

Line Listing Report

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EU Local Number	EV Gateway Receipt Date	Report Type	Primary Source Qualification	Primary Source Country for Regulatory Purposes	Literature Reference	Patient Age Group	Patient Age Group (as per reporter)	Patient Sex	Parent Child Report	Reaction List PT (Duration – Outcome – Seriousness Criteria)	Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICSR Form
EU-EC-10011128675	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011128739	31/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Uveitis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011128859	31/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Paralysis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 30ug - Cutaneous])	Not reported	ICSR
EU-EC-10011129259	31/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011130494	31/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown -), 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	ICSR
EU-EC-10011131359	31/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (0d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (0d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Vaccination site erythema (0d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011131370	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Recovered/Resolved With Sequelae - Disabling), Polymenorrhoea (n/a - Recovered/Resolved With Sequelae - Disabling)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011131383	31/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011131411	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Not Recovered/Not Resolved -), Gait disturbance (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hemihypoesthesia (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Rhinitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011131505	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthritis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Important Condition), Back pain (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Inflammation (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Juvenile idiopathic arthritis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Pyrexia (5d - Recovered/Resolved - Disabling, Other Medically Important Condition)			
EU-EC-10011132237	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011132240	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pruritus (n/a - Recovering/Resolving -), Rash (n/a - Recovering/Resolving -), Skin burning sensation (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011132241	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (0d - Not Recovered/Not Resolved - Other Medically Important Condition), Cough (0d - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (0d - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011132244	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site erythema (n/a - Not Recovered/Not Resolved -), Vaccination site oedema (n/a - Not Recovered/Not Resolved -), Vaccination site warmth (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011133929	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure diastolic decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Loss of consciousness (2min - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Presyncope (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10011133944	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving -), Pulmonary embolism (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [ETHINYLESTRADIOL, LEVONORGESTREL] (S - n/a - Unknown - [n/a - n/a - n/a])	[FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011133965	31/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Furunde (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011133982	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Uveitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011133988	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011133992	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011134326	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Unknown -), Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[ATOMOXETINE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - n/a]), [DIENOGEST, ETHINYLESTRADIOL, LACTOSE MONOHYDRATE] (C - Contraception - n/a - [n/a - n/a - n/a]), [SERTRALINE] (C - Anxiety - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011135025	31/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011135180	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cold sweat (n/a - Unknown -), Pallor (n/a - Unknown -), Pyrexia (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011135337	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011135339	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved -), Chills (n/a - Recovered/Resolved -), Decreased appetite (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011135347	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Hypersomnia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Photosensitivity reaction (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10011135665	31/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericarditis (n/a - Recovering/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011135757	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (15d - Recovered/Resolved - Other Medically Important Condition), Decreased appetite (15d - Recovered/Resolved - Other Medically Important Condition), Headache (15d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) AERIUS [DESLOXATADINE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASONE PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])		ICSR
EU-EC-10011135847	31/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011135885	31/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011135961	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Recovering/Resolved -), Vaccination site pain (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011136021	31/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site discolouration (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011136101	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011136173	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (2d - Recovered/Resolved -), Immunisation reaction (3d - Recovered/Resolved -), Vision blurred (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011136177	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011136585	31/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (35min - Recovered/Resolved -), Syncope (35min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011136888	31/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Infection (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-1001114289	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperpyrexia (17d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .5{DF} - Intramuscular])	Not reported	ICSR
EU-EC-1001114293	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Movement disorder (4d - Recovered/Resolved)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										- Caused/Prolonged Hospitalisation)			
EU-EC-10011114304	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Mycocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular])	[FOLIC ACID] (C - Microcytic anaemia - n/a - [n/a - 5mg - Oral]), [VITAMIN D] (C - Vitamin D deficiency - n/a - [n/a - 1000{DF} - Oral])	ICSR
EU-EC-10011114338	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypotension (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011114372	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011114483	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011114551	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Confusional state (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Derealisation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Disorientation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Lethargy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011114556	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011114576	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Apicectomy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pneumothorax (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011115028	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Hyperhidrosis (n/a - Recovered/Resolved -), Hypotension (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Respiratory distress (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Vision blurred (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011115100	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bronchospasm (n/a - Unknown -), Cough (n/a - Unknown -), Dizziness (n/a - Unknown -), Inflammation (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

											Oedema (n/a - Unknown -), Pain (n/a - Unknown -), Pruritus (n/a - Unknown -), Pyrexia (n/a - Unknown -), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Sensitive skin (n/a - Unknown -), Vaccination site paraesthesia (n/a - Unknown -), Wheezing (n/a - Unknown -)			
EU-EC-10011115137	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncopal (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10011115140	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -), Hypotension (n/a - Recovered/Resolved -), Pain (n/a - Recovered/Resolved -), Sensitive skin (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Vision blurred (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10011115146	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Inflammation (n/a - Unknown -), Micturition urgency (n/a - Unknown - Other Medically Important Condition), Oedema (n/a - Unknown -), Pain (n/a - Unknown -), Photopsia (n/a - Unknown -), Pruritus (n/a - Unknown -), Sensitive skin (n/a - Unknown -), Urinary incontinence (n/a - Unknown - Other Medically Important Condition), Vaccination site erythema (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10011115152	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Dizziness (n/a - Unknown -), Fatigue (n/a - Unknown -), Nausea (n/a - Unknown -), Pain (n/a - Unknown -), Seizure (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	

											Sensitive skin (n/a - Unknown -)			
EU-EC-10011115161	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10011115167	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Palpitations (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10011115172	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition), Rash (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR	
EU-EC-10011115193	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Insomnia (n/a - Unknown -), Nausea (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10011115217	30/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR	

