

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-10009909375	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Rash pruritic (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-10009909408	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving -), Headache (1d - Recovered/Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nasal congestion (n/a - Recovering/Resolving -), 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-10009909786	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypertension (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-10009909801	06/09/2021	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)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR])	Not reported	ICSR
EU-EC-10009910603	06/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), 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-10009910658	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved -), Dizziness (3d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Myalgia (3d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Syncope (3d - Recovered/Resolved -)	applicable - [n/a - 1{DF} - n/a])		
EU-EC-10009910849	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009910971	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Facial paresis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Herpes zoster meningoencephalitis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Herpes zoster oticus (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009911013	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fear (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sleep disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10009911145	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (10min - Recovered/Resolved -), Feeling hot (10min - Recovered/Resolved -), Hyperhidrosis (10min - Recovered/Resolved -), Palpitations (10min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10009911346	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Periorbital swelling (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10009911430	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (4d - Recovered/Resolved -), Polymenorrhoea (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-	06/09/2021	Spontaneous	Non	European	Not	12-17	Not	Male	No	Headache (n/a -	COMIRNATY	Not reported	ICSR

10009911592			Healthcare Professional	Economic Area	available	Years	Specified			Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Malaise (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC-10009911699	06/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Bradycardia (n/a - Recovering/Resolving - Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovering/Resolving - Other Medically Important Condition), Presyncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10009911775	06/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown - Disabling, Other Medically Important Condition), Headache (n/a - Unknown - Disabling, Other Medically Important Condition), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Heavy menstrual bleeding (n/a - Unknown - Disabling, Other Medically Important Condition), Muscle spasms (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009911810	06/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Coma scale abnormal (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Cyanosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Generalised tonic-clonic seizure (10min - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	[RISPERIDONE] (C - Aggression - n/a - [n/a - n/a - n/a]), [SODIUM VALPROATE] (C - Epilepsy - n/a - [n/a - n/a - n/a])	ICSR

										Seizure (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Tonic posturing (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)			
EU-EC-10009911997	06/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blindness (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown -), Fatigue (n/a - Unknown -), Heart rate increased (n/a - Unknown -), Hypoesthesia (n/a - Unknown -), Hypotension (n/a - Unknown -), Presyncope (n/a - Unknown -), Skin discolouration (n/a - Unknown -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009912019	06/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009912184	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (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-10009912205	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (4h - Recovered/Resolved -), Vomiting (4h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009912284	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (1h - Recovered/Resolved -), Dyspnoea (1h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009912305	06/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Blood pressure increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009912447	06/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myopericarditis (n/a - 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-10009912479	06/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009912507	06/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

										Hospitalisation, Disabling), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]		
EU-EC-10009912509	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[LAMOTRIGINE] (C - Petit mal epilepsy - n/a - [n/a - 150mg - n/a])	ICSR
EU-EC-10009912679	06/09/2021	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 - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009912722	06/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Unknown -), Musculoskeletal pain (n/a - Unknown -), Nausea (n/a - Unknown -), Paraesthesia oral (n/a - Unknown -), Pyrexia (n/a - Unknown -), Vertigo (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009912785	06/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009912788	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vasculitis (6d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown - More in ICSR])	Not reported	ICSR
EU-EC-10009912828	06/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Generalised tonic-clonic seizure (1d - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009912863	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (n/a - Recovering/Resolving -), Tachycardia (n/a - Recovered/Resolved -), Tremor (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009913149	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009913298	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myalgia (5d - Recovered/Resolved -), Polymenorrhoea (5d	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

										- Recovered/Resolved -)	applicable - [n/a - 1{DF} - n/a]]		
EU-EC-10009913529	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]]	Not reported	ICSR
EU-EC-10009913545	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]]	Not reported	ICSR
EU-EC-10009913661	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolved -), Myalgia (n/a - Recovering/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-10009913686	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Tonsillar hypertrophy (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-10009913707	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]]	NON SPECIFIED O.A.C. [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a))	ICSR
EU-EC-10009913737	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]]	Not reported	ICSR
EU-EC-10009913902	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]]	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a)), [FLUTICASONE PROPIONATE, SALMETEROL] (C - n/a - n/a - [n/a - n/a - n/a))	ICSR
EU-EC-10009913914	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]]	Not reported	ICSR

EU-EC-10009913982	06/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009914004	06/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (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-10009914125	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pyrexia (1s - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009914165	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	COVID-19 (n/a - Recovering/Resolving -), Costochondritis (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009914195	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving -), Body temperature increased (n/a - Recovering/Resolving -), Chills (12h - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Hyperhidrosis (n/a - Not Recovered/Not Resolved -), Injection site pruritus (n/a - Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

											-), Nausea (2h - Recovered/Resolved -)		
EU-EC-10009914215	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	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-10009914256	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site warmth (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovering/Resolving -), 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-10009914283	06/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009897790	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009897992	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Body temperature increased (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009898014	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (1d - Recovered/Resolved -), Malaise (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Nausea (n/a - Recovering/Resolved -), Pyrexia (1d - Recovered/Resolved -)			
EU-EC-10009898024	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (2d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009898051	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Injection site erythema (2d - Recovered/Resolved -), Injection site inflammation (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Injection site swelling (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009898080	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Recovered/Resolved -), Nasopharyngitis (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-10009898176	05/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009898178	05/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009898268	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovering/Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009898327	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

										Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Not Recovered/Not Resolved -)	applicable - [n/a - 1{DF} - n/a]]		
EU-EC-10009898396	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Body temperature increased (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]]	AERIUS 5 MG FILM-COATED TABLETS [DESLOTRADINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009898500	05/09/2021	Spontaneous	Non Healthcare Professional	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 -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]]	Not reported	ICSR
EU-EC-10009898542	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]]	Not reported	ICSR
EU-EC-10009898553	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]]	Not reported	ICSR

