

Line Listing Report

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EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome – Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (D Char - Indication PT - Action taken - [Duration - Dose - Route])
EU-EC-10013623242	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Muscle twitching (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013623340	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -), Gait disturbance (n/a - Unknown -), Musculoskeletal discomfort (n/a - Unknown -), Myalgia (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-10013623556	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Alopecia areata (n/a - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	[LEVOCETIRIZINE DIHYDROCHLORIDE, LEVOCETIRIZINE HYDROCHLORIDE] (C - Seasonal allergy - n/a - [n/a - Oral use])
EU-EC-10013623593	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013623787	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (n/a - Unknown -), Myalgia (4d - Recovered/Resolved -), Pyrexia (4d - Recovered/Resolved -), Rash (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013623831	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown -), Dysphagia (n/a - Not Recovered/Not Resolved -), Insomnia (n/a - Unknown -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Secretion discharge (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])	Not reported
EU-EC-10013623835	29/09/2022	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-10013623984	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (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
EU-EC-10013624047	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (2d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

										Vaccination site pain (n/a - Recovering/Resolving -)		
EU-EC-10013624165	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013625143	29/09/2022	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-10013625491	29/09/2022	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-10013626046	29/09/2022	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-10013627421	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (n/a - Unknown -), Diplopia (n/a - Unknown -), Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Facial paresis (n/a - Unknown -), Headache (n/a - Unknown -), Limb discomfort (n/a - Recovering/Resolving -), Malaise (n/a - Unknown -), Neuralgia (n/a - Unknown -), Stridor (n/a - Unknown -), T-cell lymphoma recurrent (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), T-cell lymphoma stage IV (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Testicular swelling (n/a - Unknown -), Thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013627708	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

										Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)		
EU-EC-10013627850	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Hypersensitivity (n/a - Recovered/Resolved -), Palpitations (n/a - Recovered/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-10013628256	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pain (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Vaccination site pain (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013628330	29/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eye pain (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Lacrimation increased (n/a - Not Recovered/Not Resolved -), Photophobia (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-10013628379	29/09/2022	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])	Not reported
EU-EC-10013628413	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (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-10013628496	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown -), Myalgia (1d - Recovered/Resolved -), Pain in extremity (n/a - Unknown -), Pyrexia (2d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013628641	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -), Dizziness (1d - Recovered/Resolved -), Nausea (n/a - Unknown -), Palpitations (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

EU-EC-10013628774	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown -), Decreased appetite (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013628792	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013628848	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lip pruritus (1d - Recovered/Resolved -), Lip swelling (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013628865	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Oropharyngeal 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-10013628886	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving -), Lymphadenopathy (n/a - Recovering/Resolving -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013628965	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Alopecia universalis (399d - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013628975	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Oropharyngeal pain (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-10013629347	29/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013629788	29/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013611751	28/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (45d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013613528	28/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pain (n/a - Recovering/Resolving -), Paraesthesia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013613914	28/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved With Sequelae - Disabling, Other Medically Important Condition), Disturbance in attention (n/a - Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

										Recovered/Not Resolved - Disabling, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Disabling, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Flatulence (136d - Recovered/Resolved - Disabling, Other Medically Important Condition), Infection susceptibility increased (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition), Parosmia (122d - Recovered/Resolved - Disabling, Other Medically Important Condition), Stress (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)		
EU-EC-10013614619	28/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10013616510	28/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013617147	28/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013617247	28/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013617435	28/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Pedersen, A.. Clinical presentation and cardiac imaging findings in patient cases of perimyocarditis and pericarditis with a temporal association to SARS-CoV-2 vaccination, <i>Frontiers in Cardiovascular Medicine</i> , 2022;9:10.3389/fcvm.2022.964412. doi:10.3389/fcvm.2022.964412	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013617438	28/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Santilli, V.. Two Pediatric Cases of Multisystem Inflammatory Syndrome with Overlapping Neurological Involvement Following SARS-CoV-2 Vaccination and Unknown SARSCoV2 Infection: The Importance of Pre-Vaccination History, <i>Vaccines</i> , 2022;10(7):10.3390/vaccines10071136. doi:10.3390/vaccines10071136	12-17 Years	Not Specified	Female	No	Cytotoxic lesions of corpus callosum (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported

										Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Multisystem inflammatory syndrome in children (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC-10013617735	28/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013617744	28/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Neuralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Neuropathy peripheral (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	[MIDODRINE HYDROCHLORIDE] (C - Orthostatic intolerance - n [n/a - n/a - Oral use]), [PARACETAMOL] (C - Orthostatic intolerance - n [n/a - n/a - Oral use]), [TAK 438] (C - Orthostatic intolerance - n/a - [n/a - r Oral use])
EU-EC-10013617788	28/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Unknown -), Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Electrocardiogram ST segment elevation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electrocardiogram change (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown -), Inflammation (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Troponin I increased (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-	28/09/2022	Spontaneous	Healthcare	Non	Not available	12-17	Not	Male	No	Chest discomfort	COMIRNATY	Not reported

10013617789			Professional	European Economic Area		Years	Specified			(n/a - Recovering/Resolving -), Chest pain (n/a - Unknown -), Electrocardiogram ST segment elevation (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Pleurisy (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	
EU-EC-10013618052	28/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (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-10013618340	28/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Seizure (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use]), [INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013618523	28/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Sawatari, C.. Deep Vein Thrombosis and Pulmonary Thrombosis After BNT162b2 mRNA SARSCoV2 Vaccination. Circulation Journal. 2022;86(7):1145. doi:10.1253/circj.CJ-21-1055 Iwashima, S.. A Case of Deep Vein Thrombosis That Occurred After Vaccination with SARS-CoV2 Vaccine in a 14-year-old Male Child. The 133rd Tokai Branch Meeting of Japanese Society of Pediatric Cardiology and. 2022;133rd	12-17 Years	Not Specified	Male	No	Deep vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Unknown -), Pulmonary embolism (n/a - Unknown - Other Medically Important Condition), Pulmonary infarction (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombosis with thrombocytopenia syndrome (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013618956	28/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Pedersen, A.. Clinical presentation and cardiac imaging findings in patient cases of perimyocarditis and pericarditis with a temporal association to SARS-CoV-2 vaccination. Frontiers in Cardiovascular Medicine. 2022;9:10.3389/fcvm.2022.964412. doi:10.3389/fcvm.2022.964412	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])	Not reported
EU-EC-10013619503	28/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Pedersen, A.. Clinical presentation and cardiac imaging findings in patient cases of perimyocarditis and pericarditis with a temporal association to SARS-CoV-2 vaccination. Frontiers in Cardiovascular Medicine. 2022;9:10.3389/fcvm.2022.964412. doi:10.3389/fcvm.2022.964412	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])	Not reported
EU-EC-10013619732	28/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Migraine (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not reported
EU-EC-	27/09/2022	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Loss of	COMIRNATY	Not reported

10013602365			Healthcare Professional	Economic Area		Years	Specified				consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	
EU-EC-10013602509	27/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No		Alopecia (n/a - Not Recovered/Not Resolved -), Asthenia (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013602540	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No		Dermatitis bullous (n/a - Unknown - Other Medically Important Condition), Papillary thyroid cancer (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013602856	27/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		Asthma (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Bronchitis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013602891	27/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No		Back pain (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Urinary tract infection (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013603103	27/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Cough (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), 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-10013603371	27/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Aplastic anaemia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013603518	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No		Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Back pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

											Resolved - Other Medically Important Condition), Exercise tolerance decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC-10013604386	27/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Administration site pain (36d - Recovered/Resolved -), Body temperature increased (12h - Recovered/Resolved -), Headache (12h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular use])	Not reported	
EU-EC-10013604835	27/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Administration site pain (36d - Recovered/Resolved -), Body temperature increased (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	
EU-EC-10013604846	27/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Body temperature increased (3d - Recovering/Resolving -), Headache (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	
EU-EC-10013604884	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10013604931	27/09/2022	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-10013604997	27/09/2022	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-10013605307	27/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Kar, S., POST COVID VACCINE ACUTE KIDNEY INJURY: A CASE REPORT. <i>Kidney International Reports</i> . 2022;7(9 Suppl):S463. doi:10.1016/j.ekir.2022.07.017	12-17 Years	Not Specified	Male	No	Acute kidney injury (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-10013605862	27/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenitis (2d - Unknown -), Lymphadenopathy (2d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported	
EU-EC-10013606234	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Limb discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	

EU-EC-10013606511	27/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Resolved - Caused/Prolonged Hospitalisation) 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-10013606827	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Not Recovered/Not Resolved -), Nasal discomfort (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013607149	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a - Recovering/Resolving -), Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013607222	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10013607276	27/09/2022	Spontaneous	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), Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Uterine pain (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-10013607593	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013607807	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved -), Somnolence (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013608092	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -), Injection site reaction (3d - Recovered/Resolved -), Injection site swelling (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) [CALCIUM CARBONATE, CHOLECALCIFEROL CONCENTRATE (POWDER FORM)] (C - n/a - Unknown [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - Unknown - [n/a - n/a - n/a])	
EU-EC-10013608527	27/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Petit mal epilepsy (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-10013610240	27/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myalgia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013593787	26/09/2022	Spontaneous	Healthcare Professional	Non European	Yoshida, C., A case in which improvement of COVID-19 vaccine	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase	COMIRNATY [TOZINAMERAN] (S -)	Not reported