EU-EC-10011115219	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Other Medically Important Condition) Dyspnoea (n/a - Unknown -), Headache (n/a - Unknown -), Paraesthesia (n/a - Unknown -), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown -)	Not applicable - [1d - n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011115307	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Skin reaction (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011115310	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Unknown -), Crying (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Hypothermia (n/a - Unknown - Other Medically Important Condition), Musculoskeletal stiffness (n/a - Unknown -), Oxygen saturation decreased (n/a - Unknown -), Paraesthesia (n/a - Unknown -), Respiratory distress (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011115739	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Unknown -), Pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011116058	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Unknown - Disabling, Other Medically Important Condition), Dizziness postural (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Headache (n/a - Unknown - Disabling, Other Medically Important Condition), Syncope (n/a - Unknown - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[OMEPRAZOLE] (C - Gastrointestinal pain - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011116064	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hyperhidrosis (n/a - Unknown -), Syncope (1d - Recovered/Resolved - Other Medically Important Condition), Vision blurred (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011116289	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10011116317	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved -) Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011116334	30/12/2021	Spontaneous	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011116335	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011116341	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovered/Resolved -), Bradycardia (n/a - Recovered/Resolved - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011116730	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Eye irritation (n/a - Not Recovered/Not Resolved -), Eye pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011116734	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Atrioventricular block (4d - Recovered/Resolved - Other Medically Important Condition), Orthostatic hypotension (4d - Recovered/Resolved - Other Medically Important Condition), Seizure (0d - Recovered/Resolved - Other Medically Important Condition), Syncope (0d - Recovered/Resolved - Other Medically Important Condition), Vomiting (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	GUANFACINE [GUANFACINE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - n/a])	ICSR

EU-EC-10011116806	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011116820	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in jaw (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011116856	30/12/2021	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)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[DROSPIRENONE, ETHINYLESTRADIOL] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011116893	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -), Injection site inflammation (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Injection site swelling (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011117012	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011117549	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	IRON [IRON] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011117646	30/12/2021	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), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011117662	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011118200	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										(n/a - Unknown - Other Medically Important Condition)			
EU-EC-10011118643	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amnesia (n/a - Recovered/Resolved -), Balance disorder (n/a - Not Recovered/Not Resolved -), Disorientation (n/a - Recovered/Resolved -), Disturbance in attention (n/a - Recovered/Resolved -), Gait disturbance (n/a - Recovered/Resolved -), Memory impairment (n/a - Recovered/Resolved -), Speech disorder (n/a - Recovered/Resolved -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011118644	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Sepsis (n/a - Unknown - Caused/Prolonged Hospitalisation), Septic shock (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011118671	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011118836	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypotension (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Loss of consciousness (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Mydriasis (n/a - Unknown - Caused/Prolonged Hospitalisation), Oculogyric crisis (n/a - Unknown - Caused/Prolonged Hospitalisation), Partial seizures (1min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011118868	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (2wk - Recovered/Resolved -), Myalgia (2wk - Recovered/Resolved -), Pain in extremity (2wk - Recovered/Resolved -), Swelling (2wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011120031	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dysphagia (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10011120038	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Somnolence (n/a - Unknown -) Hypoaesthesia (n/a - Unknown - Other Medically Important Condition), Monoplegia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011120075	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Altered state of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Aphasia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dysarthria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011120101	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angioedema (n/a - Unknown - Other Medically Important Condition), Macroglossia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [22d - .3mL - Intramuscular])	[EBASTINE] (C - Angioedema - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10011120120	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011120121	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovered/Resolved -), Depressed level 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	ICSR
EU-EC-10011120137	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Febrile convulsion (n/a - Unknown -), Generalised tonic-clonic seizure (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Incontinence (n/a - Unknown -), Paralysis (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10011120163	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Unknown -), Immunisation (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011120180	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Blood pressure decreased (n/a - Unknown -), Brain natriuretic peptide increased (n/a - Unknown -), Delirium febrile (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown -), Erythema (n/a - Unknown -), Gastrointestinal disorder (n/a - Unknown -), Headache (n/a - Unknown -), Inflammation (n/a - Unknown -), Kawasaki's disease (n/a - Unknown - Other Medically Important Condition), Mucosal disorder (n/a - Unknown -), Multisystem inflammatory syndrome in children (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ocular hyperaemia (n/a - Unknown -), Pyrexia (n/a - Unknown -), Systemic inflammatory response syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011120181	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Conversion disorder (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown -), Vomiting (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011120187	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Fatigue (n/a - Unknown - Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10011120189	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition), Vision blurred (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011120193	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cardio-respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Drowning (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011120198	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hypertension (n/a - Unknown - Other Medically Important Condition), Hypoaesthesia (n/a - Unknown - Other Medically Important Condition), Hypoaesthesia oral (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown - Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other Medically Important Condition), Photopsia (n/a - Unknown - Other Medically Important Condition), Rhinitis (n/a - Unknown - Other Medically Important Condition), Sensitive skin (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011120206	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving -), Dehydration (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

											-), Hypotension (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC-10011120211	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anxiety (n/a - Unknown -), Conversion disorder (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown -), Nausea (n/a - Unknown -), Paraesthesia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), [A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (S - Influenza - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011120245	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amaurosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Generalised tonic-clonic seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oropharyngeal pain (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tinnitus (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site erythema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10011120252	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011120283	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypotonic-hyporesponsive episode (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011120473	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovered/Resolved -), Hypoaesthesia (n/a - Recovered/Resolved -), Muscular weakness (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011120610	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asymptomatic COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011120653	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (1d - Recovered/Resolved - Life Threatening,	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

EU-EC-10011120818	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Other Medically Important Condition) Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011120867	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011120953	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011121143	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011121209	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (1d - Recovered/Resolved - Other Medically Important Condition), Dizziness (1d - Recovered/Resolved - Other Medically Important Condition), Nasal congestion (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (1d - Recovered/Resolved - Other Medically Important Condition), Pulmonary embolism (1d - Recovered/Resolved - Other Medically Important Condition), Syncope (1d - Recovered/Resolved - Other Medically Important Condition), Testicular pain (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011121236	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011121243	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011121270	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Heart rate decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Hypotonic-hyporesponsive episode (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR

EU-EC-10011121574	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (18d - Not Recovered/Not Resolved -), Dyspnoea (18d - Not Recovered/Not Resolved -), Fatigue (18d - Not Recovered/Not Resolved -), Hypotonia (18d - Not Recovered/Not Resolved -), Somnolence (18d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011121774	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011121872	30/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Fatal - Results in Death, Other Medically Important Condition), Abnormal faeces (n/a - Fatal - Results in Death), Anaemia (n/a - Fatal - Results in Death), Anaphylactic reaction (n/a - Fatal - Results in Death, Other Medically Important Condition), Defaecation disorder (n/a - Fatal - Results in Death, Other Medically Important Condition), Dizziness (n/a - Fatal - Results in Death, Other Medically Important Condition), Fatigue (n/a - Fatal - Results in Death), Lung disorder (n/a - Fatal - Results in Death), Myocarditis (n/a - Fatal - Results in Death, Other Medically Important Condition), Nerve injury (n/a - Fatal - Results in Death), Respiratory arrest (n/a - Fatal - Results in Death, Other Medically Important Condition), Shock (n/a - Fatal - Results in Death, Other Medically Important Condition), Vomiting (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011121920	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Not Recovered/Not Resolved -), Headache (1d - Not Recovered/Not Resolved -), Influenza (1d - Not Recovered/Not Resolved -), Limb discomfort (1d - Not Recovered/Not Resolved -), Malaise (1d - Not Recovered/Not Resolved -), Pyrexia (1d - Not Recovered/Not Resolved -), Somnolence (1d - Not Recovered/Not Resolved -), Tremor (1d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10011121946	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Recovered/Not Resolved -) Pharyngeal erythema (45d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Platelet count decreased (41d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (64d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Systemic lupus erythematosus (38d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombocytopenic purpura (45d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011121977	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pleural effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pleurisy (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Viral infection (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011121995	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deafness (n/a - Unknown - Disabling, Other Medically Important Condition), Pyrexia (n/a - Unknown - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011122029	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Disease recurrence (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10011122083	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (2d - Recovered/Resolved -), Menstruation delayed (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011122135	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (0d - Recovered/Resolved -), Feeling hot (0d - Recovered/Resolved -), Hyperhidrosis (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011122199	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011122248	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (12d - Recovered/Resolved -), Rash (12d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011122268	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (0d - Recovering/Resolving -), Nausea (0d - Recovering/Resolving -), Pyrexia (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011122372	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (2d - Recovered/Resolved -), Limb discomfort (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011122376	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (1d - Unknown -), Malaise (1d - Unknown -), Paraesthesia (1d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011122540	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (1d - Recovered/Resolved -), Rash erythematous (1d - Recovered/Resolved -), Urticaria (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011122580	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (1d - Recovering/Resolving -), Dizziness (1d - Recovering/Resolving -), Headache (1d - Recovering/Resolving -), Limb discomfort (1d - Recovering/Resolving -), Vomiting (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011122771	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

EU-EC-10011122778	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	- Other Medically Important Condition) Blood pressure increased (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011122789	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - Other Medically Important Condition), Hypersensitivity (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Pruritus (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011122981	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (7wk - Recovered/Resolved -), Pericarditis (7wk - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011123205	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea exertional (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011123217	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthmatic crisis (n/a - Recovering/Resolving -), Cough (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011123258	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011123380	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011123394	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	Yes	Menstrual disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011123405	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Eczema (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011123507	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abnormal uterine bleeding (32d - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anaemia (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

										Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10011123587	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Diplopia (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Respiratory distress (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011123670	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (2d - Recovered/Resolved -), Dizziness (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Limb discomfort (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011123717	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011123719	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Unknown -), Injection site pain (1d - Unknown -), Nausea (1d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011123917	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Haematoma (11d - Not Recovered/Not Resolved -), Pain in extremity (11d - Not Recovered/Not Resolved -), Rash (11d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011124020	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

			Professional	Area						Resolved -), - n/a - n/a)]			
										Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Limb discomfort (n/a - Not Recovered/Not Resolved -)			
EU-EC-10011124021	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (2d - Recovered/Resolved -), Dizziness (2d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Influenza like illness (2d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011124061	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site reaction (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011124283	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011124317	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (1d - Recovered/Resolved -), Dizziness (2d - Recovered/Resolved -), Dizziness (3d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Feeling hot (1d - Recovered/Resolved -), Head discomfort (1d - Recovered/Resolved -), Head discomfort (2d - Recovered/Resolved -), Head discomfort (3d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -), Injection site swelling (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)])	Not reported	ICSR
EU-EC-10011124326	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Aphthous ulcer (7d - Not Recovered/Not Resolved -), Chills (7d - Not Recovered/Not Resolved -), Oropharyngeal pain (7d - Not Recovered/Not Resolved -), Pyrexia (7d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011124328	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -), Injection site swelling (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Pyrexia (1d - Recovered/Resolved -), Throat irritation (1d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved -)			
EU-EC-10011124441	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site erythema (n/a - Not Recovered/Not Resolved -), Limb discomfort (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Pruritus (n/a - Not Recovered/Not Resolved -), Vaccination site reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011124479	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (2d - Recovered/Resolved -), Pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011124493	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (2d - Recovering/Resolving -), Dyspnoea (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011124540	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011124816	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011124908	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (195min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011124920	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in jaw (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Palpitations (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Presyncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sinus arrhythmia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10011125015	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR
EU-EC-10011125131	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (5d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011125265	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (40d - Not Recovered/Not Resolved -), Gastrointestinal pain (40d - Not Recovered/Not Resolved -), Injection site pain (40d - Not Recovered/Not Resolved -), Nausea (40d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011125420	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (1d - Recovering/Resolving -), Injection site pain (1d - Recovering/Resolving -), Malaise (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011125497	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Conjunctivitis (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Hordeolum (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011125567	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Body temperature increased (1d - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Somnolence (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011125866	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Erythema multiforme (10d - Recovered/Resolved - Other Medically Important Condition), Rash (10d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011125890	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Decreased appetite (9d - Not Recovered/Not Resolved -), Dizziness (9d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Recovered/Not Resolved -), Epilepsy (9d - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (7d - Not Recovered/Not Resolved -), Petit mal epilepsy (9d - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10011125985	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011126114	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hyposmia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011126171	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Faeces soft (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011126681	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (0d - Recovering/Resolving -), Nausea (0d - Recovering/Resolving -), Vomiting (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011126713	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (1d - Recovered/Resolved -), Fatigue (0d - Not Recovered/Not Resolved -), Limb discomfort (2d - Not Recovered/Not Resolved -), Pain in extremity (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011126833	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Petechiae (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011126940	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011127052	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (27d - Not Recovered/Not Resolved -), Cough (27d - Not Recovered/Not Resolved -), Dizziness (27d - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Recovered/Not Resolved -), Influenza (27d - Not Recovered/Not Resolved -), Influenza like illness (27d - Not Recovered/Not Resolved -), Injection site pain (27d - Not Recovered/Not Resolved -), Injection site swelling (27d - Not Recovered/Not Resolved -), Lymphadenopathy (27d - Not Recovered/Not Resolved -), Oropharyngeal pain (27d - Not Recovered/Not Resolved -)			
EU-EC-10011127318	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -), Hypotension (n/a - Recovering/Resolving - Other Medically Important Condition), Pain (n/a - Recovering/Resolving -), Sensitive skin (n/a - Recovering/Resolving -), Tinnitus (n/a - Recovering/Resolving -), Vision blurred (n/a - Recovering/Resolving -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011127494	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Electrocardiogram ST segment elevation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Insomnia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (146h - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										- Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Troponin I increased (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10011127583	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011127657	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011128087	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vision blurred (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011128111	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypotension (65min - Recovered/Resolved - Other Medically Important Condition), Incorrect route of product administration (n/a - Unknown -), Syncope (65min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intradermal])	Not reported	ICSR
EU-EC-10011128167	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011128180	30/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[PARACETAMOL] (C - Nasopharyngitis - Not applicable - [4d - n/a - n/a])	ICSR
EU-EC-10011128192	30/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10011128268	30/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011101293	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011101532	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Limb discomfort (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011101629	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epilepsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011101646	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR

										Hyperthermia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10011101674	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Discharge (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Face oedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lip blister (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vulvovaginal erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011101759	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal lymphadenopathy (n/a - Recovering/Resolving -), Abdominal pain (n/a - Recovering/Resolving -), Diarrhoea (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011101942	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .45mL - Intramuscular])	Not reported	ICSR
EU-EC-10011102419	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Palpitations (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Systemic lupus erythematosus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10011102428	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymph node pain (1d - Not Recovered/Not Resolved - Other Medically Important Condition), Sluggishness (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011102448	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Adjustment disorder (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DESLORATADINE] (C - Rhinitis allergic - n/a - [n/a - n/a - Oral])	ICSR

										Aggression (n/a - Recovering/Resolving - Life Threatening), Altered state of consciousness (0d - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Life Threatening, Other Medically Important Condition), Irritability (n/a - Unknown -), Malaise (30h - Recovered/Resolved -), Neutropenia (n/a - Unknown - Life Threatening, Other Medically Important Condition), Oxygen saturation decreased (30h - Recovered/Resolved - Life Threatening, Other Medically Important Condition), Physical deconditioning (n/a - Unknown - Life Threatening, Other Medically Important Condition), Suicide attempt (n/a - Recovering/Resolving - Life Threatening, Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving - Life Threatening, Other Medically Important Condition), Vomiting (2d - Recovered/Resolved - Life Threatening, Other Medically Important Condition)			
EU-EC-10011102480	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[LISDEXAMFETAMINE DIMESYLATE] (C - n/a - n/a - [n/a - 20mg - n/a]), [VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011102774	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Neck pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Palpitations (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011103100	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011103133	29/12/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a -	Not reported	ICSR

				Area						Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	Intramuscular])		
EU-EC-10011103352	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Vaginal haemorrhage (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011103367	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011103723	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011103850	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011103852	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Balance disorder (n/a - Recovered/Resolved - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Dizziness postural (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011103854	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chills (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Cough (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										- Caused/Prolonged Hospitalisation), Vertigo (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10011103859	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown -), Asthenia (n/a - Unknown -), Chills (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Disseminated Bacillus Calmette-Guerin infection (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Nausea (n/a - Unknown -), Pyrexia (n/a - Unknown -), Temporomandibular joint syndrome (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011103867	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Nausea (n/a - Unknown -), Pain (n/a - Unknown -), Sensitive skin (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition), Vision blurred (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011103875	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011103879	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Acetonaemic vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Back pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest discomfort (13d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (13d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Injection site swelling (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (12d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10011103887	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Platelet count decreased (57h - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Thrombocytopenic purpura (n/a - Unknown -)			
EU-EC-10011103888	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011103909	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011103916	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011103917	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood glucose increased (n/a - Recovered/Resolved - Other Medically Important Condition), Cerebral haemorrhage (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Epilepsy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemangioma (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Haemorrhage (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (161h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Unresponsive to stimuli (9630min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), White blood cell count increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011103918	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Nausea (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011103919	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Muscle twitching (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR

										Tremor (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10011103920	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011103923	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Motor dysfunction (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011103936	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Joint hyperextension (n/a - Unknown - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Postictal state (n/a - Unknown - Caused/Prolonged Hospitalisation), Salivary hypersecretion (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011103938	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other Medically Important Condition), Pharyngitis (n/a - Unknown - Other Medically Important Condition), Tonsillar hypertrophy (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011103943	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011103953	29/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-	Not reported	ICSR

				Economic Area							Asthenia (n/a - Unknown -), Dizziness (n/a - Unknown -), Fatigue (n/a - Unknown -), Myalgia (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	19 immunisation - Not applicable - [1d - n/a - Intramuscular]		
EU-EC-10011103955	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bradycardia (65d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (65d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Palpitations (65d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10011103957	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Unknown -), Headache (n/a - Recovered/Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10011103992	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10011104004	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Respiratory distress (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10011104006	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Anaphylactic shock (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Arthralgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bronchospasm (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	

										Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Erythema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myalgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pruritus (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Respiratory distress (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sensitive skin (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10011104019	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (35min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011104020	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011104030	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011104032	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (362h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (370h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Microcytic anaemia (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Muscular weakness (362h - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/CALIFORNIA/7/2009 (H1N1)PDM09-DERIVED STRAIN USED (NYMC X-181), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, X-263B), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), INFLUENZA VACCINE] (C - Influenza immunisation - n/a - [n/a - n/a])	ICSR
EU-EC-10011104228	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10011104340	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -), Pain (n/a - Unknown -), Sensitive skin (n/a - Unknown -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Vision blurred (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011104346	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Disorientation (1min - Recovered/Resolved -), Dizziness (n/a - Unknown -), Pain (n/a - Unknown -), Sensitive skin (n/a - Unknown -), Syncope (1min - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011104348	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011104349	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Appendicitis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011104359	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011104360	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Oedema (n/a - Unknown - Other Medically Important Condition), Pruritus (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Unknown - Other Medically Important Condition), Sensitive skin (n/a - Unknown - Other Medically Important Condition), Vaccination site erythema (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011104368	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Chills (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Inflammation (n/a - Unknown -), Irritability (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -), Mobility decreased (n/a - Not Recovered/Not Resolved -), Pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Recovered/Resolved -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Respiratory distress (n/a - Unknown - Other Medically Important Condition), Sensitive skin (n/a - Unknown -), Vaccination site erythema (n/a - Unknown -), Vaccination site oedema (n/a - Unknown -)			
EU-EC-10011104370	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Accidental overdose (n/a - Unknown -), Blood pressure increased (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Unknown -), Headache (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011104393	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Angioedema (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rash (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (0d - 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	ICSR
EU-EC-10011104399	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (42d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (42d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10011104405	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cellulitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Left ventricular failure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pericarditis (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10011104445	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011104541	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011104543	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (3h - Recovered/Resolved -), Syncope (90min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011104559	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Febrile convulsion (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011104571	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown -), Asthenia (8h - Recovered/Resolved -), Decreased appetite (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (8h - Recovered/Resolved -), Musculoskeletal pain (8h - Recovered/Resolved -), Nausea (8h - Recovered/Resolved -), Pyrexia (8h - Recovered/Resolved -), Spinal pain (150min - Recovered/Resolved -), Vaccination site pain (n/a - Unknown -), Vomiting (8h - Recovered/Resolved -), Wrong product administered (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (N - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	ICSR
EU-EC-10011104584	29/12/2021	Spontaneous	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), Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest discomfort (n/a - Unknown - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Chills (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Induration (n/a - Unknown - Other Medically Important Condition), Inflammation (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Nodule (n/a - Unknown - Other Medically Important Condition), Oedema (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), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition), Sensitive skin (n/a - Unknown - Other Medically Important Condition), Sleep paralysis (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10011104598	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Headache (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011104601	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Fatigue (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Seizure (5min - Recovered/Resolved - Other Medically Important Condition), Speech disorder (5min - Recovered/Resolved - Other Medically Important Condition), Tremor (5min - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Vomiting (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10011104688	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	EVRA 203 MICROGRAMS/24 HOURS + 33.9 MICROGRAMS/24 HOURS TRANSDERMAL PATCH [ETHINYLESTRADIOL, NORELGESTROMIN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011104780	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site lymphadenopathy (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011104956	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (2d - Recovered/Resolved -), Dyspnoea (2d - Recovered/Resolved -), Fatigue (3d - Recovered/Resolved -), Feeling cold (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Influenza (2d - Recovered/Resolved -), Pain in extremity (2d - Recovered/Resolved -), Throat irritation (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011105306	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011105517	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest discomfort (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocardial oedema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Troponin T increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011105534	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011105537	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011105544	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011105668	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	SARS-CoV-2 test positive (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011105882	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lung hyperinflation (n/a - Not Recovered/Not Resolved - Other Medically Important)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN]	Not reported	ICSR

										Condition), Nodule (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	(S - n/a - n/a - [n/a - n/a - n/a])		
EU-EC-10011106001	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Apathy (n/a - Recovered/Resolved -), Asthenia (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011106037	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	SARS-CoV-2 test positive (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011106448	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	SARS-CoV-2 test positive (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011106584	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovered/Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -), Presyncope (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011106585	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011106619	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Troponin increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011106689	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011106999	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Atrial tachycardia (n/a - Recovered/Resolved With Sequelae - Life Threatening), SARS-CoV-2 test negative (n/a - Recovered/Resolved With Sequelae - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	29/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Male	No	COVID-19 (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011107074			Professional	Economic Area	available	Years				Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	(S - n/a - n/a - [n/a - n/a - Intramuscular])		
EU-EC-10011107549	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011107555	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood immunoglobulin E increased (n/a - Unknown -), Cold sweat (n/a - Recovered/Resolved -), Food allergy (n/a - Unknown -), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (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 - Intramuscular])	[FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10011107560	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Unknown -), Malaise (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011107561	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved - Other Medically Important Condition), Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011107578	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10011107581	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

EU-EC-10011107596	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Encephalomyelitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Feeling cold (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Opsoclonus myoclonus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Palpitations (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011107599	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (45min - Recovered/Resolved -), Hypotension (n/a - Unknown -), Syncope (45min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011107603	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011107606	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Palpitations (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011107608	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Heart rate irregular (n/a - Recovered/Resolved - Other Medically Important Condition), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-	29/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Male	No	Chest discomfort	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011107615			Professional	European Economic Area	available	Years	Specified			(n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -), Dehydration (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pneumothorax (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC-10011107616	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011107621	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Decreased activity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011107627	29/12/2021	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 discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Cold sweat (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Contusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hypertension (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Mitral valve prolapse (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	IRON [IRON] (C - Iron deficiency anaemia - n/a - [n/a - n/a - n/a])	ICSR