EU-EC-10009898621	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - 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-10009898669	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009898786	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (7h - Recovered/Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (1d - Recovered/Resolved -), Nausea (7h - Recovered/Resolved -), Pyrexia (5h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009898788	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009898805	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009898822	05/09/2021	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 -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC-10009898823	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009898845	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site inflammation (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site warmth (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009899007	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009899351	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009899354	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (0d - Recovered/Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009899377	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Malaise (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-10009899395	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovering/Resolving -)	immunisation - Not applicable - [n/a - 1{DF} - n/a]		
EU-EC-10009899417	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Extensive swelling of vaccinated limb (n/a - Recovering/Resolving -), Injection site erythema (n/a - Recovering/Resolving -), Injection site pruritus (n/a - Recovering/Resolving -), Injection site swelling (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009899432	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009899438	05/09/2021	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 -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ACETYSALICYLIC ACID] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009899547	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -), Myalgia (1d - Recovered/Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009899582	05/09/2021	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 -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC-10009899613	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (2d - Recovered/Resolved -), Chills (8h - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009899618	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009899621	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009899639	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (1d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009899733	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (1d - Recovered/Resolved -), Injection site inflammation (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Injection site warmth (n/a - Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (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-10009899744	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

										Headache (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - n/a]		
EU-EC-10009899793	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Injection site inflammation (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolved -), Injection site warmth (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), 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-10009899970	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (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-10009899981	05/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Body temperature increased (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										inflammation (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site warmth (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)			
EU-EC-10009899998	05/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009900013	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (6h - Recovered/Resolved -), Chills (6h - Recovered/Resolved -), Headache (n/a - Recovering/Resolving -), Injection site swelling (n/a - Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009900014	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Myalgia (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-10009900092	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Chills (4h - Recovered/Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[SALBUTAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Recovered/Not Resolved -)			
EU-EC-10009900196	05/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (3d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009900214	05/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009893308	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009893413	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (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-10009893489	04/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dermatitis (n/a - Not Recovered/Not Resolved -), Pruritus (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .5mL - Intramuscular])	Not reported	ICSR
EU-EC-10009893512	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovered/Resolved -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), 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-10009893637	04/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009893873	04/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009893933	04/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009893941	04/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (1d - Recovered/Resolved -), Pain in extremity (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - .3uL - Intramuscular])	Not reported	ICSR

										Peripheral swelling (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)			
EU-EC-10009894271	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009894336	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009894339	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009894509	04/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009894603	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation irregular (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009894621	04/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009894703	04/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009894724	04/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009894958	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC-10009895022	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009895248	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009895291	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009895298	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (2wk - Recovered/Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009895303	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (3d - Recovered/Resolved -), Chills (2d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (2d - Recovered/Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (3d - Recovered/Resolved -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009895462	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Nausea (n/a - Recovering/Resolved -), Pyrexia (n/a - Recovering/Resolved -)			
EU-EC-10009895468	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (10d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009895621	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009895644	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (1d - Recovered/Resolved -), Headache (n/a - Recovering/Resolved -), Pyrexia (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009895698	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (2d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009895800	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolved -), Headache (n/a - Recovering/Resolved -), Injection site pain (n/a - Recovering/Resolved -), Malaise (n/a - Recovering/Resolved -), Nausea (6h - Recovered/Resolved -), Pyrexia (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009896291	04/09/2021	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 - Recovering/Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009896297	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolved -), Headache (n/a - Recovering/Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009896399	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolved -), Chills (2d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolved -), Headache (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Myalgia (1d - Recovered/Resolved -)			
EU-EC-10009896555	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolved -), Hyperpyrexia (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009896614	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (3d - Recovered/Resolved -), Fatigue (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	AVAMYS 27.5 MICROGRAMS/SPRAY NASAL SPRAY SUSPENSION [FLUTICASONE FUROATE] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [CICLESONIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009896829	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolved -), Nausea (3d - Recovered/Resolved -), Palpitations (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009896911	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (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-10009897006	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009897014	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site haematoma (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Not Recovered/Not Resolved -), Injection site pruritus (n/a - Not Recovered/Not Resolved -), Injection site warmth (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009897030	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19	Not reported	ICSR

										Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	immunisation - Not applicable - [n/a - 1{DF} - n/a]		
EU-EC-10009897117	04/09/2021	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 - Not Recovered/Not Resolved -), Myalgia (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-10009897376	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ATOMOXETINE] (C - n/a - n/a - n/a)	ICSR
EU-EC-10009897413	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), 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-10009897523	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009897568	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009897569	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovering/Resolving -), Pyrexia (12h - Recovered/Resolved -)			
EU-EC-10009897641	04/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown -), Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009878938	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009878997	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Injection site paraesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Oropharyngeal pain (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009879072	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Pain (2d - Recovered/Resolved -), Pain in extremity (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10009879075	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (7d - Recovered/Resolved -), Pain in extremity (7d - Recovered/Resolved -), Somnolence (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10009879119	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaemia (n/a - Recovering/Resolving -), Leukopenia (n/a - Recovering/Resolving -), Pyrexia (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-	03/09/2021	Spontaneous	Healthcare	European	Not	12-17	Not	Male	No	Epistaxis (1d -	COMIRNATY	Not reported	ICSR

10009879120			Professional	Economic Area	available	Years	Specified				Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])		
EU-EC-10009880247	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (3d - Recovered/Resolved -), Nasopharyngitis (3d - Recovered/Resolved -), Oropharyngeal pain (3d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 30ug - Intramuscular])	[METFORMIN, METFORMIN HYDROCHLORIDE] (C - n/a - n/a - [n/a - 2{DF} - Oral])	ICSR	
EU-EC-10009880973	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10009881145	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Confusional state (n/a - Recovering/Resolving - Other Medically Important Condition), Derealisation (n/a - Recovering/Resolving - Other Medically Important Condition), Epilepsy (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling cold (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Hyperhidrosis (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Petit mal epilepsy (n/a - Recovering/Resolving - Other Medically Important Condition), Skin warm (n/a - Recovering/Resolving - Other Medically Important Condition), Time perception altered (n/a - Recovering/Resolving - Other Medically Important Condition), Tremor (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10009881223	03/09/2021	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), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR	

											Condition), Presyncope (n/a - Recovered/Resolved -)		
EU-EC-10009882063	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster meningitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009882286	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	Administration site pain (n/a - Recovering/Resolving -), Arthralgia (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009882347	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009882545	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Tachycardia (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009882713	03/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperhidrosis (n/a - Recovered/Resolved -), Loss of consciousness (1d - Recovered/Resolved - Other Medically Important Condition), Mydriasis (1d - Recovered/Resolved -), Mydriasis (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009882752	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Circumstance or information capable of leading to medication error (n/a - Unknown -), Faecal calprotectin decreased (n/a - Unknown -), Faecal calprotectin increased (n/a - Unknown -), Off label use (n/a - Unknown -), Paraesthesia (n/a - Not Recovered/Not Resolved -), Swelling (n/a - Recovering/Resolving - Other Medically Important Condition)	INFLECTRA [INFLIXIMAB] (S - Crohn's disease - Unknown - [n/a - 100mg - Oral]), TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	MERCAPTOPYRINE [MERCAPTOPYRINE] (C - Crohn's disease - n/a - [n/a - 50mg - Oral]), [OMEPRAZOLE] (C - Crohn's disease - n/a - [n/a - 40mg - Oral])	ICSR
EU-EC-10009882892	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (2min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC-10009883014	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

											Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC-10009883494	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Bone pain (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), Diarrhoea haemorrhagic (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10009883694	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Nausea (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - I{DF} - n/a])	Not reported	ICSR	
EU-EC-10009883932	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vision blurred (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - I{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10009883989	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (1d - Recovering/Resolved -), Dizziness (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10009883991	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (34d - Recovered/Resolved -), Lymphadenopathy (34d - Recovered/Resolved -), Vaccination site pain (34d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	

										Vaccination site swelling (34d - Recovered/Resolved -)			
EU-EC-10009883992	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (18d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009883993	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009883994	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009883998	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009884001	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009884004	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myalgia (n/a - Recovering/Resolving -), Paraesthesia (n/a - Recovering/Resolving -), Tachycardia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009884006	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009884008	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (4d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009884015	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pruritus (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009884016	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009884029	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009884093	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10009884589	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (0d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009884687	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (0d - Recovered/Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC-10009884753	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Tremor (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-10009885018	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rhinitis allergic (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009885477	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenitis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009885645	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009886246	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (36h - Recovered/Resolved -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009886254	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Heat exhaustion (n/a - Recovered/Resolved - Other Medically Important Condition), Insomnia (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009886258	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myelitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[HUMAN PAPILLOMAVIRUS VACCINE] (C - n/a - n/a - [1d - n/a - Intramuscular])	ICSR
EU-EC-	03/09/2021	Spontaneous	Non	Non	Not	12-17	Not	Female	No	Chills (1d -	TOZINAMERAN	Not reported	ICSR

10009886291			Healthcare Professional	European Economic Area	available	Years	Specified			Recovered/Resolved - Other Medically Important Condition), Dizziness (1d - Recovered/Resolved - Other Medically Important Condition), Feeling hot (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Hot flush (1d - Recovered/Resolved - Other Medically Important Condition), Lethargy (n/a - Recovering/Resolving - Other Medically Important Condition), Loss of personal independence in daily activities (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC-10009886348	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown -), Dyspnoea (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Feeling abnormal (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Unknown -), Lymphadenopathy (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tonsillitis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation,	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

											Other Medically Important Condition), Vaccination site joint movement impairment (n/a - Unknown -)		
EU-EC-10009886696	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Bacille Calmette-Guerin scar reactivation (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[MYCOBACTERIUM BOVIS, DANISH STRAIN 1331] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009886729	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling cold (2h - Recovered/Resolved -), Head titubation (2h - Recovered/Resolved -), Nausea (n/a - Recovering/Resolving -), Syncope (2h - Recovered/Resolved -), Vomiting (2h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009886869	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (2d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009886880	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site erythema (n/a - Recovering/Resolving -), Injection site inflammation (n/a - Recovering/Resolving -), Injection site pruritus (n/a - Recovering/Resolving -), Injection site swelling (n/a - Recovering/Resolving -), Injection site warmth (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009886895	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (8h - Recovered/Resolved -), Myalgia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009887042	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (2min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC-10009887688	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deep vein thrombosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	[DIENOGEST, ETHINYLESTRADIOL, LACTOSE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10009887808	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009888071	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Laryngeal oedema (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										- Caused/Prolonged Hospitalisation)	immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC-10009888108	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (1d - Recovered/Resolved -), Dyspnoea (1d - Recovered/Resolved - Life Threatening), Malaise (1d - Recovered/Resolved - Other Medically Important Condition), Oropharyngeal swelling (1d - Recovered/Resolved - Life Threatening), Rash (1d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009888114	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009888229	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (6d - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009888231	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009888532	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Myalgia (15h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-1000988877	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Loss of consciousness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-1000988878	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Gastrointestinal disorder (n/a - Recovering/Resolving -), Malaise (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-1000988885	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Recovered/Resolved -), Menstruation delayed (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-1000988890	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009888934	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009888936	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009888990	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site pain (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -	Not reported	ICSR

										Vasodilatation (n/a - Recovering/Resolving -)	1{DF} - Intramuscular])		
EU-EC-10009889032	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Loss of consciousness (n/a - Recovered/Resolved -), Malaise (n/a - Recovering/Resolving -), Tinnitus (n/a - Recovering/Resolving -), Vision blurred (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009889066	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009889087	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (2d - Recovered/Resolved -), Dyspnoea (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009889103	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009889138	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009889141	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009889143	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009889146	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oedema peripheral (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009889154	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009889180	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovering/Resolving -), Influenza like illness (n/a - Recovered/Resolved -), Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009889211	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Muscle spasms (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Medically Important Condition)			
EU-EC-10009889730	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009889763	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site induration (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolved -), Injection site warmth (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-10009889959	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Breast enlargement (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-10009890756	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (11d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009891133	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (n/a - Recovered/Resolved - Life Threatening), Asthma (n/a - Recovered/Resolved - Life Threatening), Chest discomfort (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Life Threatening), Eye pain (n/a - Recovered/Resolved - Life Threatening), Fatigue (n/a - Recovered/Resolved - Life Threatening), Feeling hot (n/a - Not Recovered/Not Resolved - Life Threatening), Feeling of body temperature change (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hallucination (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Life Threatening), Illness (n/a - Recovered/Resolved - Life Threatening), Myalgia (n/a -	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Recovered/Resolved - Life Threatening), Pyrexia (n/a - Not Recovered/Not Resolved - Life Threatening), Pyrexia (n/a - Recovered/Resolved - Life Threatening), Renal pain (n/a - Recovered/Resolved - Life Threatening), Seizure (n/a - Recovered/Resolved - Life Threatening), Urticaria (n/a - Recovered/Resolved - Life Threatening), Vomiting (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Wheezing (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10009891183	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Unknown - Caused/Prolonged Hospitalisation), Insomnia (n/a - Unknown - Caused/Prolonged Hospitalisation), Psychiatric symptom (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Psychotic disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009891197	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009891247	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009891373	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (4d - Recovered/Resolved -), Myalgia (2d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

