120	18/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site inflammation (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	
EU-EC-10014029426	17/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Unknown - Other Medically Important Condition), Seizure (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-10014029500	17/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocardial fibrosis (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10014029742	17/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Allergy to animal (n/a - Unknown - ), Amenorrhoea (n/a - Not Recovered/Not Resolved - ), Concomitant disease aggravated (n/a - Unknown - ), Eye pruritus (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Hypersensitivity (n/a - Not Recovered/Not Resolved - ), Lacrimation increased (n/a - Not Recovered/Not Resolved - ), Menstruation irregular (n/a - Unknown - ), Nasal congestion (n/a - Unknown - ), Nasal pruritus (n/a - Not Recovered/Not Resolved - ), Pruritus (n/a - Unknown - ), Rash (n/a - Not Recovered/Not Resolved - ), Rhinorrhoea (n/a - Not Recovered/Not Resolved - ), Seasonal allergy (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[COD-LIVER OIL] (C - n/a - n/a - ), [POTASSIUM CHLORIDE, AMMONIUM CHLORIDE, CALCIUM GLUCONATE, POTASSIUM CITRAT] (C - n/a - n/a - ), [THIAMINE HYDROCHLORIDE, RETINOL] (C - n/a - n/a - )	
EU-EC-10014030276	17/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	PIOGLITAZONE [PIOGLITAZONE] (C - Diabetes mellitus - r - [n/a - n/a - n/a]),	



EU-EC-10014031618	17/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Recovered/Not Resolved - ) Adverse reaction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Autoantibody test (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Hypoaesthesia oral (0d - Recovered/Resolved - ), Myoclonus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Palpitations (n/a - Not Recovered/Not Resolved - ), Post vaccination syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Postural orthostatic tachycardia syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tremor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Visual impairment (0d - Recovered/Resolved - Other Medically Important Condition), Wheelchair user (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a])	Not reported
EU-EC-10014031697	17/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Swelling (n/a - Unknown - ), Vaccination site erythema (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014031706	17/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site erythema (2d - Recovered/Resolved - ), Vaccination site rash (n/a - Unknown - ), Vaccination site swelling (n/a - Unknown - ), Vaccination site warmth (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014031813	17/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (6d - Recovered/Resolved - ), Headache (7d - Recovered/Resolved - ), Lymphadenopathy (8d - Recovered/Resolved - ), Malaise (8d - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

											Rash (n/a - Recovering/Resolved - ), Vaccination site pain (5d - Recovered/Resolved - )		
EU-EC-10014031929	17/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	No	Fatigue (n/a - Recovering/Resolved - ), Headache (n/a - Recovering/Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Recovered/Resolved - ), Rash (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014031951	17/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	No	Headache (n/a - Recovered/Resolved - ), Pruritus (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014031964	17/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	No	Dizziness (n/a - Unknown - ), Malaise (n/a - Unknown - ), Nausea (n/a - Unknown - ), Photopsia (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - ), Vomiting (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014031985	17/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	No	Eye swelling (n/a - Unknown - ), Pyrexia (n/a - Recovering/Resolved - ), Swelling face (n/a - Recovering/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014032101	17/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	No	Pyrexia (n/a - Unknown - ), Rash erythematous (n/a - Recovering/Resolved - ), Rash macular (n/a - Recovering/Resolved - ), Rash pruritic (n/a - Unknown - ), Swelling face (n/a - Recovering/Resolved - ), Swelling of eyelid (n/a - Recovering/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014032216	17/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	No	Headache (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Recovered/Resolved With Sequelae - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014032441	17/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	No	Erythema (n/a - Recovered/Resolved - ), Fatigue (n/a - Recovered/Resolved - ), Oedema (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014032659	17/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	No	Chest pain (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Recovering/Resolved - ), Myalgia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported



										Resolved - ), Tenderness (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - )		
EU-EC-10014034581	17/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash pruritic (n/a - Unknown - ), Urticaria (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014034642	17/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved - ), Malaise (n/a - Recovered/Resolved - ), Menstruation delayed (n/a - Recovered/Resolved - ), Vaccination site pain (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014034702	17/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Insomnia (n/a - Unknown - ), Menstrual disorder (n/a - Unknown - ), Palpitations (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014034811	17/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (2d - Recovered/Resolved - ), Back pain (n/a - Unknown - ), Chills (1d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Malaise (1d - Recovered/Resolved - ), Myalgia (2d - Recovered/Resolved - ), Neck pain (n/a - Unknown - ), Pain (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Pyrexia (1d - Recovered/Resolved - ), Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014034814	17/11/2022	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)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014035559	17/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014035600	17/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Bone marrow failure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10014035795	17/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Recovered/Resolved - ), Vertigo (n/a - Recovered/Resolved - ), Visual field tests abnormal (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 30ug - Intramuscular use])	Not reported
EU-EC-10014036827	17/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown - ), Pyrexia (6d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014036830	17/11/2022	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Anosmia (6d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S -	INTUNIV [GUANFACINE] (C -

				Area						)	n/a - n/a - [n/a - n/a - n/a])	n/a - n/a - [n/a - n/a - Oral use]), [COLECALCIFEROL] - n/a - n/a - [n/a - r - Oral use]), [LISDEXAMFETAMIN DIMESYLATE] (C - r - n/a - [n/a - n/a - ( use)), [RISPERIDONE] (C - n/a - n/a - [n/a - n/a - Oral use])
EU-EC-10014037483	17/11/2022	Spontaneous	Healthcare Professional	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 - [1d - n/a - n/a])	Not reported
EU-EC-10014037564	17/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arrhythmia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Brain injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Cerebral atrophy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Coma (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Communication disorder (n/a - Unknown - ), Dysphagia (n/a - Unknown - Other Medically Important Condition), Hyperglycaemia (n/a - Unknown - ), Loss of consciousness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myoclonic dystonia (n/a - Unknown - ), Quadriplegia (n/a - Unknown - Other Medically Important Condition), Rales (n/a - Unknown - ), Resuscitation (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus rhythm (n/a - Unknown - ), Staphylococcus test positive (n/a - Unknown - ), Tachycardia (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

										Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular fibrillation (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Visual impairment (n/a - Unknown - )		
EU-EC-10014038522	17/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Leukopenia (n/a - Recovered/Resolved - Other Medically Important Condition), Myopericarditis (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), 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-10014038938	17/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema (0d - Recovered/Resolved - ), Swelling (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10014039050	17/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site inflammation (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10014039072	17/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10014015215	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014017190	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Recovered/Resolved - Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved - Other Medically Important Condition), Vulval ulceration (8d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY 30 MICROGRAMS/DOSE [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intravenous use])	Not reported
EU-EC-10014017499	16/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Cardiomegaly (n/a - Fatal - Results in Death, Life Threatening), Myocarditis (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10014017506	16/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Pillar, S. Posterior ocular manifestations following BNT162b2 mRNA COVID-19 vaccine: a case series. International Ophthalmology. 2022;10.1007/s10792-022-02565-2. doi:10.1007/s10792-022-02565-2	12-17 Years	Not Specified	Female	No	Scleritis (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10014017941	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved - ), Fatigue (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Injected limb mobility decreased (n/a - Unknown - ), Malaise (n/a - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[DROSPIRENONE, ETHINYLESTRADIOL LACTOSE ANHYDROUS] (C - r - n/a - [n/a - n/a - ( use)])