										Important Condition), Oxygen saturation decreased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Presyncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Sinus arrhythmia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Sinus tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10011107635	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011107655	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011107658	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Arthralgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Autonomic neuropathy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Back pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Neck pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Postural orthostatic tachycardia syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Weight decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011107728	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR

										Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition), Myocarditis (15d - Recovered/Resolved - Other Medically Important Condition), Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition), Tachycardia (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10011107779	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Thrombotic stroke (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011107801	29/12/2021	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 - Life Threatening, Caused/Prolonged Hospitalisation), Asthenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Dysstasia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Haemolytic anaemia (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Jaundice (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011107939	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										-), Headache (n/a - Recovered/Resolved -)			
EU-EC-10011108023	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Myalgia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011108090	29/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hodgkin's disease (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011108230	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Unknown -), Muscle twitching (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011108338	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vasculitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10011108350	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011108372	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Limb discomfort (6d - Recovered/Resolved -), Pyrexia (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011108378	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Local reaction (1d - Recovering/Resolving -), Pyrexia (1d - Recovering/Resolving -), Vaccination site pain (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011108872	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011108918	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cyanosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Febrile convulsion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Increased bronchial secretion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Respiratory distress (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Septic shock (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011108922	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Chills (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Dizziness (n/a - Unknown -), Fatigue (n/a - Unknown -), Hypothermia (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown -), Oropharyngeal discomfort (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Palpitations (n/a - Unknown -), Tachycardia (n/a - Unknown -)			
EU-EC-10011108926	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011108930	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011108968	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition aggravated (n/a - Unknown - Other Medically Important Condition), Dermatosis (n/a - Unknown - Other Medically Important Condition), Erythema (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011108978	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown -), Asthenia (n/a - Unknown -), Disorientation (n/a - Unknown -), Dizziness (n/a - Unknown -), Headache (n/a - Unknown -), Myalgia (n/a - Unknown -), Nausea (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011108988	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Unknown - Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	29/12/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Female	No	Areflexia (n/a -)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011109081			Professional	Economic Area	available	Years	Specified			Unknown - Other Medically Important Condition), Febrile convulsion (n/a - Unknown - Other Medically Important Condition), Guillain-Barre syndrome (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	(S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular])		
EU-EC-10011109083	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hepatitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Transaminases increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011109172	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Electrocardiogram abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Troponin increased (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011109296	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypotonic-hyporesponsive episode (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011109298	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Cough (1wk - Recovered/Resolved -), Electrocardiogram ambulatory abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR

										Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (1wk - Recovered/Resolved -)			
EU-EC-10011109304	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Balance disorder (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypotonia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypotonic-hyporesponsive episode (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vaccination site reaction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Visual field defect (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011109337	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011109373	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Gait disturbance (n/a - Unknown -), Hand deformity (n/a - Unknown -), Vertigo (27d - Recovered/Resolved - Other Medically Important Condition), Vestibular disorder (27d - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011109374	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Urticaria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011109377	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown -), Cough (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Headache (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR

										Unknown -), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10011109479	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination failure (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011109540	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Unknown -), Erythema (n/a - Unknown - Other Medically Important Condition), Pruritus (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011109603	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011109701	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cerebrovascular accident (n/a - Unknown - Caused/Prolonged Hospitalisation), Hemiparesis (n/a - Unknown - Caused/Prolonged Hospitalisation), Slow response to stimuli (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011109744	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase MB increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Blood creatine phosphokinase increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Heart rate abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocardial hypoxia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011109763	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angioedema (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011109834	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Toxic skin eruption (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011109913	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pneumothorax (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	29/12/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Female	No	Intermenstrual	COMIRNATY [TOZINAMERAN]	[DOXYCYCLINE,	ICSR

10011109951			Healthcare Professional	Economic Area	available	Years				bleeding (n/a - Not Recovered/Not Resolved -), Premenstrual syndrome (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular])	DOXYCYCLINE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10011110122	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericardial effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [23d - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011110159	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paralysis (2wk - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011110368	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypoaesthesia (n/a - Recovered/Resolved -), Lip oedema (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011110466	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011110590	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011110621	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011110767	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011110784	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	C-reactive protein increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Conjunctival hyperaemia (48h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash maculo-papular (48h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Red blood cell sedimentation rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Serum ferritin increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011110831	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011110840	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anal sphincter atony (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Anisocoria (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Bladder sphincter	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										<p>atony (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Bradycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Chest discomfort (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Creptitations (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Cyanosis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Dyskinesia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Dyspnoea (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Jugular vein distension (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Nervous system disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Oxygen saturation immeasurable (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Postictal state (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Seizure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Syncope (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p> <p>Ventricular fibrillation (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation),</p>			
EU-EC-10011110859	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	<p>Dizziness (1d - Recovered/Resolved -),</p> <p>Feeling hot (1d - Recovering/Resolving -),</p> <p>Nausea (1d - Recovered/Resolved -),</p> <p>Vomiting (1d - Recovered/Resolved -)</p>	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011110979	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	<p>Application site haemorrhage (4d - Recovered/Resolved -),</p> <p>Injection site erythema (4d - Recovered/Resolved -),</p> <p>Local reaction (4d - Recovered/Resolved -)</p>	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10011110989	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (1d - Not Recovered/Not Resolved -), Vomiting (1d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011110991	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Chills (n/a - Unknown -), Dizziness (n/a - Unknown -), Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011111148	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (7d - Recovered/Resolved -), Rash (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011111194	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (1d - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Influenza (1d - Recovered/Resolved -), Injection site swelling (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011111209	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011111219	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Recovering/Resolving -), Rash pruritic (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011111225	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (1d - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Influenza (1d - Recovered/Resolved -), Injection site swelling (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011111382	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Feeling hot (2d - Recovered/Resolved -), Pain in extremity (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011111564	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011111593	29/12/2021	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 -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011111764	29/12/2021	Spontaneous	Non Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Other Medically Important)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

				Economic Area						Condition), Dizziness postural (2d - Recovered/Resolved - Other Medically Important Condition), Hallucination (0d - Recovered/Resolved - Other Medically Important Condition), Headache (1d - Recovered/Resolved - Other Medically Important Condition), Muscular weakness (2d - Recovered/Resolved - Other Medically Important Condition), Paralysis (n/a - Unknown - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition)	Not applicable - [n/a - n/a - n/a])		
EU-EC-10011111775	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011111833	29/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood glucose fluctuation (n/a - Unknown -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011111854	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011111906	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Guillain-Barre syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011112269	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011112281	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011112297	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Respiratory distress (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011112363	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Acidosis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Autonomic nervous system imbalance (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Depressed level of consciousness (2d - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

											- Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling abnormal (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Loss of consciousness (1995min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Orthostatic intolerance (n/a - Unknown -), Presyncope (1995min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (1995min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sluggishness (1995min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (1995min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination site pain (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)		
EU-EC-10011112379	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (10min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011112510	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .5mL - Intramuscular])	Not reported	ICSR
EU-EC-10011112528	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Hyperhidrosis (n/a - Recovered/Resolved -), Hypotension (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved -), Pain (n/a - Recovered/Resolved -), Paraesthesia (n/a - Recovered/Resolved -), Sensitive skin (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011112774	29/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

EU-EC-10011113158	29/12/2021	Spontaneous	Healthcare Professional	Economic Area European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Other Medically Important Condition) Altered state of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Anaphylactic reaction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Gaze palsy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypotonic-hyporesponsive episode (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pallor (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Unresponsive to stimuli (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Wheezing (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	Not applicable - [1d - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011113174	29/12/2021	Spontaneous	Healthcare Professional	Economic Area European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011113241	29/12/2021	Spontaneous	Healthcare Professional	Non Economic Area European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vision blurred (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011113423	29/12/2021	Spontaneous	Healthcare Professional	Economic Area European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (1d - Recovered/Resolved -), Vaccination site reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011113458	29/12/2021	Spontaneous	Healthcare Professional	Economic Area European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011113462	29/12/2021	Spontaneous	Healthcare Professional	Economic Area European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (4d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011113475	29/12/2021	Spontaneous	Healthcare Professional	Economic Area European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash maculo-papular (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011113488	29/12/2021	Spontaneous	Non Healthcare Professional	Non Economic Area European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Erythema (n/a - Unknown - Disabling, Other Medically Important Condition), Immunisation (n/a - Unknown - Disabling, Other Medically Important Condition), Injection site mass (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Resolved - Disabling, Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - Disabling, Other Medically Important Condition), Off label use (n/a - Unknown - Disabling, Other Medically Important Condition), Pain (n/a - Unknown - Disabling, Other Medically Important Condition), Pain in extremity (n/a - Unknown - Disabling, Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Disabling, Other Medically Important Condition)			
EU-EC-10011113630	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Nausea (n/a - Unknown -), Respiratory distress (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011113753	29/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011113801	29/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011088808	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (8d - Recovered/Resolved -), Vaccination failure (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011089124	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Extrasystoles (n/a - Not Recovered/Not Resolved -), Fibrin D dimer increased (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

										Resolved -), Hypotension (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not Recovered/Not Resolved -)			
EU-EC-10011089241	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovered/Resolved -), Diarrhoea (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Muscle spasms (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Rash (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011089453	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011089914	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011089917	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011089925	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011090068	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011090198	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovered/Resolved -), Bradycardia (n/a - Recovered/Resolved - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011090199	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving -), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10011090200	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011090223	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

EU-EC-10011090305	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Hypoaesthesia (n/a - Recovering/Resolving -), Muscular weakness (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10011090362	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (2d - Recovered/Resolved -), Lymphadenopathy (2d - Recovered/Resolved -), Peripheral swelling (2d - Recovered/Resolved -), Vomiting (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [2s - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011090859	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10011090919	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011091102	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011091280	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011091466	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011091887	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Contusion (n/a - Unknown -), Eosinophilia (n/a - Unknown -), Petechiae (n/a - Unknown -), Rhinitis (n/a - Unknown -), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011091910	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition), Chills (n/a - Recovered/Resolved -), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[IBUPROFEN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Condition), Troponin T increased (n/a - Recovered/Resolved -)			
EU-EC-10011092090	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011092121	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovering/Resolving -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011092173	28/12/2021	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 -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011092196	28/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypersensitivity (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lip swelling (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Throat tightness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011092200	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011092221	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Malaise (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[PARACETAMOL] (C - Headache, Pyrexia - n/a - [n/a - n/a - Oral])	ICSR

										Recovered/Not Resolved - Disabling, Other Medically Important Condition), Urticaria (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)			
EU-EC-10011092228	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011092252	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (16min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011092255	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (15min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011092276	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011092285	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011092290	28/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown -), Immunisation (n/a - Unknown - Other Medically Important Condition), Muscular weakness (n/a - Unknown -), Off label use (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011092311	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011092320	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011092364	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (10s - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011092381	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011092383	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asymptomatic COVID-19 (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vaccination failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR

EU-EC-10011092385	28/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Burns third degree (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011092398	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Limb injury (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011092424	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011092425	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition), Heart rate decreased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011092428	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diplopia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Multiple sclerosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Neuromyelitis optica spectrum disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nystagmus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Visual pathway disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011092492	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -), Oligomenorrhoea (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011092749	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Angioedema (n/a - Unknown -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-	28/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Eyelid oedema (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011092803			Professional	Economic Area	available	Years				Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Uveitis (n/a - Recovering/Resolving - Other Medically Important Condition), Visual impairment (n/a - Recovering/Resolving - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC-10011093155	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not 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])	Not reported	ICSR
EU-EC-10011093200	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Chills (1h - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011093647	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), C-reactive protein increased (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Ear pain (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011094131	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011094470	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011094812	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095003	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deafness neurosensory (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10011095029	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011095046	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Troponin I abnormal (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095050	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hypoesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Oral pain (n/a - Recovering/Resolving -), Respiration abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10011095081	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lower respiratory tract infection (n/a - Not Recovered/Not Resolved -), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011095089	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Asthenopia (n/a - Recovering/Resolving - Other Medically Important Condition), Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Hepatitis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