EU-EC-10009891413	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Injection site swelling (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009891513	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (2d - Recovered/Resolved -), Chills (1d - Recovered/Resolved -), Extensive swelling of vaccinated limb (3d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (2d - Recovered/Resolved -), Injection site erythema (3d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -), Injection site swelling (3d - Recovered/Resolved -), Injection site warmth (3d - Recovered/Resolved -), Malaise (3d - Recovered/Resolved -), Myalgia (n/a - Recovering/Resolving -), Pyrexia (1d - Recovered/Resolved -), Syncope (5min - Recovered/Resolved -), Tinnitus (5min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009891656	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Dizziness (1d - Recovered/Resolved -), Dizziness (n/a - Recovering/Resolving -), Hyperhidrosis (1d - Recovered/Resolved -), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Condition), Presyncope (1d - Recovered/Resolved -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Tinnitus (1d - Recovered/Resolved -)			
EU-EC-10009891776	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009892088	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Back pain (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Flank pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hepatic enzyme abnormal (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - n/a]), [TRIMETHOPRIM] (C - Urinary tract infection - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009892284	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009892287	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009892306	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009892323	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (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-10009892338	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovered/Resolved -), Lymphadenopathy	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										(n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved -)			
EU-EC-10009892429	03/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Inappropriate schedule of product administration (n/a - Unknown -), Near drowning (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009892624	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (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-10009892626	03/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a]), [VARICELLA VIRUS OKA/MERCK STRAIN (LIVE, ATTENUATED), VARICELLA VIRUS OKA/MERCK STRAIN, (LIVE, ATTENUATED) PRODUCED IN HUMAN DIPLOID (MRC-5) CELLS] (S - Immunisation - Drug withdrawn - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009892726	03/09/2021	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 - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009892834	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009892859	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009892869	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009892870	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (0d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Not Recovered/Not Resolved -), 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-	03/09/2021	Spontaneous	Non	European	Not	12-17	Not	Female	No	Fatigue (n/a -	COMIRNATY	Not reported	ICSR

10009893168			Healthcare Professional	Economic Area	available	Years	Specified			Recovering/Resolving -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])		
EU-EC-10009893245	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving -), 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-10009893525	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pain of skin (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009893821	03/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [MINERALS NOS, VITAMINS NOS] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009893828	03/09/2021	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 -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), 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-10009864872	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema (n/a - Recovering/Resolving -), Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 300uL - Intramuscular])	[BILASTINE] (C - Dermatitis atopic - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009864895	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Septic shock (26d - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	[CLOBAZAM] (C - n/a - n/a - [n/a - 20mg - n/a]), [ESOMEPRAZOLE] (C - n/a - n/a - [n/a - 30mg - n/a]), [SODIUM VALPROATE, VALPROIC ACID, SODIUM VALPROATE] (C - n/a - n/a - [n/a - 450mg - n/a])	ICSR
EU-EC-10009864922	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Recovered/Resolved -), Oligomenorrhoea	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a -	Not reported	ICSR

										(n/a - Recovered/Resolved -)	n/a - Intramuscular])		
EU-EC-10009864993	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (3d - Recovered/Resolved -), Rash (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC-10009864995	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009865010	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009865553	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Confusional state (n/a - Recovered/Resolved With Sequelae - Life Threatening), Epilepsy (n/a - Recovered/Resolved With Sequelae - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009867409	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Herpes zoster (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-10009867410	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -), Limb discomfort (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	AVAMYS 27.5 MICROGRAMS/SPRAY NASAL SPRAY SUSPENSION [FLUTICASONE FUROATE] (C - n/a - n/a - [n/a - n/a - n/a]), [FLUTICASONE PROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009868188	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009868255	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (1d - Recovered/Resolved -), Hyperhidrosis (n/a - Recovered/Resolved -), Pallor (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovering/Resolving -), Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009868352	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypoaesthesia (n/a - Unknown - Other Medically Important Condition), Hypotonic-hyporesponsive episode (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009868604	02/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovering/Resolving - Other Medically Important Condition), Hypoaesthesia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Oropharyngeal pain (n/a - Recovering/Resolving -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Throat irritation (n/a - Recovered/Resolved -), Throat tightness (n/a - Recovered/Resolved -)			
EU-EC-10009868797	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009868869	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Injection site inflammation (n/a - Recovered/Resolved -), Injection site pain (n/a - Recovered/Resolved -), Injection site swelling (n/a - Recovered/Resolved -), Malaise (2h - Recovered/Resolved -), Muscle contractions involuntary (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009868946	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009869283	02/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain (2d - Recovered/Resolved -), Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009869354	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (1d - Recovered/Resolved -), Injection site pain (8d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Syncope (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR

										-), Vomiting (1d - Recovered/Resolved -)			
EU-EC-10009869361	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (3d - Recovering/Resolving -), Myalgia (3d - Recovering/Resolving -), Pyrexia (3d - Recovering/Resolving -)	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009869575	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (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-10009869877	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Petechiae (609d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009870107	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009870300	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (8h - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Nausea (4h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009870492	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown -), Joint swelling (n/a - Unknown -), Malaise (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Tremor (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009871018	02/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009871047	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Colitis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Diarrhoea haemorrhagic (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Haemolysis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Multiple organ dysfunction syndrome (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009871195	02/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blepharitis (n/a - Not Recovered/Not Resolved - Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

										Condition), Blood urine present (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Renal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urine abnormality (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	applicable - [1d - n/a - n/a])		
EU-EC-10009871474	02/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Immunisation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009872131	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown -), Myalgia (n/a - Unknown -), Pain in extremity (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009872439	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -), Vaccination site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - Intramuscular])	Not reported	ICSR
EU-EC-10009872585	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Recovering/Resolved -), Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009872622	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Nausea (1h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009872646	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not reported	ICSR