				Economic Area	related myocarditis could be observed on cardiac contrast MRI examination. The 133rd Kinki Branch Regular Meeting of The Japanese Circulation Society, 2022;133rd:63					increased (124h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (124h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Inflammation (124h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (124h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Troponin T increased (124h - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	
EU-EC-10013595164	26/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (2d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013595529	26/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013596639	26/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Asthenia (1d - Recovered/Resolved -), Head discomfort (1d - Recovered/Resolved -), Presyncope (1d - Recovered/Resolved -), Vision blurred (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013596671	26/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (2d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013596949	26/09/2022	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-10013597358	26/09/2022	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-10013598349	26/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Unknown - Other Medically Important Condition), Polymenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013598441	26/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Blood pressure decreased (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-	26/09/2022	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Male	No	Conjunctivitis (1d -	COMIRNATY	Not reported

Run Line Listing Report

10013598743			Professional	Economic Area		Years				Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	
EU-EC-10013598762	26/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013599744	26/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Confusional state (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Injection site reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Memory impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mental impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013600286	26/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Rash (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013601088	26/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hodgkin's disease (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013601683	26/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a n/a - Oral use]), [PARACETAMOL] (C - Pain n/a - [n/a - n/a - Oral use]
EU-EC-10013577389	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (11mo - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Rapid eye movement sleep behaviour disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sleep attacks (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013578747	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013579022	23/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Ankylosing spondylitis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Juvenile idiopathic arthritis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	INTUNIV [GUANFACINE] (Attention deficit hyperactivity disorder - n/a - [n/a - n/a Oral use]), [CALCIUM, MAGNESIUM] n/a - n/a - [n/a - n/a - n/a - n/a - n/a], [METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a Oral use])

EU-EC-10013579675	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013579689	23/09/2022	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 -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013579732	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain in extremity (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013579852	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (21d - Recovering/Resolving -), Dyspnoea (21d - Recovering/Resolving -), Headache (21d - Recovering/Resolving -), Paraesthesia (21d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013579906	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013579957	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Varicella meningitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013580079	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Body temperature increased (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013580188	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Body temperature increased (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013580245	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Unknown -), Irritability (1d - Unknown -), Mood altered (1d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013580478	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (1d - Recovered/Resolved -), Body temperature increased (1d - Recovered/Resolved -), Eosinophilia (n/a - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Rash (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	[BETAMETHASONE DIPROPIONATE] (C - n/a - n/a - [n/a - n/a - Topical]) [FUSIDIC ACID] (C - n/a - [n/a - n/a - Topical]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - Oral use)
EU-EC-10013580506	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenitis (3d - Recovering/Resolving -), Lymphadenopathy (3d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013580588	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Educational problem (n/a - Unknown -), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported

										Recovered/Not Resolved - Disabling), Impaired quality of life (n/a - Unknown -)		
EU-EC-10013581528	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013581995	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Autoantibody positive (n/a - Unknown -), Chronic fatigue syndrome (n/a - Not Recovered/Not Resolved - Disabling), Celiac disease (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Disturbance in attention (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Food intolerance (n/a - Not Recovered/Not Resolved -), Heart rate increased (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Muscle spasms (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Post vaccination syndrome (n/a - Not Recovered/Not Resolved - Disabling), Weight bearing difficulty (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013582343	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menometrorrhagia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Weight decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]), [CYPROTERONE ACETATE, ETHINYLESTRADIOL] (S - Contraception - Drug withdrawn - [n/a - 1{DF} - Oral use])	Not reported
EU-EC-10013582467	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013582563	23/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cyanosis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported

											Dysaesthesia (n/a - Not Recovered/Not Resolved -)	immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	
EU-EC-10013582669	23/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Night sweats (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013583909	23/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Fall (n/a - Unknown -), Heart rate decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Neck pain (n/a - Unknown -), Pain (n/a - Unknown -), Vision blurred (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013583962	23/09/2022	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), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013584626	23/09/2022	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 (n/a - Recovering/Resolving -), Diarrhoea (n/a - Unknown -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Unknown -), Pyrexia (n/a - Not Recovered/Not Resolved -), Vaccination site erythema (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Recovering/Resolving -), Vaccination site pruritus (n/a - Recovering/Resolving -), Vaccination site swelling (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013584693	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (n/a - Not Recovered/Not Resolved -), Peripheral swelling (n/a - Not Recovered/Not Resolved -), Pruritus (n/a - Not Recovered/Not Resolved -), Rash macular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10013584732	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anxiety (n/a - Unknown -), Bone pain (n/a - Recovering/Resolving -), Chest discomfort	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	

										(n/a - Recovering/Resolving -), Dyspnoea (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Pyrexia (n/a - Unknown -)		
EU-EC-10013585157	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown -), Depressed mood (n/a - Unknown -), Nausea (n/a - Unknown -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013585198	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Malaise (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Unknown -), Rhinorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013585201	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (28d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013585277	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (1d - Recovered/Resolved -), Somnolence (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013585280	23/09/2022	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 -), Malaise (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Vaccination site erythema (3d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -), Vaccination site pruritus (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013585360	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Hypoesthesia (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Unknown -), Nausea (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-10013585466	23/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nasopharyngitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013585704	23/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Polyarthritis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	INTUNIV [GUANFACINE] (Attention deficit hyperactivity disorder - n/a - [n/a - n/a Oral use]), [METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a Oral use])
EU-EC-10013586452	23/09/2022	Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Unknown - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	[FLUTICASON PROPRION/SALMETEROL, FLUTICASC PROPRIONATE, SALMETEROL]

				Economic Area						Condition), Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Hot flush (n/a - Recovered/Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Tremor (n/a - Recovered/Resolved - Other Medically Important Condition), Vertigo (n/a - Recovering/Resolving - Other Medically Important Condition), Vision blurred (n/a - Recovering/Resolving - Other Medically Important Condition)	immunisation - Not applicable - [1d - n/a - n/a]) [PARACETAMOL] (C - Headache - n/a - [n/a - n/a]), [SALBUTAMOL, SALBUTAM MICRONIZED, SALBUTAM SULFATE] (C - Asthma - n, [n/a - n/a - n/a])	XINAFOATE] (C - Asthma n/a - [n/a - n/a - n/a]),
EU-EC-10013568297	22/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), 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-10013569464	22/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Infection susceptibility increased (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Malaise (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-10013570068	22/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain lower (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Abnormal faeces (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Arthralgia (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ear pain (38d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Epstein-Barr virus infection (38d - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

										Resolved - Caused/Prolonged Hospitalisation), Fatigue (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (37d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Influenza (38d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Listless (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myalgia (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocarditis (38d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Neck pain (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (38d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sensory disturbance (38d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Sleep disorder (246d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (38d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)		
EU-EC-10013571486	22/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (n/a - Unknown - Disabling), COVID-19 (n/a - Unknown - Disabling), Chest pain (n/a - Unknown - Disabling), Extrasystoles (n/a - Unknown - Disabling), Fatigue (n/a - Unknown - Disabling), Hyperhidrosis (n/a - Unknown - Disabling), Malaise (n/a - Unknown - Disabling), Myocarditis (n/a - Unknown - Disabling)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported
EU-EC-	22/09/2022	Spontaneous	Healthcare	Non	Young, C.. Elevated tacrolimus levels	12-17	Not	Female	No	COVID-19 (n/a -	TOZINAMERAN	Not reported

10013573353			Professional	European Economic Area	after treatment with nirmatrelvir/ritonavir (Paxlovid) for COVID-19 infection in a child with a kidney transplant.. Pediatr-Nephrol. 2022	Years	Specified			Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	
EU-EC-10013573496	22/09/2022	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 -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hypotonia (n/a - Not Recovered/Not Resolved -), Injection site reaction (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013573857	22/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013573879	22/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013574281	22/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013574302	22/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chronic fatigue syndrome (126d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (126d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Post viral fatigue syndrome (126d - 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-10013575097	22/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), C-reactive protein increased (n/a - Unknown -), Hypoesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Motor dysfunction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), White blood cell count increased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	[DROSPIRENONE, ETHINYLESTRADIOL, LACTOSE, LACTOSE HYDROUS, LACTOSE MONOHYDRATE] (C - Dysmenorrhoea - n/a - [n/a - Oral use])
EU-EC-10013576203	22/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Recovered/Resolved -), Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported

										Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	applicable - [n/a - n/a - n/a])	
EU-EC-10013576222	22/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Testicular pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular use])	Not reported
EU-EC-10013576292	22/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013556657	21/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Unknown -), Menstruation delayed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menstruation irregular (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013556833	21/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bedridden (n/a - Unknown -), Dysphonia (n/a - Unknown -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Eyelid ptosis (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Gait disturbance (n/a - Not Recovered/Not Resolved - Disabling), Headache (n/a - Not Recovered/Not Resolved -), Hyperacusis (n/a - Unknown -), Hyperventilation (n/a - Not Recovered/Not Resolved -), Illness (n/a - Recovered/Resolved -), Initial insomnia (n/a - Not Recovered/Not Resolved -), Listless (n/a - Unknown -), Loss of personal independence in daily activities (n/a - Unknown -), Muscle spasms (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (n/a - Unknown -), Photophobia (n/a - Unknown -), Pyrexia (n/a - Unknown -), Speech disorder (n/a - Not Recovered/Not Resolved -), Supportive care (n/a - Unknown -), Wheelchair user (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013557082	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	IRON [IRON] (C - n/a - n/a), [THIAMINE]

										Educational problem (n/a - Unknown -), Heavy menstrual bleeding (n/a - Recovering/Resolving -), Mineral supplementation (n/a - Unknown -)		HYDROCHLORIDE, RETIN (C - n/a - n/a -)
EU-EC-10013557176	21/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hyperhidrosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013557271	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Lymphadenopathy (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013557604	21/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -), Syncope (1d - Recovered/Resolved - Other Medically Important Condition), Vision blurred (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013557691	21/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Insomnia (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - Muscle spasms - n/a - [n/a - n/a]), [PARACETAMOL] (C - Pain n/a - [n/a - n/a - n/a])
EU-EC-10013557728	21/09/2022	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 - Other Medically Important Condition), Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dehydration (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ASCORBIC ACID PH. EUR PARACETAMOL PH. EUR,] Rhinorrhoea - n/a - [n/a - n/a]), [PARACETAMOL] (C - Oropharyngeal pain - n/a [1d - n/a - n/a])
EU-EC-10013558221	21/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Candida infection (n/a - Unknown - Other Medically Important Condition), Urinary tract infection (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMOXICILLIN, AMOXICIL TRIHYDRATE] (C - Urinary tract infection - n/a - [n/a - n/a]), [FLUCONAZOLE] (C - Canc infection - n/a - [n/a - n/a n/a])

											- Other Medically Important Condition), Vulvovaginal candidiasis (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC-10013558232	21/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal distension (n/a - Not Recovered/Not Resolved - Disabling), Abdominal pain (n/a - Unknown - Disabling), Chills (n/a - Recovering/Resolving - Disabling), Dizziness (n/a - Recovering/Resolving - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Headache (n/a - Recovering/Resolving - Disabling), Insomnia (n/a - Unknown - Disabling), Myalgia (n/a - Not Recovered/Not Resolved - Disabling), Nausea (n/a - Recovering/Resolving - Disabling), Retching (n/a - Recovering/Resolving - Disabling), Vomiting (2d - Recovered/Resolved With Sequelae - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Hormone level abnormal - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a [n/a - n/a - n/a])	
EU-EC-10013559678	21/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown - Disabling, Other Medically Important Condition), Influenza (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Influenza like illness (n/a - Unknown - Disabling, Other Medically Important Condition), Nasopharyngitis (n/a - Unknown - Disabling, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CEFATRIZINE PROPYLENE GLYCOL] (C - Rhinitis - n/a [n/a - n/a - n/a]), [DROSPIRENONE, ETHINYLESTRADIOL, LEVONORGESTREL] (C - Hormone level abnormal - [n/a - n/a - n/a])	
EU-EC-10013559799	21/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Gastroenteritis (n/a - Unknown -), Urinary tract infection (n/a - Unknown -), Vomiting (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported	
EU-EC-10013560313	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash macular (8d - Recovered/Resolved -), Rash pruritic (8d - Recovered/Resolved -), Skin disorder (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	
EU-EC-10013560947	21/09/2022	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 -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	

EU-EC-10013561645	21/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site pruritus (n/a - Unknown - Other Medically Important Condition), Vaccination site swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013561985	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Injection site reaction (n/a - Recovered/Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013563029	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menometrorrhagia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013563198	21/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013564416	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Headache (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-10013564532	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -), Dizziness (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	CIRCADIN [MELATONIN] (n/a - n/a - [n/a - n/a - Oral use]), [LISDEXAMFETAMINE DIMESYLATE] (C - n/a - n, [n/a - n/a - Oral use]), [MELATONIN] (C - n/a - n, [n/a - n/a - Oral use]), [SERTRALINE] (C - n/a - r [n/a - n/a - Oral use])
EU-EC-10013564612	21/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abnormal behaviour (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013564625	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (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 -), Vaccination site pain (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-	21/09/2022	Spontaneous	Non	European	Not available	12-17	Not	Male	No	Lymphadenopathy	COMIRNATY	Not reported

10013564982			Healthcare Professional	Economic Area		Years	Specified			(n/a - Not Recovered/Not Resolved -), Swelling (n/a - Unknown -)	[TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10013565112	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling cold (n/a - Unknown -), Headache (n/a - Unknown -), Insomnia (n/a - Unknown -), Malaise (n/a - Not Recovered/Not Resolved -), Pain (n/a - Recovering/Resolving -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013565188	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	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-10013565232	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013566230	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (0d - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[BUDESONIDE] (C - n/a - [n/a - n/a - Inhalation us [SALBUTAMOL, SALBUTAM SULFATE] (C - n/a - n/a - n/a - n/a - n/a)), [TRANEXAMIC ACID] (C - n/a - n/a - n/a - Oral us
EU-EC-10013566327	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013566959	21/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Nausea (0d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013546098	20/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved -), Chest pain (n/a - Recovered/Resolved -), Dyspnoea exertional (n/a - Recovered/Resolved -), Palpitations (n/a - Recovered/Resolved -), Pericarditis (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-10013546241	20/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (n/a - Not Recovered/Not Resolved -), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported

EU-EC-10013546963	20/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Medically Important Condition) Seizure (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-10013547482	20/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling of body temperature change (n/a - Unknown - Other Medically Important Condition), Lymph node pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013547708	20/09/2022	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), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Eye pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypotension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013548005	20/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013548070	20/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Condition aggravated (n/a - Not Recovered/Not Resolved -), Orthostatic intolerance (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013549004	20/09/2022	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 rash (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

										Recovering/Resolving -), Injection site reaction (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Skin disorder (n/a - Recovering/Resolving -)		
EU-EC-10013549908	20/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013551048	20/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013551115	20/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013551143	20/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Circulatory collapse (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FLUTICASONE PROPION/ SALMETEROL, FLUTICASC PROPIONATE, SALMETER(XINAFOATE] (C - Asthma n/a - [n/a - 2{DF} - Inhalation use]), [SALBUTAMOL, SALBUTAN SULFATE] (C - Asthma - n, [n/a - n/a - Inhalation use
EU-EC-10013551153	20/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013551952	20/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown -), Heavy menstrual bleeding (n/a - Unknown -), Heavy menstrual bleeding (n/a - Unknown - Disabling), Menstruation irregular (n/a - Unknown -), Red blood cell count decreased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013552300	20/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug	Not reported

											withdrawn - [1d - 1{DF} - Intramuscular use])	
EU-EC-10013552813	20/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013554801	20/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Pericarditis (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-10013555100	20/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular use])	Not reported
EU-EC-10013536838	19/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition), Nasopharyngitis (n/a - Unknown - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Somnolence (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013537292	19/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pruritus (n/a - Not Recovered/Not Resolved -), Injection site urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013537640	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chills (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013538410	19/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Lethargy (n/a - Not Recovered/Not Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

										Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling face (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC-10013538518	19/09/2022	Spontaneous	Non Healthcare Professional	Non 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-10013538820	19/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Presyncope (n/a - Recovered/Resolved -), Pyrexia (64d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013539121	19/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Body temperature increased (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013539314	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Aviel, Y.. Case Series of Myocarditis Following mRNA COVID Vaccine Compared to Pediatric Multisystem Inflammatory Syndrome: Multicenter Retrospective Study, Vaccines, 2022;10(8):10.3390/vaccines10081207. doi:10.3390/vaccines10081207	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - 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-10013539479	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Aviel, Y.. Case Series of Myocarditis Following mRNA COVID Vaccine Compared to Pediatric Multisystem Inflammatory Syndrome: Multicenter Retrospective Study, Vaccines, 2022;10(8):10.3390/vaccines10081207. doi:10.3390/vaccines10081207	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - 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-10013539548	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Aviel, Y.. Case Series of Myocarditis Following mRNA COVID Vaccine Compared to Pediatric Multisystem Inflammatory Syndrome: Multicenter Retrospective Study, Vaccines, 2022;10(8):10.3390/vaccines10081207. doi:10.3390/vaccines10081207	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-10013539901	19/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (31d - Recovering/Resolving -), Pyrexia (31d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013540220	19/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013540970	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	Yes	Cardiac valve sclerosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	Not reported

										Other Medically Important Condition), Myopericarditis (n/a - Recovering/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericardial effusion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC-10013541063	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Aviel, Y. Case Series of Myocarditis Following mRNA COVID Vaccine Compared to Pediatric Multisystem Inflammatory Syndrome: Multicenter Retrospective Study. Vaccines. 2022;10(8):10.3390/vaccines10081207. doi:10.3390/vaccines10081207	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013541065	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Cole, L. Multisystem Inflammatory Syndrome after Breakthrough SARS-CoV-2 Infection in 2 Immunized Adolescents, United States. Emerging Infectious Diseases. 2022;28(7):1456-1459. doi:10.3201/eid2807.220560	12-17 Years	Not Specified	Male	No	Breakthrough COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013541097	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Breathing-related sleep disorder (9d - Recovered/Resolved -), Chest pain (9d - Recovered/Resolved -), Cough (9d - Recovered/Resolved -), Haematemesis (9d - Recovered/Resolved - Other Medically Important Condition), Palpitations (9d - Recovered/Resolved -), Wheezing (9d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013541242	19/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardiac flutter (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Lethargy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013541387	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

										Condition), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved -)		
EU-EC-10013541724	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Sanada, H.. Two Cases of Pericarditis Following COVID-19 Vaccination. The 58th Annual Meeting of Japanese Society of Pediatric Cardiology and Cardiac. 2022;58th	12-17 Years	Not Specified	Male	No	Condition aggravated (n/a - Unknown -), Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition), Troponin I increased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013542135	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dermatitis atopic (n/a - Unknown -), Ecchymosis (n/a - Unknown - Life Threatening), Petechiae (n/a - Unknown - Life Threatening), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013542358	19/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovering/Resolving - Other Medically Important Condition), Polymenorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013542495	19/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013542693	19/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013542694	19/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Recovering/Resolving -), Menstruation delayed (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013543857	19/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Aviel, Y.. Case Series of Myocarditis Following mRNA COVID Vaccine Compared to Pediatric Multisystem Inflammatory Syndrome: Multicenter Retrospective Study. Vaccines. 2022;10(8):10.3390/vaccines10081207. doi:10.3390/vaccines10081207	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-10013544764	19/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013545227	19/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013535193	17/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hyperhidrosis (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular use])	Not reported

EU-EC-10013535214	17/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013535377	17/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nephritic syndrome (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-10013535489	17/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Acne (n/a - Recovered/Resolved -), Asthenia (n/a - Recovered/Resolved -), Electrocardiogram T wave inversion (n/a - Recovered/Resolved - Other Medically Important Condition), Myalgia (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Skin depigmentation (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013535532	17/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Recovering/Resolving -), Muscle fatigue (n/a - Recovering/Resolving -), Tachycardia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular use])	Not reported
EU-EC-10013524590	16/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (3d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[LYMECYCLINE] (C - Acne n/a - [n/a - n/a - n/a])
EU-EC-10013524948	16/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Anaemia (n/a - Recovering/Resolving - Other Medically Important Condition), Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Constipation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Deafness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

										Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lower respiratory tract infection (n/a - Recovering/Resolving - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Productive cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Taste disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC-10013525145	16/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Recovering/Resolving -), Product administered to patient of inappropriate age (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Tremor (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]), VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)] (S - n/a - Unknown - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013525687	16/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Body temperature increased (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013525694	16/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (2d - Recovering/Resolving -), Headache (3d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013526714	16/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Paranoia (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013526812	16/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[BISOPROLOL FUMARATE] - Hypertrophic cardiomyopathy - n/a - [n, n/a - n/a]
EU-EC-10013527102	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovering/Resolving - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

										Condition), Tremor (n/a - Unknown - Other Medically Important Condition)		
EU-EC-10013527235	16/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Administration site pain (1d - Recovered/Resolved -), Body temperature increased (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013527261	16/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Arthralgia (n/a - Unknown -), Body temperature increased (n/a - Unknown -), Headache (n/a - Unknown -), Myalgia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013527883	16/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013528030	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angina pectoris (143d - Not Recovered/Not Resolved - Other Medically Important Condition), Angina pectoris (148d - Not Recovered/Not Resolved - Other Medically Important Condition), Angina pectoris (155d - Not Recovered/Not Resolved - Other Medically Important Condition), Arrhythmia (143d - Not Recovered/Not Resolved - Other Medically Important Condition), Arrhythmia (155d - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (143d - Not Recovered/Not Resolved -), Dyspnoea (148d - Not Recovered/Not Resolved -), Dyspnoea (155d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013528210	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (27d - Not Recovered/Not Resolved -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013528341	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Eye pain (59d - Recovering/Resolving -), Headache (31d - Recovered/Resolved -), Myalgia (71d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013528364	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Disorientation (236d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (236d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (236d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (236d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported

										Resolved - Caused/Prolonged Hospitalisation), Muscle atrophy (236d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (236d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)		
EU-EC-10013528566	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Breakthrough COVID-19 (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Infection susceptibility increased (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013528806	16/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Psychotic disorder (n/a - Not Recovered/Not Resolved -), Suicidal ideation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013529368	16/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (1d - Recovered/Resolved With Sequelae - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[MEFENAMIC ACID] (C - Dysmenorrhoea - n/a - [n, n/a - n/a])
EU-EC-10013529819	16/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown -), Lethargy (n/a - Unknown -), Post-acute COVID-19 syndrome (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-10013530403	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menometrorrhagia (n/a - Not Recovered/Not Resolved -), Menstruation delayed (n/a - Not Recovered/Not Resolved -), Vulvovaginal mycotic infection (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 2{DF} - Intramuscular use])	Not reported
EU-EC-10013530515	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (30d - Recovered/Resolved -), Intermenstrual bleeding (30d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013531221	16/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013531314	16/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Hirai, Y.. A case of myopericarditis in a 15-year-old boy following mRNA coronavirus disease 2019 vaccination. Japanese Journal of Pediatrics. 2022;75(4):627-632	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Electrocardiogram ST segment elevation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Electrocardiogram T wave inversion (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	[A/HONG KONG/4801/201 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/201 X-263B), B/BRISBANE/60/2008-LIK STRAIN (B/BRISBANE/60/2008, W TYPE), A/CALIFORNIA/7/2 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-11 A/HONG KONG/4801/201 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/201 X-263B), B/BRISBANE/60/2008-LIK STRAIN (B/BRISBANE/60/2008, W TYPE), A/MICHIGAN/45/21 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/21 VR-180), INFLUENZA VACCINE] (C - Immunisation n/a - [n/a - n/a - Subcutaneous use])

										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Troponin T increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vaccination site pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)		
EU-EC-10013532176	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (n/a - Unknown -), Dizziness (n/a - Not Recovered/Not Resolved -), Illness (n/a - Unknown -), Pain in extremity (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])	Not reported
EU-EC-10013532596	16/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza like illness (n/a - Unknown - Other Medically Important Condition), Musculoskeletal pain (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Vaccination site haemorrhage (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013532607	16/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dysphonia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported

											- Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pruritus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash erythematous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)		
EU-EC-10013532615	16/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Unknown -), Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013532737	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain (n/a - Unknown -), Pain in extremity (n/a - Unknown -), 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-10013532757	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Chills (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 -), Pain (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013533092	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Unknown -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pain (n/a - Unknown -), Vaccination site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013533137	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lip swelling (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013533400	16/09/2022	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-10013533591	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	

										Medically Important Condition), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Myocardial necrosis marker increased (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC-10013534019	16/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013534043	16/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013534075	16/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013513795	15/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysarthria (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Expired product administered (n/a - Unknown -), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Sensory loss (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013514313	15/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pityriasis rosea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013515265	15/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Body temperature increased (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013515460	15/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Administration site erythema (36h - Recovered/Resolved -), Administration site oedema (36h - Recovered/Resolved -), Body temperature increased (1d - Recovered/Resolved -), Chest pain (8h - Recovered/Resolved -), Dyspnoea (8h - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013515687	15/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Monoplegia (3d - Recovered/Resolved - Other Medically Important Condition), Pain (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL] (C - Headache - n/a - [n/a - n/a]), [SERTRALINE, SERTRALIN HYDROCHLORIDE] (C - n/a - [n/a - n/a - n/a])

										Condition), Vaccination site pain (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC-10013515694	15/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - Disabling), Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Disabling), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Disabling)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Dizziness, Dysmenorrhoea n/a - [n/a - n/a - n/a])
EU-EC-10013515776	15/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure diastolic increased (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Mycoplasma test positive (n/a - Unknown - Other Medically Important Condition), Pyrexia (19d - Recovered/Resolved - Other Medically Important Condition), Vomiting (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-10013516061	15/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Peripheral swelling (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling), Surgery (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), 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 - [n/a - n/a])	Not reported
EU-EC-10013518564	15/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Inappropriate schedule of product administration (n/a - Unknown -), Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Off label use (n/a - Unknown -), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013519583	15/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Arai, S., A Case of Acute Myocarditis After SARS-CoV-2 Vaccination, The 58th Annual Meeting of Japanese Society of Pediatric Cardiology and Cardiac. 2022;58th	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Electrocardiogram ST segment elevation (n/a - Unknown - Other Medically Important Condition), Myocardial necrosis marker increased	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported

										(n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown -)		
EU-EC-10013519849	15/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Suffocation feeling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013520167	15/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Recovered/Resolved -), Seizure (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013520204	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovering/Resolving -), Oligomenorrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013520237	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	[LACTULOSE, PARAFFIN WHITE SOFT, LIQUID PARAFFIN, LACTULOSE, VASELINE, LIQUID PARAFFIN] (C - n/a - n/a - [n/a - n/a - n/a]), [TRIMEBUTINE] (C - n/a - [n/a - n/a - n/a])
EU-EC-10013520310	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Recovered/Resolved -), Seizure (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [304d - 1{DF} - Intramuscular use])	[PHLEUM PRATENSE (225 C - n/a - n/a - [n/a - n/a n/a])
EU-EC-10013520579	15/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myasthenia gravis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013520613	15/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Optic neuritis (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-10013522071	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blister (n/a - Unknown -), Erythema (n/a - Unknown -), Herpes zoster (n/a - Recovering/Resolving -), Pain (n/a - Unknown -), Pruritus (n/a - Unknown -), Rash (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013522531	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Impaired work ability (n/a - Unknown -), Mobility decreased (n/a - Recovered/Resolved -), Pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013522636	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013522659	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Insomnia (n/a - Unknown -), Muscle twitching (5d - Recovered/Resolved -), Vaccination site	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

											erythema (2d - Recovered/Resolved -)		
EU-EC-10013522699	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013522781	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Joint swelling (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013522822	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood glucose fluctuation (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	INSULIN LISPRO SANOFI [INSULIN LISPRO] (C - n/a - [n/a - n/a - n/a]), [METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - [n/a - n/a - Oral use)	
EU-EC-10013522824	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown -), Nausea (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013523192	15/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Fatigue (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013504223	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use)	Not reported	
EU-EC-10013504646	14/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Immunodeficiency (n/a - Unknown - Other Medically Important Condition), 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-10013505320	14/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Heavy menstrual bleeding (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Muscle spasms (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013505363	14/09/2022	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 - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tearfulness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site pain	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	MELATONIN [MELATONIN] - Insomnia - n/a - [n/a - n/a]), SENNA [SENNOSIDE A+B] [SENNOSIDE A+B] (C - Constipation - n/a - [n/a - n/a]), [SERTRALINE, SERTRALIN HYDROCHLORIDE] (C - Depression - n/a - [n/a - r n/a])	

										(n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC-10013505420	14/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved - Other Medically Important Condition), Nausea (1d - Recovering/Resolving - Other Medically Important Condition), Palpitations (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013506251	14/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dengue virus test positive (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Platelet count decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013506859	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (14d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013507526	14/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Vaginal haemorrhage (n/a - Recovering/Resolving - Other Medically Important Condition), Vision blurred (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013507833	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Alopecia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013508604	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013508674	14/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown -), Musculoskeletal stiffness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013508775	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (21d - Recovered/Resolved -), Dysmenorrhoea (n/a - Recovered/Resolved -), Heavy menstrual bleeding (n/a - Recovered/Resolved -), Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013508828	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menarche (n/a - Recovered/Resolved -), Menstruation irregular (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013508840	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013510151	14/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Formanek, A.. Myocarditis following mRNA vaccine, Wien Med Wochenschr. 2022;10.1007/s10354-022-00959-6, doi:10.1007/s10354-022-00959-6	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported

EU-EC-10013511115	14/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Other Medically Important Condition) Body temperature increased (1d - Recovered/Resolved - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Fatigue (1d - Recovered/Resolved - Other Medically Important Condition), Limb discomfort (1d - Recovered/Resolved - Other Medically Important Condition), Nausea (1d - Recovered/Resolved - Other Medically Important Condition), Pain (1d - Recovered/Resolved - Other Medically Important Condition), Peripheral coldness (1d - Recovered/Resolved - Other Medically Important Condition), Tinnitus (0d - Recovered/Resolved - Other Medically Important Condition), Tremor (1d - Recovered/Resolved - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013511127	14/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013511178	14/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown - Other Medically Important Condition), Headache (1d - Recovered/Resolved - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - Other Medically Important Condition), Tremor (n/a - Unknown - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

EU-EC-10013511975	14/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Medically Important Condition) Condition aggravated (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Systemic lupus erythematosus (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-10013512202	14/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013512494	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (368d - Recovered/Resolved -), Nausea (368d - Recovered/Resolved -), Pain in extremity (368d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013512518	14/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Unknown -), Pyrexia (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-10013512548	14/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain upper (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[IBUPROFEN] (C - Malaise Unknown - [n/a - n/a - n/a])
EU-EC-10013512561	14/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hyperprolactinaemia (n/a - Recovering/Resolving - Other Medically Important Condition), Menstruation irregular (n/a - Unknown -), Urticaria (3d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013491544	13/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Presyncope (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013491572	13/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (30d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013492196	13/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013493061	13/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S -	Not reported

										Hospitalisation), Post herpetic neuralgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	n/a - n/a - [1d - n/a - Intramuscular use])	
EU-EC-10013493656	13/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY CONCENTRATE FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013494484	13/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved - Other Medically Important Condition), Dizziness (1d - Recovered/Resolved - Other Medically Important Condition), Headache (1d - Recovered/Resolved - Other Medically Important Condition), Hypoesthesia (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (1d - Recovered/Resolved - Other Medically Important Condition), Seizure (0d - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (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-10013494522	13/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - Other Medically Important Condition), Heart rate increased (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Hypoaacusis (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - 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-10013495718	13/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown -), Impaired work ability (n/a - Unknown -), Mobility decreased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013496474	13/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013496543	13/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Inappropriate schedule of product administration (n/a - Unknown -), Menstruation delayed (n/a - Not Recovered/Not Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

EU-EC-10013497246	13/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Medically Important Condition) COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013497249	13/09/2022	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)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	INTUNIV [GUANFACINE] (n/a - n/a - [n/a - n/a - n/a]) [CALCIUM, MAGNESIUM] n/a - n/a - [n/a - n/a - n/a] [METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])
EU-EC-10013498984	13/09/2022	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-10013501463	13/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Unknown -), Nausea (n/a - Unknown -), Odynophagia (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID-19 MRNA VACCIN MODERNA (CX-024414)] (COVID-19 immunisation - applicable - [1d - 1{DF} - n/a])
EU-EC-10013482722	12/09/2022	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 -), Polymenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013482737	12/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Body temperature increased (2d - Recovered/Resolved -), Fatigue (5d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013482989	12/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oligomenorrhoea (n/a - Recovered/Resolved -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CYANOCOBALAMIN] (C - n/a -)
EU-EC-10013483002	12/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Administration site pain (1d - Recovered/Resolved -), Arthralgia (1d - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013483508	12/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-	12/09/2022	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	Depression (n/a -)	TOZINAMERAN	Not reported

10013484565			Healthcare Professional	European Economic Area		Years	Specified			Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Immune thrombocytopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Laziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Spleen disorder (n/a - Unknown - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	
EU-EC-10013485112	12/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Cole, L. Multisystem Inflammatory Syndrome after Breakthrough SARS-CoV-2 Infection in 2 Immunized Adolescents, United States. Emerging Infectious Diseases. 2022;28(7):1456-1459, doi:10.3201/eid2807.220560	12-17 Years	Not Specified	Female	No	Multisystem inflammatory syndrome (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-10013485347	12/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pruritus (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pustule (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Rash (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Rash maculo-papular (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Rash vesicular (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Stevens-Johnson syndrome (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Vaccination site erythema (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Vaccination site swelling (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013486795	12/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysgeusia (n/a - Recovering/Resolving -), Respiratory tract haemorrhage (0d - Recovered/Resolved - Other Medically Important Condition), Sneezing (n/a - Unknown -), Vaginal haemorrhage	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CODEINE PHOSPHATE, PARACETAMOL DC, CODE PHOSPHATE, PARACETAM DC 96 %, PARACETAMOL, CODEINE PHOSPHATE] (C n/a - n/a - [n/a - n/a - n/a]) [DESOGESTREL] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])

EU-EC-10013486853	12/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	(n/a - Not Recovered/Not Resolved -) Paraesthesia (n/a - Not Recovered/Not Resolved -), Peripheral coldness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013486867	12/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Allodynia (n/a - Unknown - Other Medically Important Condition), Amnesia (n/a - Recovering/Resolving - Other Medically Important Condition), Balance disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Blindness (n/a - Unknown - Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Conversion disorder (n/a - Unknown - Other Medically Important Condition), Deafness unilateral (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dysphagia (n/a - Recovering/Resolving - Other Medically Important Condition), Ear haemorrhage (n/a - Unknown - Other Medically Important Condition), Ear pain (n/a - Unknown - Other Medically Important Condition), Erythema (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling abnormal (n/a - Unknown - Other Medically Important Condition), Gastrointestinal disorder (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hyperaesthesia (n/a - Unknown - Other Medically Important Condition), Loss of personal independence in daily activities (n/a - Unknown - Other Medically Important Condition), Memory impairment (n/a - Not Recovered/Not Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - n/a - n/a - [n/a - 400mg - n/a]), [AMITRIPTYLINE HYDROCHLORIDE] (C - Neuralgia - n/a - [314d - 50mg - n/a])

										Medically Important Condition), Muscular weakness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown - Other Medically Important Condition), Otorrhoea (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain of skin (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition), Visual impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)		
EU-EC-10013486972	12/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013487011	12/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary mass (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Lymphadenitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Lymphoma (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Mass (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pectus excavatum (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Skin disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Swelling (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Tenderness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013487307	12/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013488002	12/09/2022	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S -	Not reported

			Professional	Area									
EU-EC-10013488339	12/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (0d - Recovered/Resolved -) Abdominal pain (1d - Recovered/Resolved - Disabling, Other Medically Important Condition), Arthralgia (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Headache (1d - Recovered/Resolved - Disabling, Other Medically Important Condition), Hyperaesthesia (1d - Recovered/Resolved - Disabling, Other Medically Important Condition), Lymphadenopathy (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Pericarditis (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Disabling, Other Medically Important Condition), Vaccination site pain (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition)	n/a - n/a - [n/a - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) [ESCITALOPRAM, ESCITALOPRAM OXALATE] - Depression - n/a - [n/a - n/a]), [NORETHISTERONE ACETATE] (C - Contracept - n/a - [n/a - n/a - n/a])		
EU-EC-10013488370	12/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash erythematous (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013488734	12/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blister (n/a - Unknown -), 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-10013488858	12/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (3d - Recovered/Resolved -), Pain in extremity (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	
EU-EC-10013489734	12/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Cole, L.. Multisystem Inflammatory Syndrome after Breakthrough SARS-CoV-2 Infection in 2 Immunized Adolescents, United States. Emerging Infectious Diseases, 2022;28(7):1456-1459. doi:10.3201/eid2807.220560	12-17 Years	Not Specified	Male	No	Multisystem inflammatory syndrome (n/a - Recovering/Resolving - 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-10013476397	11/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (n/a - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) [SERTRALINE, SERTRALIN HYDROCHLORIDE] (C - Depression - n/a - [n/a - r n/a])		
EU-EC-10013463514	09/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	
EU-EC-10013465077	09/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Body temperature increased (n/a - Unknown -), Confusional state (1h - Unknown -), Delusion (1h - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Subcutaneous use])	Not reported	

										Heart rate abnormal (1h - Not Recovered/Not Resolved -), Hyperhidrosis (1h - Unknown -)		
EU-EC-10013465113	09/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenitis (1mo - Unknown -), Lymphadenopathy (1mo - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013466744	09/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Crohn's disease (91d - Recovered/Resolved With Sequelae - Other Medically Important Condition), Nausea (91d - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013466848	09/09/2022	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 - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013467039	09/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (388d - Recovered/Resolved With Sequelae -), Vasculitis (388d - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013467265	09/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL, FERRI FUMARATE] (C - Menstrua irregular - n/a - [n/a - n/a - n/a])
EU-EC-10013468660	09/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Sleep disorder (n/a - Not Recovered/Not Resolved -), Visual impairment (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013469654	09/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Headache (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013470817	09/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Moncada-madrado, M.. To keep in scope: vulvar aphthous ulcers after COVID-19 vaccination. Journal of Pediatric and Adolescent Gynecology. 2022;35(2):235. doi:10.1016/j.jpag.2022.01.112 Moncada-madrado, M.. "Supplementary data" To keep in scope: vulvar aphthous ulcers after COVID-19 vaccination. Journal of Pediatric and Adolescent Gynecology. 2022;35(2):235. doi:10.1016/j.jpag.2022.01.112	12-17 Years	Not Specified	Female	No	Aphthous ulcer (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-10013471039	09/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Wilson, H.. Late Gadolinium Enhancement after COVID-19 Vaccination. Radiol Cardiothorac Imaging. 2021;3(5):10.1148/ryct.2021210199. doi:10.1148/ryct.2021210199	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Recovering/Resolving - 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-10013471066	09/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

			Professional	Economic Area						Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	
EU-EC-10013471278	09/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash pruritic (n/a - Recovering/Resolving -), Urticaria (n/a - Recovering/Resolving -), Vaccination site rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013471400	09/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Cardiac arrest (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown -), Myocardial necrosis marker increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Fatal - Results in Death, Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013472154	09/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013453907	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Joint effusion (n/a - Recovered/Resolved -), Lymphadenopathy (29d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10013454490	08/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Infection susceptibility increased (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013454491	08/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Juvenile idiopathic arthritis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Migraine (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013454720	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013455178	08/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Other Medically Important Condition), Nerve stimulation test abnormal (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013455772	08/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Haematoma (3wk - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013455977	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported

										Lymphadenopathy (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)		
EU-EC-10013456226	08/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Cough (n/a - Not Recovered/Not Resolved -), Hypotonia (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -), Weight bearing difficulty (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013456696	08/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Haematoma (n/a - Recovered/Resolved -), Heavy menstrual bleeding (n/a - Recovered/Resolved -), Petechiae (n/a - Recovered/Resolved -), Pruritus (n/a - Recovered/Resolved -), Rash (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013457487	08/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -), Sudden hearing loss (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tinnitus (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013458429	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovered/Resolved -), Dysmenorrhoea (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-10013458525	08/09/2022	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])	[VALPROIC ACID, SODIUM VALPROATE] (C - Epilepsy n/a - [n/a - n/a - n/a])
EU-EC-10013458551	08/09/2022	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 - n/a - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013458682	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013458976	08/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Baird, T.. Severe Rhabdomyolysis Temporarily Associated with sars-cov-2 Vaccine in an Adolescent. Pediatrics. 2022;149(1):272	12-17 Years	Not Specified	Female	No	Rhabdomyolysis (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-10013459005	08/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Baird, T.. Severe Rhabdomyolysis Temporarily Associated with sars-cov-2 Vaccine in an Adolescent. Pediatrics. 2022;149(1):272	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Life Threatening, Other Medically Important Condition), Rhabdomyolysis (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-10013459015	08/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Baird, T.. Severe Rhabdomyolysis Temporarily Associated with sars-cov-2 Vaccine in an Adolescent. Pediatrics. 2022;149(1):272	12-17 Years	Not Specified	Female	No	Rhabdomyolysis (n/a - Unknown - Life Threatening, Other Medically Important Condition), Caused/Prolonged Hospitalisation,	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

EU-EC-10013459749	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Other Medically Important Condition) Arthralgia (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Irritability (n/a - Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), 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-10013460568	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Contusion (n/a - Recovering/Resolving -), Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013460592	08/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Autonomic neuropathy (n/a - Recovering/Resolving - Other Medically Important Condition), Encephalitis autoimmune (n/a - Recovering/Resolving - Other Medically Important Condition), Exophthalmos (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013460648	08/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013460652	08/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Baird, T. Severe Rhabdomyolysis Temporarily Associated with sars-cov-2 Vaccine in an Adolescent. Pediatrics. 2022;149 (1):272	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Overdose (n/a - Unknown - Other Medically Important Condition), Product preparation error (n/a - Unknown - Other Medically Important Condition), Rhabdomyolysis (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-10013461186	08/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Baird, T. Severe Rhabdomyolysis Temporarily Associated with sars-cov-2 Vaccine in an Adolescent. Pediatrics. 2022;149(1):272	12-17 Years	Not Specified	Male	No	Myalgia (n/a - Unknown - Other Medically Important Condition), Rhabdomyolysis (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-10013461660	08/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])	Not reported
EU-EC-10013444423	07/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (3d - Recovered/Resolved -), Dysmenorrhoea (n/a - Recovered/Resolved -), Dyspnoea (11d - Recovered/Resolved With Sequelae -), Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not reported
EU-EC-10013444466	07/09/2022	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Not Specified	Female	No	Back pain (3d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S -	Not reported

				Area						-), Injection site pain (3d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -), Somnolence (3d - Recovered/Resolved -)	COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use])	
EU-EC-10013447724	07/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Administration site pain (n/a - Recovered/Resolved -), Body temperature increased (2d - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013448292	07/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Body temperature increased (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013448717	07/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Fall (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Muscular weakness (n/a - Recovering/Resolving -), Vision blurred (n/a - Recovering/Resolving -), Visual impairment (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[LYMECYCLINE, TETRACYCLINE] (C - n/a - Unknown - [n/a - n/a - n/a])
EU-EC-10013448718	07/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (230d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pericarditis (230d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	[ALLERGEN EXTRACT, ALLERGENS, POLLEN & PLANT EXTRACT, ALNUS GLUTINOSA L., AMBROSIA/ ARTEMISIFOLIA, ANTHOXANTHUM ODORA' L., ARTEMISIA VULGARIS AVENA FATUA WHOLE., BROMUS INERMIS WHOLE/ DACTYLIS GLOMERATA L., PHELEUM PRATENSE L., ANTHOXANTHUM ODORA' L., LOLIUM PERENNE L., P PRATENSIS L., HOLCUS LANATUS, FESTUCA PRATENSIS HUDSON, AGROSTIS CAPILLARIS L., CYNODON DACTYLON (L.), PERS., ARRHENATHERUM ELATIUS, AVENA SATIVA L TRITICUM AESTIVUM, DACTYLIS GLOMERATA L., PHELEUM PRATENSE L., ANTHOXANTHUM ODORA' L., LOLIUM PERENNE L., P PRATENSIS L., ZEA MAYS HORDEUM VULGARE L., AVENA SATIVA L., TRITICI AESTIVUM, ZEA MAYS L., HORDEUM VULGARE L., BETULA, BETULA PENDUL ROTH., BETULA POLLEN EXTRACT, CORYLUS POLL EXTRACT, ALNUS GLUTINI POLLEN EXTRACT, BETUL/ CORYLUS AVELLANA L., ALNUS GLUTINOSA L., BETULA, CORYLUS AVELL L., CARPINUS BETULUS L. ALNUS GLUTINOSA L., BIF POLLEN ALLERGOID GLUTARALDEHYDE MODIFIED, BLOMIA TROPICALIS, CARPINUS BETULUS L., CAT EPITHEL CORYLUS AVELLANA L., CORYLUS AVELLANA L., BETULA PENDULA ROTH., ALNUS GLUTINOSA L., CYNODON DACTYLON (L.), PERS., DACTYLIS GLOMEF

												L, DACTYLIS GLOMERATA PHLEUM PRATENSE L, ANTHOXANTHUM ODORA L., LOLIUM PERENNE L., P PRATENSIS L., DACTYLIS GLOMERATA L., PHLEUM PRATENSE L., LOLIUM PERENNE L., DERMATOPHAGOIDES FARINAE, DERMATOPHAGOIDES PTERONYSSINUS, DERMATOPHAGOIDES PTERONYSSINUS, DERMATOPHAGOIDES FARINAE, DOG EPITHELIA FRAXINUS EXCELSIOR L., HAZEL POLLEN ALLERGOI FORMALDEHYDE MODIFIED ALDER POLLEN ALLERGOI FORMALDEHYDE MODIFIED BIRCH POLLEN ALLERGOI GLUTARALDEHYDE MODIFIED, JUNIPERUS ASHEI BUCHHOLZ, LOLIUM PERENNE L., OLEA EUROPA L., PARIETARIA JUDAICA I PARIETARIA OFFICINALIS PHLEUM PRATENSE L., PC PRATENSIS L., SECALE CEREALE L.] (C - Immune enhancement therapy - n/ [n/a - 4[drp] - Sublingual use])
EU-EC-10013448783	07/09/2022	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 -), Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013448849	07/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -), Balance disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood alkaline phosphatase decreased (n/a - Unknown -), Blood copper decreased (n/a - Unknown -), Blood creatinine decreased (n/a - Unknown -), Blood urea decreased (n/a - Unknown -), CSF glucose increased (n/a - Unknown - Other Medically Important Condition), CSF protein decreased (n/a - Unknown -), Dyskinesia (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Gastritis (n/a - Unknown -), Headache (n/a - Recovered/Resolved -), Mean cell haemoglobin concentration increased (n/a - Unknown -), Myocarditis (n/a - Unknown - Other Medically Important Condition), Nervous system disorder (n/a - Unknown -), Respiratory disorder (n/a - Unknown -), Salivary hypersecretion (n/a - Unknown -), Tremor (n/a - Not Recovered/Not	AZATHIOPRINE [AZATHIOPRINE] (S - n/a - Unknown - [n/a - 100mg - n/a]), IVABRADINE HYDROCHLORIDE [IVABRADINE HYDROCHLORIDE] (S - n/a - Unknown - [n/a - 10mg - n/a]), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (S - n/a - Unknown - [n/a - 40mg - n/a]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [COLECALCIFEROL, CALCIUM] (S - n/a - Unknown - [n/a - 500mg - n/a]), [COLECALCIFEROL] (S - n/a - Unknown - [n/a - n/a - n/a]), [METOPROLOL TARTRATE] (S - n/a - Unknown - [n/a - 50mg - n/a]), [PREDNISOLONE] (S - n/a - Unknown - [n/a - 30mg - n/a - More in ICSR])	Not reported

EU-EC-10013449639	07/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (65h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myopericarditis (65h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013450050	07/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Genital haemorrhage (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013450142	07/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Menometrorrhagia (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-10013450147	07/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Sinus tachycardia (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-10013450161	07/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 2{DF} - Intramuscular use])	Not reported
EU-EC-10013450219	07/09/2022	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), Polymenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013450232	07/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013450235	07/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Polymenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013450680	07/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition), Immunisation (n/a - Fatal - Results in Death, Other Medically Important Condition), Off label use (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013450725	07/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Nishibayashi, H.. Myocarditis in 13-Year-Old Monochorionic Diamniotic Twins After COVID-19 Vaccination, Journal of Clinical Immunology. 2022;115th:10.1007/s10875-022-01360-z. doi:10.1007/s10875-022-	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Electrocardiogram ST	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

					01360-z Nishibayashi, H.. Monochorionic-diamniotic twin sibling cases of myocarditis that developed after COVID-19 vaccination, The 115th Oita Regional Meeting of Japan Pediatric Society, 2022;3, doi:10.1007/s10875-022-01360					segment elevation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Sick relative (n/a - Unknown -)		
EU-EC-10013450985	07/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Confusional state (n/a - Recovered/Resolved -), Eye movement disorder (n/a - Recovered/Resolved -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition), Tremor (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use]), [INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013452696	07/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Malaise (n/a - Unknown -), Nausea (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-10013452702	07/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Unknown -), Malaise (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013452764	07/09/2022	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-10013433881	06/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Maternal exposure timing unspecified (n/a - Unknown - Other Medically Important Condition), Vaginal haemorrhage (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-10013433968	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angioedema (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013434841	06/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Sutcu, M.. Rhabdomyolysis after BNT162b2 mRNA Covid-19 vaccine in an adolescent male, Malawi Medical Journal. 2022;34(2):154-156, doi:10.4314/mmj.v34i2.13	12-17 Years	Not Specified	Male	No	Rhabdomyolysis (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-10013435075	06/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013435584	06/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Extensive swelling of vaccinated limb (4d - Recovered/Resolved -), Headache (4d - Recovered/Resolved -), Injection site reaction (4d - Recovered/Resolved -), Lymphadenopathy (4d - Recovered/Resolved -), Oral pruritus (4d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

										Pyrexia (4d - Recovered/Resolved -), Skin disorder (4d - Recovered/Resolved -)		
EU-EC-10013435778	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (1min - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013435853	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Administration site erythema (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Orthostatic hypotension (1min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013435869	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Tinnitus (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013436797	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (236d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Muscular weakness (236d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013436981	06/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013437410	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blindness (1d - Recovered/Resolved - Other Medically Important Condition), Deafness (1d - Recovered/Resolved - Other Medically Important Condition), Dizziness (1d - Recovered/Resolved - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Hypoesthesia (1d - Recovered/Resolved - Other Medically Important Condition), Nausea (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PIZOTIFEN, PIZOTIFEN MALATE] (C - Migraine - n [n/a - n/a - n/a])
EU-EC-10013438489	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013438592	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013438640	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

										Condition), Myalgia (n/a - Recovering/Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC-10013438661	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Unknown -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013439149	06/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oligomenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013439299	06/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013439430	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013439485	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not reported
EU-EC-10013439846	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (1d - Recovered/Resolved - Other Medically Important Condition), Limb discomfort (n/a - Recovering/Resolved - Other Medically Important Condition), Pain (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013440298	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hyperhidrosis (0d - Recovered/Resolved -), Hypotension (0d - Recovered/Resolved -), Malaise (0d - Recovered/Resolved -), Vertigo (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013440361	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (20min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013440421	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperhidrosis (20min - Recovered/Resolved -), Hypotension (20min - Recovered/Resolved -), Malaise (20min - Recovered/Resolved -), Presyncope (20min - Recovered/Resolved -), Vertigo (20min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013440884	06/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Nishibayashi, H.. Monochorionic-diamniotic twin sibling cases of myocarditis that developed after COVID-19 vaccination. The 115th Oita	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (n/a - Recovering/Resolved	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported

					Regional Meeting of Japan Pediatric Society, 2022;115th:3 Nishibayashi, H., Myocarditis in 13-Year-Old Monochorionic Diamniotic Twins After COVID-19 Vaccination. Journal of Clinical Immunology, 2022;10.1007/s10875-022-01360-z, doi:10.1007/s10875-022-01360-z					- Caused/Prolonged Hospitalisation), Brain natriuretic peptide increased (n/a - Recovering/Resolving - 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), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Sick relative (n/a - Unknown -)	applicable - [n/a - n/a]	
EU-EC-10013440905	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vision blurred (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL] (C - Dysmenorrhoea - n/a - [n, n/a - n/a])
EU-EC-10013440915	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling abnormal (n/a - Unknown -), Limb discomfort (n/a - Unknown - Other Medically Important Condition), Loss of personal independence in daily activities (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013440965	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved - Other Medically Important Condition), Dizziness (1d - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Influenza like illness (3d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FOLIC ACID] (C - Blood folate - n/a - [n/a - n/a - n/a])

										Condition), Pain (n/a - Unknown - Other Medically Important Condition)		
EU-EC-10013442376	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site pain (n/a - Unknown - Other Medically Important Condition), Vaccination site swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013442514	06/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Martinez-cabiales, S.. Comment on "Toxic epidermal necrolysis (TEN) after first dose of Pfizer (BNT162b2) vaccination and pharmacogenomic-based-point-care support: First case report in pediatric and review of literature";. Pediatric Dermatology, 2022;39(4):671-672. doi:10.1111/pde.14987 Siripattanamongkol, N.. Toxic epidermal necrolysis after first dose of Pfizer-BioNTech (BNT162b2) vaccination with pharmacogenomic testing. Pediatric Dermatology, 2022;39(4):601-605. doi:10.1111/pde.15074	12-17 Years	Not Specified	Female	No	Toxic epidermal necrolysis (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])	Not reported
EU-EC-10013442545	06/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013442783	06/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Neurological examination normal (n/a - Not Recovered/Not Resolved -), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[SERTRALINE, SERTRALIN HYDROCHLORIDE] (C - n/a - [n/a - n/a - n/a])
EU-EC-10013442786	06/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013443189	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Nodule (n/a - Recovering/Resolving -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013443214	06/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Depressed mood (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Rhinorrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013423883	05/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Muscle spasms (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013423928	05/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Contusion (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DESGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])

										Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)		
EU-EC-10013424761	05/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013425320	05/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013426544	05/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013426861	05/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Hypotension (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Postural orthostatic tachycardia syndrome (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	Not reported
EU-EC-10013429147	05/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013429214	05/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Testicular torsion (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013429502	05/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intravenous use])	Not reported

EU-EC-10013429650	05/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Chest pain (n/a - Unknown -), Malaise (n/a - Unknown -), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not reported
EU-EC-10013429739	05/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Nasal congestion (n/a - Unknown - Other Medically Important Condition), Presyncope (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DESOGESTREL, ETHINYLESTRADIOL] (C - Hormone level abnormal - [n/a - n/a - n/a]), [PROCHLORPERAZINE] (C Nausea - n/a - [n/a - n/a - n/a])
EU-EC-10013429924	05/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013430811	05/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition), Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Hyperhidrosis (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013430871	05/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Taste disorder (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013430874	05/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (0d - Recovered/Resolved -), Fall (n/a - Unknown -), Thirst (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-10013430890	05/09/2022	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 -), Nausea (n/a - Not Recovered/Not Resolved -), 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-10013431037	05/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pruritus (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S -)	Not reported

										Rash macular (n/a - Unknown -), Urticaria (n/a - Not Recovered/Not Resolved -)	n/a - n/a - [n/a - n/a - n/a]	
EU-EC-10013431090	05/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	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-10013432238	05/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not reported
EU-EC-10013418482	03/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013418552	03/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a -)
EU-EC-10013409082	02/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Paraesthesia (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	NOVORAPID [INSULIN ASPART] (C - Type 1 diabetes mellitus - n/a - [n/a - n/a - n/a])
EU-EC-10013409278	02/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	SARS-CoV-2 test positive (n/a - Unknown -), Vaccination failure (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013409351	02/09/2022	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 - Disabling), Ageusia (n/a - Not Recovered/Not Resolved - Disabling), Catatonia (n/a - Not Recovered/Not Resolved - Disabling), Central nervous system inflammation (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Malaise (n/a - Not Recovered/Not Resolved - Disabling), Musculoskeletal disorder (n/a - Not Recovered/Not Resolved - Disabling), Nausea (n/a - Not Recovered/Not Resolved - Disabling), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Disabling), Pyrexia (n/a - Not Recovered/Not Resolved - Disabling), Seizure (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

										Selective mutism (n/a - Not Recovered/Not Resolved - Disabling), Syncope (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Tic (n/a - Not Recovered/Not Resolved - Disabling), Tourette's disorder (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)		
EU-EC-10013409579	02/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	SARS-CoV-2 test positive (n/a - Unknown -), Vaccination failure (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013409580	02/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	SARS-CoV-2 test positive (n/a - Unknown -), Vaccination failure (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013409654	02/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -), Vomiting (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013409773	02/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	SARS-CoV-2 test positive (n/a - Unknown -), Vaccination failure (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013410023	02/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Body temperature increased (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013410292	02/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	SARS-CoV-2 test positive (n/a - Unknown -), Vaccination failure (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013411043	02/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Unknown - Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013411141	02/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Recovering/Resolving - Other Medically Important Condition), Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Recovering/Resolving - Other Medically Important Condition), Inappropriate	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported

										schedule of product administration (n/a - Unknown -), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Piloerection (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC-10013411209	02/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Breast neoplasm (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013414196	02/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Unknown -), Menstruation delayed (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013414282	02/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Inflammation (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013414739	02/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Tremor (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CODEINE PHOSPHATE HEMIHYDRATE PHEUR, IBUPROFEN PH. EUR., CODEINE PHOSPHATE PH.EUR., IBUPROFEN, CODEINE PHOSPHATE, IBUPROFEN, CODEINE PHOSPHATE HEMIHYDRATE] (C - Temporomandibular joint syndrome - n/a - [n/a - n/a]), [DIAZEPAM] (C - Temporomandibular joint syndrome - n/a - [n/a - n/a]), [DICLOFENAC, DICLOFEN. POTASSIUM, DICLOFENAC SODIUM] (C - Temporomandibular joint syndrome - n/a - [n/a - n/a]), [FLUTICASON PROPRION/ FORMOTEROL FUMARATE DIHYDRATE, FLUTICASON PROPRIONATE, FORMOTER FUMARATE DIHYDRATE PH.EUR.] (C - n/a - n/a - [- n/a - n/a]), [PARACETAMOL, CODEINE PHOSPHATE] (C - Temporomandibular joint syndrome - n/a - [n/a - n/a]), [SALBUTAMOL SULFATE] (
EU-EC-10013414761	02/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Patel, S., Ouch!My Chest. Pfizer-biotech COVID-19 Vaccination Induced Acute Myopericarditis: A Case Report, Pediatrics, 2022;149 (1):830	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown -), Hypoaesthesia (n/a - Unknown -), Myalgia (n/a - Unknown -), Myopericarditis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paraesthesia (n/a - Unknown -), Scar (n/a - Unknown -), Vomiting (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported
EU-EC-10013415138	02/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - ,3mL - Intramuscular use])	Not reported

										Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC-10013415331	02/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Suspected COVID-19 (1d - Recovered/Resolved - Other Medically Important Condition), Vulval disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - n/a])	[DESGESTREL] (C - Premenstrual syndrome - [n/a - n/a - n/a])
EU-EC-10013415479	02/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual discomfort (119d - Not Recovered/Not Resolved -), Menstruation irregular (119d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013415609	02/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Breast engorgement (2d - Not Recovered/Not Resolved -), Chest pain (2d - Not Recovered/Not Resolved -), Skin swelling (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013415639	02/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Disturbance in attention (234d - Not Recovered/Not Resolved -), Disturbance in attention (n/a - Unknown -), Dizziness (234d - Not Recovered/Not Resolved -), Dizziness (n/a - Unknown -), Gait disturbance (234d - Not Recovered/Not Resolved -), Gait disturbance (n/a - Unknown -), Headache (234d - Not Recovered/Not Resolved -), Headache (n/a - Unknown -), Hypoesthesia (234d - Not Recovered/Not Resolved -), Hypoesthesia (n/a - Unknown -), Musculoskeletal discomfort (234d - Not Recovered/Not Resolved -), Musculoskeletal discomfort (n/a - Unknown -), Myalgia (234d - Not Recovered/Not Resolved -), Myalgia (n/a - Unknown -), Nausea (234d - Not Recovered/Not Resolved -), Nausea (n/a - Unknown -), Paraesthesia (n/a - Unknown -), Tremor (234d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013415763	02/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site lymphadenopathy (1d - Not Recovered/Not Resolved -), Lymphadenopathy (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013416224	02/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Colitis ulcerative (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported

										Important Condition), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea haemorrhagic (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Flatulence (n/a - Unknown - Caused/Prolonged Hospitalisation)	applicable - [1d - n/a - n/a])	
EU-EC-10013416350	02/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Choi, J.. Two adolescent cases of acute tubulointerstitial nephritis after second dose of COVID-19 mRNA vaccine. Human Vaccines & Immunotherapeutics. 2022;18(5):1-6. doi:10.1080/21645515.2022.2059308	12-17 Years	Not Specified	Male	No	Tubulointerstitial nephritis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013417153	02/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Choi, J.. Two adolescent cases of acute tubulointerstitial nephritis after second dose of COVID-19 mRNA vaccine. Human Vaccines & Immunotherapeutics. 2022;18(5):1-6. doi:10.1080/21645515.2022.2059308	12-17 Years	Not Specified	Male	No	Metabolic acidosis (n/a - Unknown -), Sinus arrhythmia (n/a - Unknown -), Tubulointerstitial nephritis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013398182	01/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Sartor, R.. Association of COVID-19 Vaccination with Vulvar Ulcers in Adolescent Females. Journal of Pediatric and Adolescent Gynecology. 2022;35(2):234. doi:10.1016/j.jpag.2022.01.110	12-17 Years	Not Specified	Female	No	Vulval ulceration (13d - 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-10013398825	01/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Unknown - Other Medically Important Condition), Vomiting (0d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported
EU-EC-10013398849	01/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vomiting (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-10013399150	01/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	SARS-CoV-2 test positive (n/a - Unknown -), Vaccination failure (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013399162	01/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Influenza (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported

										Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)		
EU-EC-10013399201	01/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013399556	01/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Sartor, R.. Association of COVID-19 Vaccination with Vulvar Ulcers in Adolescent Females, Journal of Pediatric and Adolescent Gynecology, 2022;35(2):234, doi:10.1016/j.jpjag.2022.01.110	12-17 Years	Not Specified	Female	No	Vulval ulceration (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013400158	01/09/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Okada, M.. An adolescent girl diagnosed with IgA nephropathy following the first dose of the COVID-19 vaccine, CEN Case Reports, 2022;11:376-379, doi:10.1007/s13730-021-00679-7	12-17 Years	Not Specified	Female	No	Haematuria (n/a - Recovered/Resolved - Other Medically Important Condition), Haematuria (n/a - Unknown - Other Medically Important Condition), IgA nephropathy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013400323	01/09/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (n/a - Unknown - Other Medically Important Condition), Tremor (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported
EU-EC-10013401459	01/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported
EU-EC-10013401510	01/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Fatigue (n/a - Unknown -), Headache (2d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Vaccination site pain (3d - Recovered/Resolved -), Vomiting (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-10013401856	01/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	SARS-CoV-2 test positive (n/a - Unknown -), Vaccination failure (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(Df) - Intramuscular use])	Not reported
EU-EC-10013402271	01/09/2022	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), Feeling abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypoesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tremor (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)		
EU-EC-10013403414	01/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013403567	01/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013403620	01/09/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not reported
EU-EC-10013403710	01/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported
EU-EC-10013403806	01/09/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use])	Not reported

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