										Condition), Inflammation (n/a - Recovering/Resolving - Other Medically Important Condition), Liver function test abnormal (n/a - Recovering/Resolving - Other Medically Important Condition), Pericardial effusion (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10011095103	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011095104	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Clonic convulsion (n/a - Recovering/Resolving - Other Medically Important Condition), Confusional state (n/a - Recovering/Resolving -), Visual impairment (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011095156	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095159	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095165	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095167	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095169	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011095170	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chromaturia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Glomerulonephritis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Haematuria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Red blood cells urine positive (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urinary occult blood positive (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	28/12/2021	Spontaneous	Healthcare	Non	Not	12-17	Not	Female	No	Dizziness (1h -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011095172			Professional	European Economic Area	available	Years	Specified			Recovered/Resolved -), Headache (1h - Recovered/Resolved -), Syncope (1h - Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])		
EU-EC-10011095173	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095176	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011095177	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood creatine phosphokinase increased (118h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (118h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (118h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myoglobin blood increased (118h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Troponin increased (118h - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011095178	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095185	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypotension (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Palpitations (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095187	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (0d - Recovered/Resolved -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095197	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved -), Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011095198	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095202	28/12/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Cold sweat (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -)	Not reported	ICSR

				Economic Area						Headache (n/a - Unknown -), Nausea (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition), Visual impairment (n/a - Unknown -)	Not applicable - [n/a - n/a - n/a])		
EU-EC-10011095210	28/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (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	ICSR
EU-EC-10011095219	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095220	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Alanine aminotransferase increased (n/a - Unknown -), Blood lactate dehydrogenase increased (n/a - Unknown -), Blood potassium decreased (n/a - Unknown -), Blood uric acid increased (n/a - Unknown -), Headache (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095228	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (25min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095232	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Oxygen saturation decreased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095298	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095327	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095332	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011095388	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10011095512	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (15min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011095529	28/12/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Male	No	Discomfort (n/a - Not Recovered/Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

			Professional	Economic Area						Resolved - Other Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mobility decreased (n/a - Unknown - Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other Medically Important Condition)	Not applicable - [1d - n/a - n/a])		
EU-EC-10011095750	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Disturbance in attention (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011095779	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Cough (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Lethargy (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 -), Rash (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011095824	28/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Condition aggravated (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Inappropriate schedule of product administration (n/a - Unknown -), Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Muscle fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Post viral fatigue syndrome (n/a - Unknown - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10011096204	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011096208	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Testicular pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011096364	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011096391	28/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Thrombosis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011096418	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011096615	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling cold (n/a - Unknown -), Musculoskeletal stiffness (n/a - Unknown -), Unresponsive to stimuli (n/a - Fatal - Results in Death, Other Medically Important Condition), Vaccination site pain (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not reported	ICSR
EU-EC-10011096637	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (n/a - Recovering/Resolved - Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Recovering/Resolved -), Chest pain (n/a - Recovering/Resolved - Caused/Prolonged Hospitalisation), Inflammation (n/a - Recovering/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011096640	28/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Recovering/Resolved - Other Medically Important Condition), Musculoskeletal chest pain (n/a - Not Recovered/Not Resolved - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

EU-EC-10011096658	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Medically Important Condition) Facial paresis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Monoplegia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR
EU-EC-10011096695	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011096738	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (7d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011096988	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011097009	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Heart rate irregular (n/a - Not Recovered/Not Resolved -), Infection (n/a - Not Recovered/Not Resolved -), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011097086	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved -), Hyperhidrosis (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Recovered/Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tinnitus (n/a - Not Recovered/Not Resolved -), Visual impairment (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011097112	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Glomerulonephritis membranous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011097116	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Appendicitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Troponin increased (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-	28/12/2021	Spontaneous	Healthcare	European	Not	12-17	Adolescent	Female	No	Arthralgia (n/a -	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

10011097135			Professional	Economic Area	available	Years				Recovered/Resolved - Other Medically Important Condition), Inflammation (n/a - Recovered/Resolved - Other Medically Important Condition)	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC-10011097304	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011097380	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Psoriasis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011097419	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site erythema (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011097423	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011097437	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pruritus (n/a - Recovered/Resolved -), Vaccination site papule (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011097502	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Skin exfoliation (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011097588	28/12/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate affect (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle rigidity (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Muscle spasms (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (30min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10011097731	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Vaccination site urticaria (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10011097755	28/12/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Dyspnoea (1d - Recovered/Resolved -), Face oedema (1d - Recovered/Resolved -), Immunisation reaction (2d - Recovered/Resolved -), Lethargy (3d - Recovered/Resolved -), Malaise (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	[BILASTINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10011097817	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination failure (13d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10011097854	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011098756	28/12/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011098855	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diabetic ketoacidosis (n/a - Fatal - Results in Death, Other Medically Important Condition), Dyspnoea (n/a - Fatal - Results in Death), Palpitations (n/a - Fatal - Results in Death), Pyrexia (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011098871	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ageusia (n/a - Unknown -), Anosmia (n/a - Unknown -), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown -), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain (n/a - Unknown -), Pyrexia (n/a - Unknown -), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Shock (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10011098878	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown -), Electrocardiogram ST segment elevation (n/a - Unknown - Other Medically Important Condition), Electrocardiogram abnormal (n/a - Unknown -), Sinus bradycardia (n/a - Unknown -), Troponin increased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10011098895	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011098910	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10011098917	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10011099073	28/12/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Discomfort (0d - Recovered/Resolved - Other Medically Important Condition), Dizziness (0d - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved -), Fear (n/a - Recovered/Resolved - Other Medically Important Condition), Heart rate decreased (0d - Recovered/Resolved - Other Medically Important Condition), Hypoxia (2h - Recovered/Resolved - Other Medically Important Condition), Lethargy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR

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