										Headache (1d - Recovered/Resolved -), Injection site pain (6d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -), Palpitations (1d - Recovered/Resolved -)	applicable - [n/a - 1{DF} - n/a])		
EU-EC-10009872864	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (0d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Vaccination site pain (29h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009873015	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009873021	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (1d - Recovered/Resolved - Other Medically Important Condition), Seizure (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009873022	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Renal vein thrombosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	HIZENTRA [HUMAN IMMUNOGLOBULIN G, HUMAN NORMAL IMMUNOGLOBULIN] (C - n/a - n/a -), JAKAVI [RUXOLITINIB, RUXOLITINIB PHOSPHATE] (C - n/a - n/a -), PANTOPRAZOLE [PANTOPRAZOLE, PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - n/a - n/a -), [ACETYLCYSTEINE] (C - n/a - n/a -), [CALCIUM CARBONATE] (C - n/a - n/a -), [COLISTIMETHATE SODIUM] (C - n/a - n/a -), [EVEROLIMUS] (C - n/a - n/a -), [HYDROXYCHLOROQUINE SULFATE] (C - n/a - n/a -), [MACROGOL 4000] (C - n/a - n/a -), [MAGNESIUM, MAGNESIUM CARBONATE, MAGNESIUM PIDOLATE] (C - n/a - n/a -), [PARACETAMOL] (C - n/a - n/a -), [PREDNISONE] (C - n/a - n/a -), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a -), [SULFAMETHOXAZOLE, TRIMETHOPRIM] (C - n/a - n/a -), [TACROLIMUS, TACROLIMUS MONOHYDRATE] (C - n/a - n/a -), [VALACICLOVIR HYDROCHLORIDE] (C - n/a - n/a -)	ICSR
EU-EC-	02/09/2021	Spontaneous	Non	European	Not	12-17	Adolescent	Male	No	Dysarthria (1d -	COMIRNATY	Not reported	ICSR

10009873047			Healthcare Professional	Economic Area	available	Years				Recovered/Resolved - Other Medically Important Condition), Mobility decreased (1d - Recovered/Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular])		
EU-EC-10009873067	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009873078	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovering/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009873086	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Kawasaki's disease (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009873374	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Acne (n/a - Unknown -), Dysmenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009873405	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Bell's palsy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009873510	02/09/2021	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 - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009873530	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema multiforme (3wk - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009873640	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	[ETHINYLESTRADIOL, LEVONORGESTREL, PLACEBO] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009873666	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009873669	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009873670	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009873684	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009873944	02/09/2021	Spontaneous	Non Healthcare Professional	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 -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Tremor (1d - Recovered/Resolved -)			
EU-EC-10009873945	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash pruritic (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009873950	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving -), Body temperature increased (n/a - Not Recovered/Not Resolved -), Chills (n/a - Recovering/Resolving -), Fatigue (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 -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009874194	02/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009874619	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (2d - Recovered/Resolved -), Urticaria (48h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[BECLOMETASONE DIPROPIONATE] (C - Asthma - n/a - [n/a - n/a - n/a]), [SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009874812	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash pruritic (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-10009874873	02/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Basophil count increased (n/a - Unknown -), Blood alkaline phosphatase increased (n/a - Unknown -), Blood glucose increased (n/a - Unknown -), Haematocrit increased (n/a - Unknown -), Haemoglobin increased (n/a - Unknown -), Loss of consciousness (1min - Recovered/Resolved - Other Medically Important Condition), Monocyte count increased (n/a - Unknown -), Musculoskeletal stiffness (n/a - Unknown -), Neutrophil count increased (n/a -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - .1mg - n/a])	ICSR

										Unknown -), Pallor (n/a - Unknown -), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Tremor (n/a - Unknown -), White blood cell count increased (n/a - Unknown -)			
EU-EC-10009874987	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10009875162	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tonic convulsion (10s - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009875322	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epilepsy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10009875401	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009875671	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009875836	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - Immunisation	Not reported	ICSR

										Hospitalisation), Rash (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Urticaria (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	- n/a - [n/a - n/a - n/a]		
EU-EC-10009875872	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Breast pain (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Influenza (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009875979	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Eyelid ptosis (25d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009876022	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyelonephritis (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009876040	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Somnolence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009876069	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cardiovascular disorder (16d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Decreased appetite (16d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Disturbance in attention (16d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dizziness (16d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Fatigue (16d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (16d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Muscle strength abnormal (16d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Palpitations (16d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Tremor (16d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Weight decreased (16d - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										- Caused/Prolonged Hospitalisation)			
EU-EC-10009876305	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (1d - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009876458	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Blepharospasm (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Feeling of body temperature change (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypoaesthesia (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ocular discomfort (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009876461	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Blood creatine phosphokinase increased (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Troponin increased (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009876687	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009876787	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Agitation (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dysarthria (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Encephalopathy (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Visual impairment (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009876865	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Angina pectoris (1d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10009877032	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain upper (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Back pain (4d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Decreased appetite (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypophagia (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (2d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009877151	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest discomfort (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Electrocardiogram ST segment elevation (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Limb discomfort (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Malaise (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Troponin increased (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009877173	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (14d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (14d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (14d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paraesthesia (14d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Presyncope (14d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Hospitalisation), Tremor (14d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10009877187	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009877309	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ocular myasthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009877352	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oropharyngeal discomfort (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Peripheral swelling (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pruritus (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tongue pruritus (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009877554	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Haematoma (13d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009877602	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (1d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009877925	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Clonic convulsion (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009877934	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[ISOTRETINOIN] (C - Acne - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009877949	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	[VARICELLA VIRUS OKA/MERCK STRAIN (LIVE, ATTENUATED), VARICELLA VIRUS OKA/MERCK STRAIN, (LIVE, ATTENUATED) PRODUCED IN HUMAN DIPLOID (MRC-5) CELLS] (C - Immunisation - Drug withdrawn - [1d - n/a - n/a])	ICSR
EU-EC-10009878023	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Conversion disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Monoplegia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - 18mg - Oral])	ICSR