											Recovering/Resolving - ), Nausea (0d - Recovered/Resolved - ), Pain in extremity (n/a - Unknown - ), Vaccination site pain (n/a - Not Recovered/Not Resolved - )	
EU-EC-10014017950	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014017961	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014018251	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014018451	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Unknown - ), Mastication disorder (n/a - Unknown - ), Muscle twitching (n/a - Recovered/Resolved - ), Myalgia (3d - Recovered/Resolved - ), Pain in jaw (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014018530	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Menstrual disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014018681	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (6d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014019116	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014019211	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014019456	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Disturbance in attention (406d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Lymphadenopathy (406d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Muscle twitching (401d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Sleep disorder (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014019760	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014019799	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Muscle spasms (n/a - Recovering/Resolving - ), Pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014019803	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (1d - Recovered/Resolved - ), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014019829	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

											Eye pain (n/a - Unknown - ), Headache (n/a - Not Recovered/Not Resolved - )	
EU-EC-10014021973	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Behaviour disorder (n/a - Not Recovered/Not Resolved - ), Encephalitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10014022017	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014022070	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Influenza like illness (n/a - Unknown - ), Malaise (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014022179	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Recovering/Resolving - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Nausea (1d - Recovered/Resolved - ), Pyrexia (n/a - Recovering/Resolving - ), Vaccination site lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10014022262	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Guillain-Barre syndrome (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10014022279	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014022298	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014022443	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Disturbance in attention (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Nasal congestion (n/a - Unknown - ), Nasopharyngitis (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014022525	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

										Headache (1d - Recovered/Resolved - ), Nausea (1d - Recovered/Resolved - )		
EU-EC-10014023198	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (2d - Recovered/Resolved - ), Cough (n/a - Recovering/Resolving - ), Malaise (3d - Recovered/Resolved - ), Myalgia (2d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - ), Vaccination site pain (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014023253	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Hyperacusis (n/a - Not Recovered/Not Resolved - ), Migraine (n/a - Unknown - ), Nausea (n/a - Unknown - ), Photophobia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014023273	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymph node pain (n/a - Unknown - ), Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014023370	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	INSULIN ASPART SANOFI [INSULIN ASPART] (C - n/a - n/a - [n/a - n/a - Subcutaneous use])  [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (n/a - n/a - [n/a - n/a - Oral use])
EU-EC-10014023414	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Pyrexia (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[IBUPROFEN] (C - n/a - n/a - [n/a - n/a - Oral use]),  [PARACETAMOL, CAFFEINE] (C - n/a - n/a - [n/a - n/a - Oral use])
EU-EC-10014024437	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Alanine aminotransferase decreased (n/a - Unknown - ), Blood bilirubin increased (n/a - Unknown - ), Blood cholinesterase increased (n/a - Unknown - ), Blood homocysteine increased (n/a - Unknown - ), Blood pressure diastolic increased (n/a - Unknown - ), Blood urea decreased (n/a - Unknown - ), Bone contusion (n/a - Unknown - ), Coagulopathy (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported



										Caused/Prolonged Hospitalisation), Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Tachycardia (n/a - Unknown - ), Tension headache (n/a - Unknown - ), Tremor (n/a - Unknown - ), Vision blurred (n/a - Unknown - ), Visual impairment (2h - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Visual impairment (n/a - Unknown - ), Vomiting (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Weight decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - )		
EU-EC-10014024513	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - ), Chronic fatigue syndrome (n/a - Not Recovered/Not Resolved - ), Depressed mood (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - ), Respiratory distress (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014024609	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10014025119	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014025217	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014025218	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (1d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014025304	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014025672	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Unknown - ), Heavy menstrual bleeding (n/a - Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

										Recovered/Not Resolved - ), Menstruation irregular (n/a - Not Recovered/Not Resolved - )		
EU-EC-10014025716	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cyanosis (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Peripheral coldness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014025763	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014025773	16/11/2022	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 - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014025811	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Mobility decreased (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Peripheral swelling (n/a - Not Recovered/Not Resolved - ), Skin discolouration (n/a - Unknown - ), Tenderness (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014025815	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown - ), Nausea (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014025819	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving - ), Hypoaesthesia (n/a - Unknown - ), Nausea (n/a - Recovering/Resolving - ), Pain in extremity (n/a - Unknown - ), Presyncope (n/a - Unknown - ), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014025865	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epilepsy (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014025923	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (41d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014025970	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (8d - Recovered/Resolved - ), Nausea (8d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[DICLOFENAC, DICLOFENAC DIETHYLAMINE, DICLOFENAC EPOLAMINE, DICLOFENAC POTASSIUM, DICLOFENAC RESINATE, DICLOFENAC SODIUM, DICLOFENAC SODIUM PH. EUR.] (C - n/a - n/a - [n/a - n/a - Rectal use]), [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM DIHYDRATE, ESOMEPRAZOLE SODIUM] (C - n/a - n/a - [n/a - n/a - Or use]), [METOCLOPRAMIDE HYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE ANHYDROUS] (C - r - n/a - [n/a - n/a - (C use)], [SERTRALINE] (C - n/a - [n/a - n/a - (C use)])
EU-EC-10014025984	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported

											Chest pain (n/a - Unknown - ), Headache (1d - Recovered/Resolved - ), Nausea (1d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - ), Vaccination site pain (3d - Recovered/Resolved - )	n/a - n/a - [n/a - n/a - n/a]	
EU-EC-10014025986	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014026088	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Unknown - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014026089	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Poor quality sleep (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014026101	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ageusia (n/a - Recovering/Resolving - ), Dizziness (n/a - Recovering/Resolving - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Recovering/Resolving - ), Vaccination site pain (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - Or use])	
EU-EC-10014026121	16/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown - ), Eye pain (n/a - Unknown - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Photophobia (n/a - Not Recovered/Not Resolved - ), Vaccination site swelling (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - n/a - n/a - [n/a - n/a - Or use]), [MELATONIN] (C - r - n/a - [n/a - n/a - C use]), [METHYLPHENIDAT HYDROCHLORIDE] (C - n/a - n/a - [n/a - r - Oral use]), [PROPIOMAZINE, PROPIOMAZINE MALEATE] (C - n/a - n/a - [n/a - n/a - Or use])	
EU-EC-10014026128	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (n/a - Not Recovered/Not Resolved - ), Pain (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014027549	16/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (n/a - Unknown - ), Headache (n/a - Unknown - ), Increased viscosity of upper respiratory secretion (n/a - Unknown - ), Sneezing (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	
EU-EC-10014027702	16/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Aggression (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling), Chronic fatigue syndrome (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	

											Resolved - Caused/Prolonged Hospitalisation, Disabling), Freezing phenomenon (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Panic attack (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling), Tremor (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling)		
EU-EC-10014002719	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	[DIENOGEST, ETHINYLESTRADIOLACTOSE, LACTOSE ANHYDROUS] (C - Amenorrhoea - n/a [n/a - n/a - n/a])	
EU-EC-10014002999	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (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-10014004116	15/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Hypoaesthesia (n/a - Not Recovered/Not Resolved - ), Peripheral swelling (n/a - Not Recovered/Not Resolved - ), Swelling of eyelid (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported	
EU-EC-10014004802	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Recovering/Resolving - ), Chills (1d - Recovered/Resolved - ), Swelling (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014005395	15/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Pescosolido, E.. Clinical and immunological data from chronic urticaria onset after mRNA SARS-CoV-2 vaccines. Clinical and Experimental Allergy, 2022;52(11):1343-1346. doi:10.1111/cea.14214	12-17 Years	Not Specified	Male	No	Urticaria chronic (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10014006432	15/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - ), Condition aggravated (n/a - Unknown - ), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diabetes mellitus (36d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diabetic ketoacidosis (36d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hyperglycaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), Interchange of vaccine products (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	



										Off label use (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown - ), Peripheral circulatory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Type 1 diabetes mellitus (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation), Weight decreased (n/a - Unknown - )		
EU-EC-10014006452	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014006850	15/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Visual field defect (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	COMIRNATY [TOZINAMERAN] (C COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]), [DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE MONOHYDRATE] (C Acne - Dose not changed - [n/a - n/a - n/a])
EU-EC-10014006890	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Autoimmune thyroiditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menstruation delayed (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10014006915	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving - ), Chills (1d - Recovered/Resolved - ), Malaise (n/a - Recovering/Resolving - ), Myalgia (n/a - Recovering/Resolving - ), Nasal congestion (n/a - Unknown - ), Oropharyngeal pain (n/a - Unknown - ), Pyrexia (2d - Recovered/Resolved - ), Vaccination site pain (3d - Recovered/Resolved - ), Vaccination site swelling (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014006935	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

											Unknown - Caused/Prolonged Hospitalisation)		
EU-EC-10014007098	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported	
EU-EC-10014007139	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported	
EU-EC-10014008041	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain (n/a - Not Recovered/Not Resolved - ), Pruritus (n/a - Not Recovered/Not Resolved - ), Vaccination site swelling (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014008274	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Enlarged uvula (1d - Recovered/Resolved - ), Oropharyngeal pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014008515	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (n/a - Unknown - ), Headache (4d - Recovered/Resolved - ), Limb discomfort (4d - Recovered/Resolved - ), Myalgia (6d - Recovered/Resolved - ), Pain (4d - Recovered/Resolved - ), Pyrexia (5d - Recovered/Resolved - ), Rash (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014008585	15/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Lymphadenitis (n/a - Not Recovered/Not Resolved - ), Neck pain (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014008646	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Palpitations (n/a - Not Recovered/Not Resolved - ), Sleep disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014008676	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Not Recovered/Not Resolved - ), Chills (n/a - Recovering/Resolving - ), Dyspnoea (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Recovering/Resolving - ), Hypoaesthesia (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	



										Recovered/Resolved - ), Malaise (n/a - Unknown - ), Swelling (5d - Recovered/Resolved - ), Vaccination site oedema (n/a - Unknown - )		
EU-EC-10014010616	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - ), Menstrual disorder (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014010641	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Recovering/Resolving - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014010713	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - ), Vaccination site pain (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014010856	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014011015	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (2d - Recovered/Resolved - ), Erythema (n/a - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - ), Influenza like illness (n/a - Recovered/Resolved - ), Malaise (2d - Recovered/Resolved - ), Nausea (2d - Recovered/Resolved - ), Pyrexia (2d - Recovered/Resolved - ), Vaccination site pain (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014011111	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - ), Ear pain (n/a - Unknown - ), Headache (n/a - Recovered/Resolved - ), Ocular hyperaemia (n/a - Not Recovered/Not Resolved - ), Oropharyngeal pain (n/a - Recovering/Resolving - ), Pain in extremity (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014011136	15/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site erythema (n/a - Not Recovered/Not Resolved - ), Pyrexia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported



				Area							- )	n/a - n/a - [n/a - n/a - n/a]	
EU-EC-10014012209	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cold sweat (n/a - Unknown - ), Headache (2d - Recovered/Resolved - ), Illness (n/a - Unknown - ), Nausea (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014012228	15/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Persistent postural-perceptual dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10014012611	15/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypertension (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[NORETHISTERONE ACETATE, ETHINYLESTRADIOL (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10014012775	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Recovering/Resolving - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (n/a - n/a - [n/a - n/a - n/a] - Oral use)	
EU-EC-10014012832	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (1d - Recovered/Resolved - ), Malaise (n/a - Unknown - ), Pyrexia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014012927	15/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - ), Dizziness (0d - Recovered/Resolved - ), Fatigue (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Malaise (n/a - Recovering/Resolving - ), Myalgia (n/a - Recovering/Resolving - ), Nausea (0d - Recovered/Resolved - ), Vaccination site erythema (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Recovering/Resolving - ), Vaccination site pruritus (n/a - Not Recovered/Not Resolved - ), Vaccination site swelling (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014012966	15/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - ), Electrocardiogram T wave inversion (n/a - Recovering/Resolving - ), Nausea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10014013527	15/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	
EU-EC-10014013832	15/11/2022	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	

EU-EC-10013993272	14/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Abdominal pain upper (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Arthralgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Eye swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Eyelid oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Henoch-Schonlein purpura (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Joint swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myalgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Rash (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013994089	14/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Kukita, S.. Two Cases of Young Patients Presenting with Acute Perimyocarditis Due to Post-COVID-19 Vaccination Adverse Reaction. The 70th Annual Scientific Session of the Japanese College of Cardiology, 2022;70th:56	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 - [n/a - n/a - n/a])	Not reported
EU-EC-10013995104	14/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[BUDESONIDE, BUDESONIDE, MICRONISIDE] (C - r - n/a - [n/a - n/a - n/a]), [HYDROXYZINE DIHYDROCHLORIDE HYDROXYZINE HYDROCHLORIDE] (C - r - n/a - n/a - [n/a - r - Oral use]), [MELATONIN] (C - r - n/a - [n/a - n/a - C use]), [SERTRALINE] (C - r - n/a - [n/a - n/a - C use])
EU-EC-10013995250	14/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

										Localised oedema (4d - Recovered/Resolved - ), Lymphadenopathy (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 - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Vomiting (n/a - Not Recovered/Not Resolved - )		
EU-EC-10013996596	14/11/2022	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
EU-EC-10013997113	14/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (48h - Recovered/Resolved - ), Chills (48h - Recovered/Resolved - ), Headache (48h - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013997380	14/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Unknown - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10013998192	14/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Horino, T.. Newly diagnosed IgA nephropathy with gross haematuria following COVID-19 vaccination. QJM. 2022;115(1):28-29. doi:10.1093/qjmed/hcab305	12-17 Years	Not Specified	Male	No	IgA nephropathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013998331	14/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dermatitis allergic (0d - Recovered/Resolved - ), Lip swelling (0d - Recovered/Resolved - ), Pruritus (0d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013998537	14/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual cycle management (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013998567	14/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved - ), Dizziness (1d - Recovered/Resolved - ), Fatigue (1d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved - ), Hyperhidrosis (n/a - Unknown - ), Malaise (1d - Recovered/Resolved - ), Malaise (n/a - Unknown - ), Pyrexia (1d - Recovered/Resolved - ), Vaccination site pain (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013998683	14/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pruritus (n/a - Unknown - ), Rash (5d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported



EU-EC-10013998876	14/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013999256	14/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovering/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013999554	14/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - ), Blister (n/a - Unknown - ), Herpes zoster (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10014001203	14/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Peripheral swelling (4d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013987882	12/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (4d - Recovered/Resolved - ), Pyrexia (24h - Recovered/Resolved - ), Vaccination site pain (1wk - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013977939	11/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolved - Other Medically Important Condition), 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-10013977966	11/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (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-10013978351	11/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Post vaccination syndrome (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013978990	11/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Disturbance in attention (n/a - Unknown - ), Memory impairment (n/a - Unknown - ), Muscular weakness (n/a - Recovering/Resolved - ), Pain in extremity (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Subcutaneous use])	Not reported
EU-EC-10013979561	11/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (7d - Recovered/Resolved - Other Medically Important Condition), Peripheral swelling (4d - Recovered/Resolved - Other Medically Important Condition), Skin temperature (5d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013979605	11/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 30ug - Intramuscular use])	Not reported
EU-EC-10013981160	11/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - ), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])  ABILIFY [ARIPIPRAZOLE] (C - Autism spectrum disorder - n/a - [n/a - n/a - Oral use]),  [LITHIUM CARBONATE] (C - Autism spectrum disorder - n/a - [n/a - n/a - Oral use]),  [RISPERIDONE] (C - Autism spectrum disorder - n/a - [n/a - n/a - Oral use])	
EU-EC-10013981668	11/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013982248	11/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovered/Resolved With Sequelae - Disabling),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported

										Arthritis (152d - Recovered/Resolved With Sequelae - Disabling), Disturbance in attention (48d - Recovered/Resolved - Disabling, Other Medically Important Condition), Dysstasia (48d - Recovered/Resolved - Disabling, Other Medically Important Condition), Feeling abnormal (48d - Recovered/Resolved - Disabling, Other Medically Important Condition), Headache (48d - Recovered/Resolved - Disabling, Other Medically Important Condition), Juvenile idiopathic arthritis (n/a - Recovered/Resolved With Sequelae - Disabling, Other Medically Important Condition), Malaise (48d - Recovered/Resolved - Disabling, Other Medically Important Condition), Pyrexia (48d - Recovered/Resolved - Disabling, Other Medically Important Condition)	applicable - [1d - n/a - n/a]	
EU-EC-10013982258	11/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved - ), Feeling cold (n/a - Recovered/Resolved - ), Nasopharyngitis (n/a - Recovered/Resolved - ), Oropharyngeal pain (n/a - Recovered/Resolved - ), Rhinorrhoea (n/a - Recovered/Resolved - ), Vomiting (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[SOMATROPIN] (C - n/a - n/a - [n/a - 1.35mg - n/a])
EU-EC-10013983606	11/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Nakayama, M.. COVID-19 vaccination-related intraocular inflammation in Japanese patients. Graefes Archive for Clinical and Experimental Ophthalmology, 2022;1-3. doi:10.1007/s00417-022-05866-5	12-17 Years	Not Specified	Female	No	Autoimmune retinopathy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013983627	11/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013984596	11/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Recovering/Resolving - ), Headache (n/a - Recovered/Resolved - ), Hyperhidrosis (n/a - Recovered/Resolved - ), Pyrexia (n/a - Recovered/Resolved - ), Tonsillitis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013965169	10/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Encephalitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013965473	10/11/2022	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Body temperature increased (3d -	COMIRNATY [TOZINAMERAN] (S -	Not reported

				Area							Recovered/Resolved - )	COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]	
EU-EC-10013967617	10/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Disturbance in attention (n/a - Not Recovered/Not Resolved - ), Dyspnoea exertional (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Post vaccination syndrome (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013971062	10/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013971064	10/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Extrasystoles (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013972780	10/11/2022	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	
EU-EC-10013972790	10/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Colitis ulcerative (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Crohn's disease (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Inflammatory bowel disease (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-10013972968	10/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Kitazawa, T. A case of acute pericarditis that developed after the second novel corona virus vaccination. The 22nd Chiba Regional Meeting of the Japan Pediatric Society [The 1463rd, 2022;22nd:9	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Electrocardiogram ST segment elevation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Supraventricular extrasystoles (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Ventricular extrasystoles (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013973905	10/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Unknown - ), Lacrimation increased (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Rhinorrhoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported	
EU-EC-10013954855	09/11/2022	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Male	No	Lymph node pain (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S -	Not reported	

				Area									
EU-EC-10013955301	09/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Unknown - )	COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use]		Not reported
EU-EC-10013955361	09/11/2022	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), Interchange of vaccine products (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	DULOXETINE [DULOXETINE, DULOXETINE HYDROCHLORIDE] (n/a - n/a - [n/a - 60mg - n/a]), PREGABALIN [PREGABALIN] (C - n/a - [n/a - 75mg n/a]), [DROSPIRENONE, ETHINYLESTRADIOL LACTOSE, LACTOSE HYDROUS, LACTOSE MONOHYDRATE] (C Contraception - n/a [n/a - n/a - n/a])	
EU-EC-10013957373	09/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Guillain-Barre syndrome (27d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular use])		Not reported
EU-EC-10013958624	09/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Recovered/Resolved - ), Vaccination site erythema (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])		Not reported
EU-EC-10013959472	09/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenitis (10d - Recovering/Resolving - ), Lymphadenopathy (10d - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])		Not reported
EU-EC-10013959472	09/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])		Not reported
EU-EC-10013959996	09/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Diarrhoea (5d - Recovered/Resolved - ), Migraine (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])		Not reported
EU-EC-10013960928	09/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Gomes, S.. HERPES ZOSTER AND COVID-19 VACCINE: APURPOSE OF A CASE REPORT. Rev Port Med Geral Fam. 2022;38 (suppl 8):S53 Gomes, S.. HERPES ZOSTER E VACINA COVID-19: A PROPOSITO DE UM RELATO DE CASO. Rev Port Med Geral Fam. 2022;38 (suppl 8):S53	12-17 Years	Not Specified	Female	No	Herpes zoster (n/a - Unknown - ), Vaccination site pain (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])		Not reported
EU-EC-10013962363	09/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypomenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])		Not reported
EU-EC-10013962411	09/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])		Not reported
EU-EC-10013962488	09/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])		Not reported
EU-EC-10013962500	09/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vision blurred (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		Not reported
EU-EC-10013962510	09/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypomenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	DES Loratadine Tabletts [DES LORATADINE] (n/a - n/a - [n/a - n/a - Oral use]), [BUDESONIDE] (C - Asthma - n/a - [n/a n/a - Inhalation use]) [DES LORATADINE] (n/a - Seasonal allergy - [n/a - n/a - Oral	



										Hospitalisation), Disturbance in attention (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Performance status decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	immunisation - n/a - [n/a - 2{DF} - n/a]	
EU-EC-10013950459	08/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Chimatapu, S.. TWO CASES OF GRAVES&apos; DISEASE IN ADOLESCENTS FOLLOWING COVID-19 VACCINATIONS. Thyroid, 2022;32(Suppl 1):A111. doi:10.1089/thy.2022.29140.lb,abstracts	12-17 Years	Not Specified	Male	No	Basedow's disease (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013934046	07/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (14d - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (18d - Recovered/Resolved - Other Medically Important Condition), Nausea (16d - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013934353	07/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chills (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pain in extremity (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013934749	07/11/2022	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
EU-EC-10013936072	07/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported

											Vaccination failure (n/a - Unknown - Other Medically Important Condition)		
EU-EC-10013936777	07/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	BUDESONIDE [BUDESONIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [CETIRIZINE DIHYDROCHLORIDE] (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]), [SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a - n/a])	
EU-EC-10013936792	07/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Soft tissue swelling (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013936803	07/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10013936985	07/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved - ), Pain in extremity (1d - Recovered/Resolved - ), Pyrexia (1d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	[BENFOTIAMINE, CYANOCOBALAMIN, BENFOTIAMINE, PYRIDOXINE HYDROCHLORIDE] (C - n/a - n/a - )	
EU-EC-10013937524	07/11/2022	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 - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	
EU-EC-10013937780	07/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Recovering/Resolving - Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	
EU-EC-10013937910	07/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Substance-induced psychotic disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - 2{DF} - Intramuscular use])	Not reported	
EU-EC-10013939778	07/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Intracranial pressure increased (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-10013941671	07/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	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])	[INFLUENZA VIRUS] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10013932337	05/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pruritus (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Unknown - ), Urticaria (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013932378	05/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	AERIUS 5 MG FILM-COATED TABLET [DESLORATADINE] (C - n/a - n/a - [n/a - r - Oral use])	
EU-EC-10013932381	05/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Sluggishness (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	

										- Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC-10013921016	04/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Insomnia (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - ), Restlessness (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013921361	04/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Jongvilaikasem, P. CHILDHOOD NEPHROTIC SYNDROME AND ACUTE KIDNEY INJURY FOLLOWING THE SARS-COV-2 BNT162B2 VACCINE. Pediatric Nephrology, 2022;37(11):2865-2866. doi:10.1007/s00467-022-05630-1	12-17 Years	Not Specified	Male	No	Acute kidney injury (n/a - Unknown - Life Threatening, Other Medically Important Condition), Nephrotic syndrome (n/a - Unknown - Life Threatening, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013923799	04/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Body temperature increased (2d - Recovered/Resolved - ), Chills (1d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013925037	04/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abnormal loss of weight (n/a - Unknown - Caused/Prolonged Hospitalisation), Coeliac disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Muscle discomfort (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Somnolence (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013925051	04/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Alopecia areata (n/a - Not Recovered/Not Resolved - Disabling), Lymphadenopathy (n/a - Not	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - n/a - n/a - [n/a - 75ug - n/a]),



										Recovered/Not Resolved - Disabling)		[METHYLPHENIDAT (C - n/a - n/a - [n/a 20mg - n/a])
EU-EC-10013926054	04/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain lower (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013926565	04/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Petruzzelli, L.. Nephritis following SARS-COV-2 Vaccine: Causal or incidental correlation?, Pediatric Nephrology, 2022;37(11):2910-2911 Petruzzelli, L.. Nephritis following SARS-COV-2 Vaccine: Causal or incidental correlation?, Pediatric Nephrology, 2022;37(11):2911-2912. doi:10.1007/s00467-022-05630-1	12-17 Years	Not Specified	Male	No	Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Nephritis (n/a - Unknown - Life Threatening, Other Medically Important Condition), Weight increased (n/a - Unknown - )	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])	Not reported
EU-EC-10013926807	04/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Alopecia (n/a - Not Recovered/Not Resolved - ), Anxiety (n/a - Unknown - ), Cardiovascular disorder (n/a - Not Recovered/Not Resolved - ), Decreased appetite (n/a - Not Recovered/Not Resolved - ), Disturbance in attention (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Not Recovered/Not Resolved - ), Dyspnoea exertional (n/a - Unknown - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (1wk - Recovered/Resolved - ), Nausea (1wk - Recovered/Resolved - ), Performance status decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Post viral fatigue syndrome (n/a - Unknown - ), Pyrexia (1wk - Recovered/Resolved - ), Sense of oppression (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013926819	04/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood prolactin increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Disturbance in attention (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

										Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Labile hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Obesity (n/a - Unknown - Caused/Prolonged Hospitalisation), Post viral fatigue syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Throat irritation (n/a - Unknown - Caused/Prolonged Hospitalisation)		
EU-EC-10013926839	04/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Tremor (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013927357	04/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Menometrorrhagia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013929954	04/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenitis (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013908327	03/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (5d - Recovered/Resolved - ), Pyrexia (5d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013909836	03/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Unknown - ), Chest pain (n/a - Unknown - ), Chills (n/a - Unknown - ), Headache (n/a - Unknown - ), Malaise (n/a - Unknown - ), Tachycardia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10013911165	03/11/2022	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
EU-EC-10013911705	03/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (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

										Condition), Heavy menstrual bleeding (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC-10013913043	03/11/2022	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
EU-EC-10013913800	03/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Saito, C., A Case of Thyroid Crisis That Occurred After COVID-19 Vaccination. Folia Endocrinologica Japonica, 2022;98(2):585	12-17 Years	Not Specified	Female	No	Hyperthyroidism (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thyrotoxic crisis (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
EU-EC-10013915251	03/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Acne (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (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-10013915331	03/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Recovering/Resolving - ), Influenza like illness (n/a - Recovering/Resolving - ), Nausea (n/a - Recovering/Resolving - ), Palpitations (n/a - Recovering/Resolving - ), Vomiting (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013919308	03/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pruritus (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[AMOXICILLIN TRIHYDRATE] (C - r - n/a - [7d - n/a - n/a])
EU-EC-10013919389	03/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Encephalitis autoimmune (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013919906	03/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Flank pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (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-100139195816	02/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Gastrointestinal disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

										Hospitalisation, Disabling), Liver disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Nerve injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Nervous system disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Skin disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)		
EU-EC-10013897901	02/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Silis, P. Early experience with myocarditis and pericarditis in adolescents following vaccination against COVID-19 in Latvia.. <i>Cardiol-Young.</i> 2022;32 (Suppl. 2):S228	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-1001389670	02/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Mohamed, S., Case Report: Retinal vasculitis in two adolescents after COVID-19 vaccination. <i>Ocular Immunology and Inflammation.</i> 2022;10.1080/09273948.2022.2129694. doi:10.1080/09273948.2022.2129694	12-17 Years	Not Specified	Female	No	Periphlebitis (n/a - Recovered/Resolved - Other Medically Important Condition), Retinal vasculitis (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-1001389773	02/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (1412min - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (1412min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]), [COVID-19 VACCINE] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013901343	02/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Silis, P. Early experience with myocarditis and pericarditis in adolescents following vaccination against COVID-19 in Latvia. <i>Cardiol-Young.</i> 2022;32 (Suppl. 2):S228	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013902634	02/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Mohamed, S., Case Report: Retinal vasculitis in two adolescents after COVID-19 vaccination. <i>Ocular Immunology and Inflammation.</i> 2022;10.1080/09273948.2022.2129694. doi:10.1080/09273948.2022.2129694	12-17 Years	Not Specified	Male	No	Periphlebitis (n/a - Recovered/Resolved - Other Medically Important Condition), Retinal vasculitis (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013903688	02/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), 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])	COMIRNATY [TOZINAMERAN] (C COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])
EU-EC-10013903689	02/11/2022	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), Heavy menstrual bleeding (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-10013903860	02/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013903986	02/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Cardiovascular disorder (n/a - Unknown - ), Dyspnoea (n/a - Unknown - ), Nervous system disorder (n/a - Unknown - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

											Respiratory failure (n/a - Unknown - Other Medically Important Condition)		
EU-EC-10013905280	02/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - ), Diarrhoea (n/a - Unknown - ), Dry mouth (n/a - Unknown - ), Dyspepsia (n/a - Unknown - ), General physical health deterioration (n/a - Unknown - ), Skin swelling (n/a - Unknown - ), Vomiting (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013907184	02/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Decreased immune responsiveness (n/a - Unknown - ), Herpes zoster (n/a - Unknown - ), Infection (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013886693	01/11/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013889109	01/11/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Disorientation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Restlessness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013891811	01/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Silis, P. Early experience with myocarditis and pericarditis in adolescents following vaccination against COVID-19 in latvia. Cardiol-Young. 2022;32 (Suppl. 2):S228	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10013893520	01/11/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - ), Heart rate increased (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) [ISOTRETINOIN] (C n/a - n/a - [n/a - n/a - Oral use]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - Inhalation use])	[BUDESONIDE] (C - n/a - n/a - [n/a - n/a - Inhalation use]), [ISOTRETINOIN] (C n/a - n/a - [n/a - n/a - Oral use]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - Inhalation use])	
EU-EC-10013893630	01/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Silis, P. Early experience with myocarditis and pericarditis in adolescents following vaccination against COVID-19 in latvia. Cardiol-Young. 2022;32 (Suppl. 2):S228	12-17 Years	Not Specified	Male	No	Myocardial fibrosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	

										Medically Important Condition), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericardial fibrosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	applicable - [n/a - n/a - n/a]	
EU-EC-10013894040	01/11/2022	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 - Disabling), Menstrual disorder (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013895094	01/11/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved - ), Malaise (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[ADAPALENE, BENZOYL PEROXIDE] (C - Acne - n/a - [n/a - Cutaneous use) [IBUPROFEN] (C - P - n/a - [n/a - n/a - (C use)])
EU-EC-10013880048	31/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Ahmed, T., A report on short-term follow-up cardiac imaging and clinical outcomes of myocarditis after coronavirus disease 2019 vaccination. Journal of Cardiovascular Medicine, 2022;23(10):691-693, doi:10.2459/JCM.0000000000001341	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013880205	31/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Muscular weakness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013881247	31/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Petruzzelli, L., Nephritis following SARS-COV-2 Vaccine: Causal or incidental correlation?, Pediatric Nephrology, 2022;37(11):2911-2912, doi:10.1007/s00467-022-05630-1	12-17 Years	Not Specified	Male	No	Henoch-Schonlein purpura nephritis (n/a - Recovering/Resolving - Other Medically Important Condition), Proteinuria (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013883192	31/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest discomfort (n/a - Not Recovered/Not Resolved - ), Dyspnoea exertional (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), Palpitations (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013883958	31/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Disturbance in attention (n/a - Unknown - ), Dizziness (n/a - Unknown - ), Headache (n/a - Unknown - ), Tonsillitis (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013885044	31/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Smith, E., Multiple Evanescent White Dot Syndrome following COVID-19 mRNA Vaccination in Two Patients, Ocular Immunology and Inflammation, 2022;1-4, doi:10.1080/09273948.2022.2032198 Smith, E., Multiple Evanescent White Dot Syndrome following COVID-19 mRNA Vaccination in Two Patients, Ocular Immunology and Inflammation, 2022;30(5):1240-1243, doi:10.1080/09273948.2022.2032198	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown - ), Myalgia (n/a - Unknown - ), Retinal white dots syndrome (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013885137	31/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (2h - Recovered/Resolved - ), Loss of consciousness (2h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013885709	31/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (99h - Recovered/Resolved - Other Medically Important Condition), Dizziness (99h - Recovered/Resolved - Other Medically Important Condition), Headache (99h - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported

										Vomiting (99h - Recovered/Resolved - Other Medically Important Condition)		
EU-EC-10013886174	31/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myopericarditis (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	[ERYTHROMYCIN, ERYTHROCYCIN, ETHYLSUCCINATE, ERYTHROMYCIN ETHYLSUCCINATE F EUR., ERYTHROMYC STEARATE] (C - Abscess limb - n/a - [n/a - n/a - Oral use
EU-EC-10013886489	31/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Conversion disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dehydration (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Eating disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013887237	31/10/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013887379	31/10/2022	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 - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013878570	30/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (1d - Recovered/Resolved - ), Dyspnoea (n/a - Unknown - ), Palpitations (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

EU-EC-10013859843	28/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Palpitations (n/a - Unknown - ) Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013861192	28/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Haematoma (7d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013861521	28/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Kounisa, N.. Encephalitis, myocarditis, and thrombocytopenia after COVID-19 mRNA vaccination: Clinical and pathophysiological considerations. Journal of Neuroimmunology. 2022;373:10.1016/j.jneuroim.2022.577988. doi:10.1016/j.jneuroim.2022.577988	12-17 Years	Not Specified	Female	No	Encephalitis (n/a - Recovered/Resolved - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013861666	28/10/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Renal pain (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[SALBUTAMOL SULFATE] (C - Asthr - n/a - [n/a - n/a - n/a])
EU-EC-10013863601	28/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Electroencephalogram abnormal (n/a - Unknown - ), Epilepsy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported



										Hospitalisation, Other Medically Important Condition)		
EU-EC-10013865402	28/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Kojima, N., Case Report: Myocarditis Associated With COVID-19 mRNA Vaccination Following Myocarditis Associated With Campylobacter Jejuni. <i>Frontiers in Cardiovascular Medicine</i> . 2022;9:10.3389/fcvm.2022.837759. doi:10.3389/fcvm.2022.837759	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013866374	28/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - ), Chills (2d - Recovered/Resolved - ), Diarrhoea (n/a - Recovering/Resolving - ), Myalgia (3d - Recovered/Resolved - ), Nausea (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013866763	28/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (1d - Recovered/Resolved - ), Nausea (n/a - Recovering/Resolving - ), Rhinorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013866902	28/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - ), Chills (0d - Recovered/Resolved - ), Fatigue (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Myalgia (n/a - Not Recovered/Not Resolved - ), Nausea (n/a - Recovering/Resolving - ), Pain in extremity (n/a - Not Recovered/Not Resolved - ), Presyncope (n/a - Recovering/Resolving - ), Vomiting (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[CYPROTERONE ACETATE, ETHINYLESTRADIOL] (C - n/a - n/a - [n/a - n/a - Oral use])
EU-EC-10013867000	28/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pruritus (n/a - Not Recovered/Not Resolved - ), Rash (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013867063	28/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (7d - Recovered/Resolving - ), Oral pain (n/a - Not Recovered/Not Resolved - ), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - ), Throat irritation (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013867476	28/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Drug ineffective (108d - Recovered/Resolved - Other Medically Important Condition), Suspected COVID-19 (108d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013867504	28/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Acute respiratory distress syndrome (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Rash erythematous - n/a [n/a - n/a - n/a]), [CHLORMEZANONE]



										<p>Serum ferritin increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),</p> <p>Skin exfoliation (n/a - Not Recovered/Not Resolved - Life Threatening),</p> <p>Stevens-Johnson syndrome (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition),</p> <p>Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition),</p> <p>Toxic epidermal necrolysis (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition)</p>		
EU-EC-10013867835	28/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	<p>Asthenia (n/a - Not Recovered/Not Resolved - ),</p> <p>Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ),</p> <p>Menstrual disorder (n/a - Not Recovered/Not Resolved - ),</p> <p>Mental disorder (n/a - Not Recovered/Not Resolved - ),</p> <p>Muscle spasms (n/a - Not Recovered/Not Resolved - ),</p> <p>Pain (n/a - Not Recovered/Not Resolved - )</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013848235	27/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	<p>Burning sensation (n/a - Recovering/Resolving - ),</p> <p>Contusion (n/a - Recovering/Resolving - ),</p> <p>Fatigue (n/a - Recovering/Resolving - ),</p> <p>Pain in extremity (n/a - Recovering/Resolving - )</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10013848250	27/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	<p>Alopecia (n/a - Recovering/Resolving - ),</p> <p>Breakthrough COVID-19 (n/a - Recovered/Resolved - ),</p> <p>Food allergy (n/a - Recovering/Resolving - ),</p> <p>Weight decreased (n/a - Recovering/Resolving - )</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10013848630	27/10/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	<p>COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition),</p> <p>Cough (n/a - Unknown - ),</p> <p>Malaise (n/a - Unknown - ),</p> <p>Pyrexia (n/a - Unknown - ),</p> <p>Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013849043	27/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	<p>Headache (n/a - Not Recovered/Not Resolved - ),</p> <p>Injection site joint</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a -	Not reported

										movement impairment (n/a - Not Recovered/Not Resolved - ), Pain in extremity (n/a - Not Recovered/Not Resolved - )	[n/a - n/a - Intramuscular use]]	
EU-EC-10013850867	27/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Contusion (n/a - Recovered/Resolved - ), Rash (3d - Recovered/Resolved - )	COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]]	Not reported
EU-EC-10013852687	27/10/2022	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
EU-EC-10013853688	27/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (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
EU-EC-10013854007	27/10/2022	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 - Unknown - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013854178	27/10/2022	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
EU-EC-10013854436	27/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ), Headache (n/a - Not Recovered/Not Resolved - ), 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 - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013855226	27/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Influenza (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013855244	27/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angina pectoris (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Arrhythmia (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Body temperature decreased (n/a - Unknown - ), Bradycardia (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Brugada syndrome (n/a - Unknown - Other Medically Important Condition), Cyanosis (n/a - Unknown - ), Dyspnoea (n/a - Not Recovered/Not Resolved - Life Threatening),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]]	Not reported

										<p>Feeling cold (n/a - Not Recovered/Not Resolved - Life Threatening),</p> <p>Muscle disorder (n/a - Unknown - ),</p> <p>Muscle spasms (n/a - Unknown - Caused/Prolonged Hospitalisation),</p> <p>Pancytopenia (n/a - Unknown - Other Medically Important Condition),</p> <p>Pulse absent (n/a - Unknown - ),</p> <p>Seizure (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition),</p> <p>Speech disorder (n/a - Unknown - ),</p> <p>Tachycardia (n/a - Not Recovered/Not Resolved - Life Threatening),</p> <p>Tremor (n/a - Unknown - )</p>		
EU-EC-10013856340	27/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	<p>Alopecia (n/a - Not Recovered/Not Resolved - ),</p> <p>Altered state of consciousness (n/a - Unknown - Other Medically Important Condition),</p> <p>Cardiovascular disorder (n/a - Not Recovered/Not Resolved - ),</p> <p>Decreased appetite (n/a - Not Recovered/Not Resolved - ),</p> <p>Depressive symptom (n/a - Not Recovered/Not Resolved - ),</p> <p>Disturbance in attention (n/a - Not Recovered/Not Resolved - ),</p> <p>Dizziness (n/a - Not Recovered/Not Resolved - ),</p> <p>Dyspnoea (n/a - Not Recovered/Not Resolved - ),</p> <p>Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),</p> <p>Female reproductive tract disorder (n/a - Unknown - ),</p> <p>Headache (1wk - Recovered/Resolved - ),</p> <p>Inappropriate schedule of product administration (n/a - Unknown - ),</p> <p>Joint swelling (n/a - Unknown - ),</p> <p>Loss of consciousness (n/a - Unknown - Other Medically Important Condition),</p> <p>Memory impairment (n/a - Unknown - ),</p> <p>Menstrual disorder (n/a - Unknown - ),</p> <p>Migraine (n/a - Unknown - ),</p> <p>Nausea (1wk - Recovered/Resolved - ),</p> <p>Nervous system disorder (n/a - Unknown - ),</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

											Performance status decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (1wk - Recovered/Resolved - ), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Sense of oppression (n/a - Not Recovered/Not Resolved - ), Tremor (n/a - Unknown - )		
EU-EC-10013857241	27/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (n/a - Recovering/Resolving - ), Vaccination site pain (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[PARACETAMOL] (C n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10013857297	27/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013857510	27/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Skin reaction (n/a - Recovering/Resolving - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular use])	Not reported	
EU-EC-10013857528	27/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular use])	Not reported	
EU-EC-10013857620	27/10/2022	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 - .3mL - Intramuscular use])	Not reported	
EU-EC-10013838955	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - ), Fall (n/a - Not Recovered/Not Resolved - ), Pericardial effusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	
EU-EC-10013839246	26/10/2022	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), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular use - More in ICSR])	Not reported	
EU-EC-10013839267	26/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Heart rate increased (n/a - Unknown - ), Nasal obstruction (n/a - Recovering/Resolving - Other Medically Important Condition), Oropharyngeal pain (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular use])	Not reported	
EU-EC-10013839572	26/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013841080	26/10/2022	Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	

				Economic Area						Condition), Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	immunisation - Not applicable - [1d - n/a - n/a]	
EU-EC-10013841181	26/10/2022	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]), [COVID-19 VACCINE] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013841426	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anxiety (n/a - Recovering/Resolving - ), Cardiac discomfort (n/a - Recovering/Resolving - ), Chest discomfort (n/a - Recovering/Resolving - ), Headache (3d - Recovered/Resolved - ), Pain in extremity (n/a - Recovering/Resolving - ), Productive cough (n/a - Recovering/Resolving - ), Pyrexia (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013842337	26/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Ahmed, T.. A report on short-term follow-up cardiac imaging and clinical outcomes of myocarditis after coronavirus disease 2019 vaccination. Journal of Cardiovascular Medicine. 2022;23 (10):691-693. doi:10.2459/JCM.0000000000001341	12-17 Years	Not Specified	Male	No	Myocarditis (24h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013842429	26/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation), Deep vein thrombosis (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Muscle injury (n/a - Unknown - ), Pain in extremity (n/a - Unknown - ), Peripheral swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Surgery (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013842645	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013842649	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arrhythmia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013842724	26/10/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition), Suspected COVID-19 (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported

EU-EC-10013842908	26/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- Other Medically Important Condition) Epistaxis (5d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013842984	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oligomenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013842988	26/10/2022	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 - ), Polymenorrhoea (n/a - Not Recovered/Not Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013843164	26/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (1819h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chills (79d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (1819h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Electrocardiogram repolarisation abnormality (76d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (79d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (1818h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (1818h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (79d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013843430	26/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypersensitivity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash erythematous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Urticaria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013843552	26/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Administration site pain (3d - Recovered/Resolved - ), Body temperature increased (3d - Recovered/Resolved - ), Headache (3d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013843559	26/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Disabling), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Disabling), Iron deficiency anaemia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported



										Resolved - Disabling), Menstruation irregular (n/a - Not Recovered/Not Resolved - Disabling)		
EU-EC-10013843655	26/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Ahmed, T., A report on short-term follow-up cardiac imaging and clinical outcomes of myocarditis after coronavirus disease 2019 vaccination. Journal of Cardiovascular Medicine. 2022;23(10):691-693, doi:10.2459/JCM.0000000000001341	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013843924	26/10/2022	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), Palpitations (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-10013844251	26/10/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hyperthyroidism (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rhabdomyolysis (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
EU-EC-10013844511	26/10/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic shock (n/a - Recovered/Resolved - Other Medically Important Condition), Angioedema (n/a - Recovered/Resolved - Other Medically Important Condition), Hypotension (n/a - Recovered/Resolved - Other Medically Important Condition), Urticaria (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-10013844541	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Limb discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013844572	26/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Immunisation stress-related response (n/a - Recovered/Resolved - ), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013845921	26/10/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Immunodeficiency (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013846654	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown - ), Cough (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013846666	26/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (1d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

											Vaccination site pain (2d - Recovered/Resolved - )		
EU-EC-10013847012	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - ), Lymphadenopathy (7d - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	
EU-EC-10013847016	26/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pain in extremity (n/a - Recovering/Resolving - ), Pain threshold decreased (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	
EU-EC-10013847120	26/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	
EU-EC-10013847628	26/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Recovered/Resolved - ), Malaise (n/a - Recovered/Resolved - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10013847818	26/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Ahmed, T.. A report on short-term follow-up cardiac imaging and clinical outcomes of myocarditis after coronavirus disease 2019 vaccination. Journal of Cardiovascular Medicine. 2022;23(10):691-693. doi:10.2459/JCM.0000000000001341	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10013830162	25/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved - ), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported	
EU-EC-10013830182	25/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	COVID-19 (10172min - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (10172min - Recovered/Resolved - Other Medically Important Condition), Headache (2833min - Recovered/Resolved - Other Medically Important Condition), Pyrexia (2702min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use - More in ICSR])	Not reported	
EU-EC-10013830295	25/10/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epilepsy (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	
EU-EC-10013831805	25/10/2022	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 - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013831935	25/10/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown - ), Fatigue (n/a - Unknown - ), Headache (n/a - Unknown - ), Pyrexia (n/a - Unknown - )	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013832342	25/10/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (8d - Recovered/Resolved - ), Fatigue (8d - Recovered/Resolved - ), Injection site pain (8d - Recovered/Resolved - ),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	

											Injection site reaction (8d - Recovered/Resolved - ), Malaise (8d - Recovered/Resolved - )		
EU-EC-10013832807	25/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (9d - Recovered/Resolved - Other Medically Important Condition), Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (9d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013832852	25/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Alopecia areata (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013832951	25/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dysmenorrhoea (n/a - Unknown - ), Heavy menstrual bleeding (n/a - Recovering/Resolving - ), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013833231	25/10/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (10d - Recovered/Resolved - Other Medically Important Condition), Dizziness (10d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (10d - Recovered/Resolved - Other Medically Important Condition), Hypoaesthesia (10d - Recovered/Resolved - Other Medically Important Condition), Palpitations (10d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013833401	25/10/2022	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), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	

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