										Sensory loss (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10009878127	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (2d - Recovered/Resolved -), Musculoskeletal stiffness (n/a - Recovering/Resolving -), Myalgia (2d - Recovered/Resolved -), Tongue discolouration (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009878371	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myoclonus (4d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tic (4d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009879427	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Joint swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pruritus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Rash (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Throat irritation (n/a - Unknown - Caused/Prolonged Hospitalisation), Urticaria (n/a - 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-10009879513	02/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009879545	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009879762	02/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Not Recovered/Not Resolved - Disabling), Hallucination, visual (n/a - Not Recovered/Not Resolved - Disabling), Headache (n/a - Not Recovered/Not Resolved - Disabling), Negative thoughts (n/a - Not Recovered/Not Resolved - Disabling), Nervousness (n/a - Not Recovered/Not Resolved - Disabling),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Panic attack (n/a - Not Recovered/Not Resolved - Disabling), Personality change (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC-10009879822	02/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009849713	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009850235	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Myopericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009851105	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Vertigo (n/a - Recovered/Resolved - Other Medically Important Condition), Vision blurred (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 300uL - Intramuscular])	Not reported	ICSR
EU-EC-10009851977	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Amnesia (n/a - Not Recovered/Not Resolved -), Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Petechiae (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-10009852327	01/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [ETHINYLESTRADIOL, LEVONORGESTREL, LACTOSE ANHYDROUS] (C - Oral contraception - n/a - [303d - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a])	[DESOGESTREL, ETHINYLESTRADIOL, ETHINYLESTRADIOL PH. EUR., DESOGESTREL B.P.] (C - Oral contraception - n/a - [n/a - n/a - n/a]), [ETHINYLESTRADIOL, LEVONORGESTREL, LACTOSE ANHYDROUS] (C - Oral contraception - n/a - [303d - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hypothyroidism - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009852571	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cerebral venous sinus thrombosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10009853179	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Influenza like illness (n/a - Unknown -), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009853506	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Fall (n/a - Recovering/Resolving -), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Presyncope (n/a - Recovering/Resolving -), Tonic convulsion (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009853679	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Body temperature increased (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009853770	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Recovering/Resolving -), Chills (2d - Recovered/Resolved -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009854644	01/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypersensitivity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Lip swelling (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paraesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pharyngitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DIPHENHYDRAMINE HYDROCHLORIDE] (C - Seasonal allergy - n/a - [n/a - n/a - n/a])	ICSR

										Swelling (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Throat tightness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10009854650	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ecema (n/a - Unknown -), Erythema (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling hot (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pruritus (n/a - Recovering/Resolving - Other Medically Important Condition), Rash papulosquamous (n/a - Recovering/Resolving - Other Medically Important Condition), Skin exfoliation (n/a - Recovering/Resolving - Other Medically Important Condition), Swelling (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	CELECOXIB [CELECOXIB] (C - Anxiety - n/a - [n/a - n/a - Oral]), [CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - Oral]), [CITALOPRAM, CITALOPRAM HYDROBROMIDE, CITALOPRAM HYDROCHLORIDE] (C - n/a - n/a - [n/a - 30mg - Oral]), [ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral]), [METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - 40mg - Oral]), [METHYLPHENIDATE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10009854923	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (0d - Recovered/Resolved -), Erythema (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009855078	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site erythema (n/a - Recovered/Resolved -), Application site pain (2d - Recovered/Resolved -), Application site swelling (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009855087	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (2d - Recovered/Resolved -), Application site swelling (1d - Recovered/Resolved -), Arthralgia (1d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009855316	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Haematoma (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-10009855375	01/09/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN]	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a -)	ICSR

			Professional	Area						Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Oral discomfort (n/a - Not Recovered/Not Resolved -), Palpitations (n/a - Not Recovered/Not Resolved -), Presyncope (n/a - Not Recovered/Not Resolved -)	(S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	n/a - [n/a - n/a - n/a])	
EU-EC-10009855383	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (5min - Recovered/Resolved -), Palpitations (5min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009855558	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Feeling abnormal (n/a - Unknown -), Presyncope (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-10009855973	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Erythema (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-10009855996	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009856053	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chills (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (1d - Recovered/Resolved -), Nausea (2d - Recovered/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-10009856162	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Vision blurred (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	01/09/2021	Spontaneous	Non	Non	Not	12-17	Not	Female	No	Crying (n/a -	TOZINAMERAN	Not reported	ICSR

10009856769			Healthcare Professional	European Economic Area	available	Years	Specified			Recovering/Resolving - Other Medically Important Condition), Dysmenorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Pain (n/a - Recovering/Resolving - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC-10009856881	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009856883	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Eczema (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009857137	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anaphylactic reaction (n/a - Recovering/Resolving - Other Medically Important Condition), Circulatory collapse (n/a - Unknown - Other Medically Important Condition), Dysaesthesia (n/a - Unknown -), Erythema (n/a - Unknown -), Hot flush (n/a - Unknown -), Pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009857160	01/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009857205	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site haematoma (n/a - Unknown -), Application site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009857366	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Angina pectoris (7d - Recovered/Resolved -), Asthenia (7d - Recovered/Resolved -), Chest pain (7d - Recovered/Resolved - Caused/Prolonged	COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Hospitalisation, Other Medically Important Condition), Myocarditis (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved -)			
EU-EC-10009858329	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abnormal behaviour (n/a - Recovered/Resolved - Other Medically Important Condition), Bite (n/a - Recovered/Resolved - Other Medically Important Condition), Blood electrolytes decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Dyskinesia (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Oropharyngeal pain (n/a - Recovered/Resolved - Other Medically Important Condition), Respiratory rate decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Urinary incontinence (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	[CETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - 10mg - n/a - More in ICSR]), [HYDROXYZINE, HYDROXYZINE HYDROCHLORIDE] (C - Anxiety - n/a - [n/a - n/a - Oral]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Anxiety, Depression - n/a - [n/a - n/a - Oral]), [TRAZODONE, TRAZODONE HYDROCHLORIDE] (C - Sleep disorder - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10009858409	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Disabling), Hypoesthesia (n/a - Not Recovered/Not Resolved - Disabling), Muscle spasms (n/a - Not Recovered/Not Resolved - Disabling), Myalgia (n/a - Not Recovered/Not Resolved - Disabling), Paraesthesia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Disabling), Product administered at inappropriate site (n/a - Not Recovered/Not Resolved - Disabling)			
EU-EC-10009858455	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Appendicectomy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Appendicitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009859046	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myositis (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Palpitations (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Weight bearing difficulty (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009859083	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cardiac discomfort (n/a - Recovering/Resolving -), Influenza like illness (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009859184	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009859516	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Haemorrhage (n/a - Not Recovered/Not Resolved -), Injection site inflammation (2d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Injection site swelling (2d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009859520	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Myalgia (2d - Recovered/Resolved -), Tonsillitis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009859640	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Seizure (1d - Recovered/Resolved - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]), [AMOXICILLIN] (S - Ear infection - Drug withdrawn - [4d - 3g - n/a])	Not reported	ICSR
EU-EC-10009859647	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (5d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR

EU-EC-10009859732	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthma (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Prophylaxis - n/a - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009859735	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009859792	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Erythema nodosum (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009859798	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009859802	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009859840	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Deep vein thrombosis (1wk - Recovering/Resolving - Caused/Prolonged Hospitalisation), Influenza like illness (n/a - Recovering/Resolving -), Pulmonary embolism (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009859841	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (17d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Intermenstrual bleeding (17d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Iron deficiency anaemia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009859986	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009860001	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009860063	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009860303	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009860352	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009860433	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paralysis (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009860434	01/09/2021	Spontaneous	Non Healthcare	European Economic	Not available	12-17 Years	Adolescent	Female	No	Polymenorrhoea (2d -)	COMIRNATY [TOZINAMERAN]	Not reported	ICSR

			Professional	Area							Recovered/Resolved -)	(S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])		
EU-EC-10009860449	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10009860999	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Leukaemia (n/a - Fatal - Results in Death, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR	
EU-EC-10009861161	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10009861206	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (4d - Recovered/Resolved -), Lymphadenopathy (2d - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vomiting (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR	
EU-EC-10009861910	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Not Recovered/Not Resolved -), Chest pain (n/a - Not Recovered/Not Resolved -), Chills (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Malaise (n/a - Recovering/Resolving -), Pyrexia (1d - Recovered/Resolved -), Respiration abnormal (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [NOT AVAILABLE] (S - Pyrexia - Drug withdrawn - [n/a - n/a])	Not reported	ICSR	
EU-EC-10009861936	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lip swelling (12h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10009862309	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10009862344	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Lymphadenopathy	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	AVAMYS [FLUTICASONE FUROATE] (C - n/a - n/a -), IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - n/a - n/a -), [BECLOMETASONE DIPROPIONATE] (C - n/a - n/a -), [PARACETAMOL] (C - n/a - n/a -),	ICSR	

										(n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	[SALBUTAMOL, SALBUTAMOL MICRONIZED, SALBUTAMOL SULFATE] (C - n/a - n/a -)		
EU-EC-10009862381	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009862915	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fall (n/a - Recovered/Resolved -), Loss of consciousness (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-10009863623	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Muscle spasms (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-10009863745	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Deafness unilateral (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Dizziness (n/a - Unknown -), Headache (n/a - Unknown -), Tinnitus (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009863780	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure systolic decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Contusion (20min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dehydration (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (20min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dysstasia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fall (20min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Feeling abnormal (20min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Gait disturbance (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (20min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypophagia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Physical deconditioning (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10009863970	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10009864423	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009864501	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Appendicitis (2d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Nausea (2d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pyrexia (2d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Vomiting (2d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009864586	01/09/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hyperthermia (n/a - Unknown -), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10009865076	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Generalised tonic-clonic seizure (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009865099	01/09/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009865105	01/09/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Heart rate increased (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pain (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Palpitations (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Paraesthesia (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Peripheral coldness (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10009865760	01/09/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Brain natriuretic peptide increased (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Chills (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Conjunctivitis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Ejection fraction decreased (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Rash (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Red blood cell sedimentation rate increased (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Tongue eruption (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Troponin I increased (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009836886	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperhidrosis (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Hypotension (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved With Sequelae -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - n/a - n/a])	Not reported	ICSR

										Other Medically Important Condition)			
EU-EC-10009836947	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Vomiting (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-10009837571	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009837594	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009837640	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009837784	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vertigo (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009837861	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009837894	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysphagia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009837986	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (2d - Recovered/Resolved -), Chills (2d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -), Vomiting (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009838305	31/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009839608	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Hypersensitivity (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009839612	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (2d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	31/08/2021	Spontaneous	Non	Non	Not	12-17	Not	Female	No	Asthenia (n/a -	TOZINAMERAN [CIPROFLOXACIN,		ICSR

10009839710			Healthcare Professional	European Economic Area	available	Years	Specified			Recovering/Resolving -), Cold sweat (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Irregular breathing (n/a - Recovering/Resolving -), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving -), Muscle spasms (n/a - Recovering/Resolving -), Pain (n/a - Recovering/Resolving -), Seizure (n/a - Recovering/Resolving - Other Medically Important Condition), Tremor (n/a - Recovering/Resolving -), Vaginal haemorrhage (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE, CIPROFLOXACIN LACTATE] (C - Urinary tract infection - n/a - [13d - n/a - Oral])	
EU-EC-10009839723	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Not Recovered/Not Resolved -), Vaccination site pruritus (n/a - Not Recovered/Not Resolved -), Vaccination site rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009839846	31/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination site mass (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[AMITRIPTYLINE, AMITRIPTYLINE HYDROCHLORIDE] (C - Migraine - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009839961	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009840028	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009841007	31/08/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (0d - Recovered/Resolved	TOZINAMERAN [TOZINAMERAN] (S - COVID-19	[CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a -	ICSR

				Economic Area						- Other Medically Important Condition), Cold sweat (0d - Recovered/Resolved -), Lip swelling (0d - Recovered/Resolved -), Paraesthesia oral (0d - Recovered/Resolved -), Tachycardia (0d - Recovered/Resolved -)	immunisation - Not applicable - [1d - n/a - n/a]) [FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - Hypersensitivity - n/a - [n/a - n/a - n/a]), [HYOSCINE BUTYLBROMIDE] (C - Irritable bowel syndrome - n/a - [n/a - n/a - n/a]), [LACTULOSE] (C - Constipation - n/a - [n/a - n/a - n/a]), [LEVOTHYROXINE, LEVOTHYROXINE SODIUM] (C - Hyperthyroidism - n/a - [n/a - n/a - n/a]), [TRANEXAMIC ACID] (C - Heavy menstrual bleeding - n/a - [n/a - n/a - n/a])		
EU-EC-10009841061	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Malaise (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	CELLCEPT 250 MG CAPSULES [MYCOPHENOLATE MOFETIL] (C - n/a - n/a - [n/a - n/a - n/a]), NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [PREDNISONE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009841062	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009841672	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009842220	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Abdominal pain (n/a - Recovering/Resolving - Other Medically Important Condition), Asthenia (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Throat irritation (n/a - Recovering/Resolving -), Tinnitus (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009842288	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Bell's palsy (n/a - Recovering/Resolving -)	COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009842397	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (1d - Recovered/Resolved -), Headache (20d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Menstruation delayed (n/a - Not Recovered/Not Resolved -)			
EU-EC-10009842960	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Application site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009843277	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (2d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Nausea (3d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009843306	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Swelling face (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-10009843362	31/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Feeling abnormal (0d - Recovered/Resolved -), Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10009843575	31/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myopericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericardial effusion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009843687	31/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - More in ICSR])	Not reported	ICSR
EU-EC-10009843696	31/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a])	Not reported	ICSR
EU-EC-10009844005	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Axillary pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chills (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) HUMIRA [ADALIMUMAB] (C - Juvenile idiopathic arthritis - n/a - [n/a - n/a - Subcutaneous]), [METHOTREXATE, METHOTREXATE DISODIUM, METHOTREXATE SODIUM] (C - Juvenile idiopathic arthritis - n/a - [n/a - n/a - Subcutaneous])	Not reported	ICSR

										Peritonsillar abscess (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pharyngeal oedema (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)			
EU-EC-10009844249	31/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICSR
EU-EC-10009845215	31/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009845469	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009845511	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009845802	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Immune-mediated adverse reaction (5h - Recovered/Resolved - Other Medically Important Condition), Rash erythematous (5h - Recovered/Resolved - Other Medically Important Condition), Swelling face (5h - 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-10009846084	31/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye injury (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Nervousness (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10009846428	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (12d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009846453	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving -), Hypoaesthesia (5min - Recovered/Resolved -), Hypoaesthesia oral (5min - Recovered/Resolved -), Immunisation	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR

										reaction (10min - Recovered/Resolved -), Vision blurred (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)			
EU-EC-10009846524	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009846684	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Type I hypersensitivity (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009846691	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009846704	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009846713	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash pruritic (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009847023	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (1d - Recovered/Resolved -), Injection site pain (n/a - Unknown -), Wheezing (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009847373	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Tremor (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[PARACETAMOL, PARACETAMOL PH. EUR., PARACETAMOL, CODEINE PHOSPHATE] (C - n/a - n/a -)	ICSR
EU-EC-10009847549	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (14d - Recovered/Resolved -), Headache (14d - Not Recovered/Not Resolved -), Paraesthesia ear (14d - Recovered/Resolved -), Pyrexia (14d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009847552	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009847567	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes simplex (17d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009847626	31/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009847690	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Purpura (10d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009848717	31/08/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

EU-EC-10009848855	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Axillary pain (n/a - Recovering/Resolved -), Oropharyngeal pain (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009848998	31/08/2021	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 - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009849009	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009849016	31/08/2021	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 - Dose not changed - [n/a - 1{DF} - n/a])	AVAMYS [FLUTICASON FUROATE] (C - Rhinorrhoea - n/a - [n/a - n/a - Nasal]), [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - Urticaria - n/a - [n/a - n/a - Oral]), [MACROGOL 3350, SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL 70%, LIQUID (CRYSTALLISING), SODIUM CITRATE, SORBITOL (E420), SODIUM LAURYL SULFOACETATE, SODIUM CITRATE, SORBITOL SOLUTION 70% (CRYSTALLISING) (PH. EUR.), SODIUM LAURYL SULFOACETATE, SODIUM LAURYL SULFOACETATE, TRISODIUM CITRATE, SORBITOL 70%, LIQUID (CRYSTALLISING), SORBITOL (E420), SODIUM LAURYL SULFOACETATE, SORBITOL (E420), SODIUM LAURYL SULFOACETATE, SODIUM CITRATE DIHYDRATE, SORBITOL, LIQUID (CRYSTALLISING), SODIUM CITRATE, SODIUM LAURYL SULFOACETATE, SORBITOL, LIQUID (CRYSTALLISING), SODIUM CITRATE, SODIUM LAURYL SULFOACETATE 70%] (C - Constipation - n/a - [n/a - n/a - Rectal]), [NAPROXEN] (C - Pain - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Bronchospasm - n/a - [n/a - n/a - Respiratory (inhalation)])	ICSR
EU-EC-10009849023	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009849032	31/08/2021	Spontaneous	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 - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10009849048	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Painful respiration (n/a - Not Recovered/Not Resolved -), Palpitations (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[PHENOXYMETHYLPENICILLIN POTASSIUM] (C - Pharyngitis - n/a - [369d - n/a - Oral])	ICSR
EU-EC-10009849057	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (10min - Recovered/Resolved -), Dizziness (10min - Recovered/Resolved -), Hypersensitivity (10min - Recovered/Resolved -), Ocular hyperaemia (10min - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Throat irritation (10min - Recovered/Resolved -)			
EU-EC-10009849067	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009849070	31/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Rhinorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[CLOBETASOL PROPIONATE] (C - Eczema - n/a - [n/a - n/a - Cutaneous]), [ETHINYLESTRADIOL, LEVONORGESTREL] (C - Contraception - n/a - [n/a - n/a - Oral]), [PARACETAMOL] (C - Pain - n/a - [n/a - n/a - Oral])	ICSR
EU-EC-10009849083	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Axillary pain (n/a - Recovering/Resolving -), Dizziness (0d - Recovered/Resolved -), Oropharyngeal pain (n/a - Recovering/Resolving -), Presyncope (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009849293	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovered/Resolved -), Back pain (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10009849503	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nasal congestion (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009849519	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Diarrhoea (n/a - Not Recovered/Not Resolved -), Injection site pain (2d - Recovered/Resolved -), Myalgia (n/a -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

EU-EC-10009849677	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Injection site erythema (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Injection site swelling (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	[ETHINYLESTRADIOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009849878	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (3d - Recovered/Resolved -), Fatigue (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Malaise (3d - Recovered/Resolved -), Myalgia (5d - Recovered/Resolved -), Nausea (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009849884	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009849993	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (n/a - Not Recovered/Not Resolved -), Chills (n/a - Recovering/Resolving -), Headache (n/a - Not Recovered/Not Resolved -), Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009850030	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hot flush (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-10009850332	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR

										Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -)			
EU-EC-10009850690	31/08/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving -), Fatigue (1d - Recovered/Resolved -), Lymphadenopathy (n/a - Recovering/Resolving -), Malaise (2d - Recovered/Resolved -), Myalgia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10009824950	30/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Guillain-Barre syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Polyneuropathy (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3uL - Subcutaneous])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009825748	30/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009825785	30/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Illness (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10009825790	30/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vision blurred (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[FEXOFENADINE, FEXOFENADINE HYDROCHLORIDE] (C - Seasonal allergy - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10009825791	30/08/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hepatic failure (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Renal failure (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10009826375	30/08/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Blood pressure	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR

