

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-10010612885	10/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site inflammation (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10010613109	10/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Syncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010585678	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nephrolithiasis (15d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	PIJNSTILLER (ANALGETICUM) [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010585727	09/11/2021	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 - Recovering/Resolving -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not 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-10010586286	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving -), Dizziness (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010586304	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Muscular weakness (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010586338	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010586371	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eye swelling (1d - Recovered/Resolved - Other Medically Important Condition), Lip swelling (1d - Recovered/Resolved - Other Medically Important Condition), Periorbital swelling (n/a - Recovered/Resolved - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash erythematous (n/a - Recovered/Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Other Medically Important Condition)			
EU-EC-10010586375	09/11/2021	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), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010586450	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition), Lymphadenopathy (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-10010586452	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving -), Feeling cold (n/a - Recovering/Resolving -), Hyperhidrosis (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Syncope (0d - 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-10010586454	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lip swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010586524	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menometrorrhagia (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	IRON [IRON] (C - n/a - n/a - [n/a - n/a - n/a]), [ASCORBIC ACID, MAGNESIUM OXIDE, HEAVY, MAGNESIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010586562	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Unknown -), Menstrual disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[CYPROTERONE ACETATE, ETHINYLESTRADIOL] (C - Oral contraception - n/a - [n/a - n/a - Oral]), [DESLORATADINE] (C - Hypersensitivity - n/a - [n/a - 5mg - n/a])	ICSR
EU-EC-10010586789	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010586808	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010587172	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR

EU-EC-10010587176	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dehydration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oropharyngeal pain (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-10010587192	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Hypertension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010587794	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010587813	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010587907	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (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-10010587972	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Gait disturbance (n/a - Unknown - Other Medically Important Condition), Maternal exposure during pregnancy (n/a - Unknown -), Muscle tightness (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (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-10010587990	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pallor (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010587991	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010587997	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Pericarditis (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										- Other Medically Important Condition), Troponin increased (n/a - Recovering/Resolving -)			
EU-EC-10010588003	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (n/a - Recovering/Resolving -), Cold sweat (n/a - Recovering/Resolving -), Pallor (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Tremor (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010588028	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Myositis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010588031	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angioedema (n/a - Recovering/Resolving - Other Medically Important Condition), Lip oedema (n/a - Recovering/Resolving - Other Medically Important Condition), Oropharyngeal discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Rash (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010588073	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Troponin increased (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010588535	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arrhythmia (n/a - Not Recovered/Not Resolved -), Tachycardia (21d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010588631	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	C-reactive protein increased (n/a - Unknown -), Myocarditis (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition), Troponin I increased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010588693	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin increased (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-10010588697	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cold sweat (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pallor (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-	09/11/2021	Spontaneous	Non	European	Not available	12-17	Not	Female	No	Anaemia (n/a - Not	COMIRNATY	Not reported	ICSR

10010588814			Healthcare Professional	Economic Area		Years	Specified			Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Heavy menstrual bleeding (n/a - Unknown - Caused/Prolonged Hospitalisation), Hospitalisation (n/a - Unknown - Caused/Prolonged Hospitalisation), Transfusion (n/a - Unknown - Caused/Prolonged Hospitalisation)	[TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])		
EU-EC-10010588820	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[METHOTREXATE] (C - Dermatomyositis - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010588822	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Unknown -), Menstruation irregular (n/a - Unknown -), Polymenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010589084	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010589385	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010589820	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010589837	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010589948	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Troponin increased (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010589954	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010589974	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010589981	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10010589984	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010589985	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010589986	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Troponin increased (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010589994	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (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-10010590227	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate irregular (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate irregular (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010590250	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Somnolence (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010590263	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010590318	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Ear discomfort (0d - Not Recovered/Not Resolved -), Influenza (0d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - n/a - n/a)	Not reported	ICSR
EU-EC-	09/11/2021	Spontaneous	Non	European	Not available	12-17	Adolescent	Female	No	Urticaria (n/a - Not	COMIRNATY	Not reported	ICSR

10010590440			Healthcare Professional	Economic Area		Years				Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])		
EU-EC-10010590607	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010590751	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010591304	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Troponin increased (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) [COLCHICINE] (C - n/a - n/a - [n/a - n/a - n/a])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [COLCHICINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010591311	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Presyncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	FLUENZ TETRA [A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE STRAIN (A/HAWAII/66/2019, MEDI 326775), A/HONG KONG/2671/2019 (H3N2) - LIKE STRAIN (A/HONG KONG/2671/2019, MEDI 325078), B/PHUKET/3073/2013 - LIKE STRAIN (B/PHUKET/3073/2013, MEDI 306444), B/WASHINGTON/02/2019 - LIKE STRAIN (B/WASHINGTON/02/2019, MEDI 323797), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN (A/TEXAS/50/2012, MEDI 237514), B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (A/CALIFORNIA/7/2009, MEDI 228029), B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (A/BOLIVIA/559/2013, MEDI 255962), B/PHUKET/3073/2013 (YAMAGATA LINEAGE)-LIKE STRAIN (B/PHUKET/3073/2013, MEDI 254977), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/NEW CALEDONIA/71/2014, MEDI 263122), B/PHUKET/3073/2013 (YAMAGATA LINEAGE)-LIKE	ICSR

												STRAIN (B/PHUKET/3073/2013, MEDI 254977), A/MICHIGAN/45/2015 (H1N1)PDM09 - LIKE STRAIN (A/SLOVENIA/2903/2015, MEDI 279432), A/SINGAPORE/INFIMH-16- 0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16- 0019/2016, MEDI 291690), B/COLORADO/06/2017-LIKE STRAIN (B/COLORADO/06/2017, MEDI 293454)] (C - Immunisation - n/a - [n/a - n/a - n/a])		
EU-EC-10010591314	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	COVID-19 (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010591327	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Foster, C.. Varicella-Zoster virus reactivation following SARS-CoV-2 immunization in two patients with leukemia. Pediatric Blood and Cancer, 2021;68 (10):e29191. doi:10.1002/pbc.29191	12-17 Years	Not Specified	Female	No	Varicella zoster virus infection (n/a - Unknown - Caused/Prolonged Hospitalisation)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	METHOTREXATE [METHOTREXATE] (C - Immunosuppression - n/a - [n/a - n/a - n/a]), [MERCAPTOPYRINE MONOHYDRATE] (C - Immunosuppression - n/a - [n/a - n/a - n/a])	ICSR	
EU-EC-10010591349	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010591388	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Myocarditis (1d - Recovering/Resolving - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010591389	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010591390	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Unknown - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown])	Not reported	ICSR	

EU-EC-10010591431	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Medically Important Condition) Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010591436	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (646h - Recovered/Resolved - Other Medically Important Condition), Hypersensitivity (646h - Recovered/Resolved - Other Medically Important Condition), Lung infiltration (18d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010591457	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dyspnoea (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Troponin increased (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010591460	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010591468	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown - Other Medically Important Condition), Fall (n/a - Unknown - Other Medically Important Condition), Overdose (n/a - Unknown -), Sinus bradycardia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular])	Not reported	ICSR
EU-EC-10010591469	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ophthalmic herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010591522	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (0d - Recovered/Resolved - Life Threatening), Asthma (n/a - Recovered/Resolved - Life Threatening), Confusional state (n/a - Recovered/Resolved - Life Threatening), Cyanosis (n/a - Recovered/Resolved - Life Threatening), Dyspnoea (n/a - Recovered/Resolved - Life Threatening), Oxygen saturation decreased (n/a - Recovered/Resolved - Life Threatening), Panic attack (n/a - Recovered/Resolved - Life Threatening), Peripheral coldness (n/a - Recovered/Resolved - Life Threatening), Speech disorder (n/a - Recovered/Resolved - Life Threatening)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010591549	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Syncope (1d - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)			
EU-EC-10010591573	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [MEDROXYPROGESTERONE ACETATE] (S - n/a - Drug withdrawn - [n/a - n/a - n/a])	[ETONOGESTREL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010591711	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010591713	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010591914	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010591918	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Unknown -), Seizure (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-10010591982	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Axillary mass (n/a - Recovering/Resolving - Other Medically Important Condition), Pain (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-10010592111	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Balance disorder (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010592127	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anxiety (n/a - Unknown -), Headache (n/a - Unknown -), Movement disorder (n/a - Unknown -), Muscular weakness (n/a - Unknown -), Myelitis (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown -), Pyrexia (n/a - Unknown -), Radiculopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010592454	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition), Troponin increased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010592464	09/11/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Female	No	Syncope (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

EU-EC-10010592508	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- Other Medically Important Condition) Chills (14d - Recovered/Resolved -), Dizziness (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Not Recovered/Not Resolved -), Injection site inflammation (3d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -), Injection site warmth (3d - Recovered/Resolved -), Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (4d - Recovered/Resolved -)	Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - I{DF} - n/a])	Not reported	ICSR
EU-EC-10010592613	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Parosmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Taste disorder (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-10010592641	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vocal cord paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010592710	09/11/2021	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), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[HUMAN PAPILLOMAVIRUS VACCINE] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010592717	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved -), Rash (n/a - Recovered/Resolved -), Swollen tongue (n/a - Recovered/Resolved -), Tachycardia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010592719	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Troponin increased (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-10010592810	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -	Not reported	ICSR

EU-EC-10010593003	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	- Other Medically Important Condition) Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Troponin increased (n/a - Recovering/Resolving -)	Not applicable - [n/a - n/a - n/a]	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010593087	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010593114	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010593137	09/11/2021	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 - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010593149	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010593203	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash erythematous (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010593204	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010593209	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tachycardia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010593232	09/11/2021	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 - n/a - [26d - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010593251	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010593283	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation delayed (2mo - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010593317	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010593391	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010593861	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010593946	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Facial paralysis (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-10010593963	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Chills (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (8d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR	

EU-EC-10010593974	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Palpitations (1d - Recovered/Resolved - Other Medically Important Condition), Sense of oppression (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010594002	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Aphasia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Balance disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paraesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010594007	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Henoch-Schonlein purpura (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010594025	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Haematemesis (17h - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (17h - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010594162	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010594175	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (7d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010594279	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (n/a - Unknown -), Dizziness (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition), Vision blurred (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010594880	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hypotension (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Presyncope (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010594928	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Eyelid ptosis (1d - Recovered/Resolved -), Lip oedema (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010594963	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Testicular pain (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

										Hospitalisation), Vomiting (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)			
EU-EC-10010595252	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010595315	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tremor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010595380	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Bronchospasm (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Hyperpyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010595402	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eyelid oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nephrotic syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oedema peripheral (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-10010595438	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition), Palpitations (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Cutaneous])	Not reported	ICSR
EU-EC-	09/11/2021	Spontaneous	Healthcare	European	Not available	12-17	Not	Female	No	Dyspnoea (n/a - Not	COMIRNATY	Not reported	ICSR

10010595463			Professional	Economic Area		Years	Specified			Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])		
EU-EC-10010595954	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (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-10010595996	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Agitation (0d - Recovered/Resolved -), Clonic convulsion (30s - Recovered/Resolved - Other Medically Important Condition), Dysphoria (0d - Recovered/Resolved -), Hyperventilation (0d - Recovered/Resolved -), Hypoaesthesia (0d - Recovered/Resolved -), Loss of consciousness (30s - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010596027	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Arthralgia (n/a - Unknown -), Paraesthesia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010596239	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved -), Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved -), Poor quality sleep (n/a - Not Recovered/Not Resolved -), Productive cough (2wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[PARACETAMOL, PARACETAMOL PH. EUR.] (C - Pain - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010596551	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010596580	09/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Block vertebra (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Functional gastrointestinal disorder (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										<p>- Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Inflammation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Musculoskeletal disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Myelitis transverse (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Sensory disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),</p> <p>Sensory loss (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)</p>			
EU-EC-10010596595	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	<p>Arthralgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),</p> <p>Blood creatine phosphokinase increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),</p> <p>C-reactive protein increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),</p> <p>Drug interaction (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),</p> <p>Localised oedema (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation),</p> <p>Myalgia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Troponin I increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),</p>	<p>COMIRNATY [TOZINAMERAN] (I - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]),</p> <p>[MINOCYCLINE] (I - Acne - Drug withdrawn - [10d - n/a - n/a])</p>	Not reported	ICSR

											Urticaria (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10010596611	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Muscle spasms (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving -), Pallor (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010596665	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Paraesthesia (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010596776	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010596797	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pyrexia (20d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010596941	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Fatigue (0d - Not Recovered/Not Resolved -), Injection site pain (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010597115	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10010597209	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (24d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Paraesthesia (24d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010597277	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010597590	09/11/2021	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 - Unknown - [n/a - 1{DF} - n/a])	GARDASIL 9 [HUMAN PAPILLOMAVIRUS TYPE 31 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 33 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 45 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 52 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 58 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 11 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 16 L1 PROTEIN - ADSORBED - IN THE FORM	ICSR	

												OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 6 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS-LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, AMORPHOUS ALUMINIUM HYDROXYPHOSPHATE] (C - n/a - n/a - [n/a - n/a - n/a])	
EU-EC-10010597596	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Dysuria (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Haematuria (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Ocular hyperaemia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Tubulointerstitial nephritis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	OPATANOL [OLOPATADINE, OLOPATADINE HYDROCHLORIDE] (C - Rhinitis allergic - n/a - [n/a - n/a - Ophthalmic]), [MECILLINAM, PIVMECILLINAM, PIVMECILLINAM HYDROCHLORIDE] (C - Urinary tract infection - n/a - [45d - n/a - Oral])	ICSR
EU-EC-10010597613	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Parosmia (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-10010597624	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010597635	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010597661	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain in extremity (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010597673	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[ADAPALENE] (C - Acne - n/a - [n/a - n/a - Cutaneous])	ICSR
EU-EC-10010597678	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain (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 - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010597692	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Dizziness (0d - Recovered/Resolved -), Nausea (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010597929	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Not Recovered/Not Resolved -), Injection site pain (1d - Not Recovered/Not Resolved -), Limb discomfort (0d -	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

										Not Recovered/Not Resolved -), Malaise (1d - Not Recovered/Not Resolved -), Myalgia (0d - Not Recovered/Not Resolved -)			
EU-EC-10010597941	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010597974	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Recovered/Resolved -), Injection site pain (2d - Recovering/Resolving -), Pyrexia (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010597984	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (3d - Not Recovered/Not Resolved -), Feeling hot (3d - Not Recovered/Not Resolved -), Influenza (3d - Not Recovered/Not Resolved -), Pyrexia (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010598008	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10010598011	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Transient ischaemic attack (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010598045	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Unknown -), Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10010598059	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pain in extremity (n/a - Unknown -), Somnolence (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR
EU-EC-10010598109	09/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain in extremity (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010598127	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bradycardia (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-10010598183	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Injection site pain (1d - Recovered/Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010598192	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site pain (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010598226	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Troponin I increased (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010598251	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (0d - Recovering/Resolving -), Pyrexia (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010598350	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (2d -)	COMIRNATY [TOZINAMERAN] (S -)	Not reported	ICSR

EU-EC-10010598481	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (1d - Not Recovered/Not Resolved -), Pyrexia (0d - Recovered/Resolved -)	Immunisation - n/a - [n/a - n/a]	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-10010598547	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (1d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Injection site pain (1d - Recovering/Resolving -), Nausea (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-10010598592	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-10010599135	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Facial paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-10010599222	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (3d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-10010599246	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza (0d - Not Recovered/Not Resolved -), Pyrexia (0d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-10010599249	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Injection site pain (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-10010599258	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cough (2d - Recovered/Resolved -), Fatigue (3d - Recovered/Resolved -), Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-10010599268	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (0d - Unknown -), Limb discomfort (0d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-10010599290	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (4d - Not Recovered/Not Resolved -), Injection site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-10010599719	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Body temperature increased (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Syncope (1d - Recovered/Resolved - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-10010599831	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Not Specified	No	Dizziness (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 -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a])	Not reported	ICSR
EU-EC-10010599843	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Not Recovered/Not Resolved -), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

											Condition),			
EU-EC-10010599865	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No		Vomiting (n/a - Not Recovered/Not Resolved -) Chills (1d - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -), Nausea (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010599866	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No		Fatigue (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010599917	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No		Injection site pain (1d - Recovered/Resolved -), Tachycardia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010599931	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No		Chills (1d - Recovered/Resolved -), Dizziness (2d - Recovered/Resolved -), Fatigue (2d - Recovering/Resolving -), Injection site erythema (3d - Recovered/Resolved -), Injection site pain (4d - Recovered/Resolved -), Injection site swelling (1d - Recovered/Resolved -), Malaise (0d - Recovered/Resolved -), Nausea (0d - Recovered/Resolved -), Paraesthesia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010599943	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No		Paraesthesia (2d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010599945	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No		Dizziness (0d - Recovering/Resolving -), Fatigue (1d - Not Recovered/Not Resolved -), Headache (1d - Not Recovered/Not Resolved -), Nausea (3d - Not Recovered/Not Resolved -), Vomiting (0d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010599960	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No		Influenza (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010599967	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No		Injection site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010600027	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No		Fatigue (1d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR

											Influenza (0d - Recovered/Resolved -), Injection site pain (1d - Recovered/Resolved -), Limb discomfort (0d - Recovered/Resolved -), Myalgia (1d - Not Recovered/Not Resolved -), Vaccination site reaction (1d - Recovered/Resolved -)			
EU-EC-10010600063	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010600141	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Feeling hot (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Headache (1d - Recovering/Resolving -), Injection site pain (2d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010600170	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain in extremity (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010600255	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (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-10010600378	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Dizziness (n/a - Unknown -), Nausea (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition), Visual impairment (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010600589	09/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Palpitations (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (n/a - Recovering/Resolving -), Troponin increased (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010600775	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Back pain (37d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (37d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Hypoaesthesia (37d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (37d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Seizure (37d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010600797	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (2d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	

										Pyrexia (1d - Recovered/Resolved -)			
EU-EC-10010600818	09/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (42d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010574907	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Recovering/Resolving -), Peripheral swelling (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010574981	08/11/2021	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 - Recovering/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), 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-10010575116	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010575182	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010575196	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Myocarditis (n/a - Unknown - Other Medically Important Condition), Palpitations (0d - Recovered/Resolved - Other Medically Important Condition), Pericarditis (n/a - Unknown - Other Medically Important Condition), Tachycardia (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-10010575522	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling of body temperature change (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Photophobia (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR

										Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10010575863	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hand deformity (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Hypersensitivity (1d - Recovered/Resolved - Other Medically Important Condition), Muscle rigidity (n/a - Unknown - Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other Medically Important Condition), Pharyngeal paraesthesia (n/a - Unknown - Other Medically Important Condition), Rash (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-10010575864	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Bronchospasm (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Confusional state (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dilatation ventricular (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

Hospitalisation, Other Medically Important Condition),
Electroencephalogram abnormal (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),
Encephalitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),
Encephalopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),
Feeling drunk (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),
Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),
Hypertension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),
Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),
Neurological symptom (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),
Pericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),
Pneumonia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),
Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),
Somnolence (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),
Vision blurred (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),
Visual impairment (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)

EU-EC-10010575865	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Contusion (n/a - Unknown -), Fall (n/a - Unknown -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Muscular weakness (n/a - Unknown -), Skin abrasion (n/a - Unknown -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010575870	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Influenza (n/a - Recovering/Resolving - Other Medically Important Condition), Influenza like illness (n/a - Unknown - Other Medically Important Condition), Pyrexia (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-10010575879	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Ulcer (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vulvovaginal ulceration (n/a - Recovering/Resolving - Other Medically Important Condition), Vulvovaginal ulceration (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	CIRCADIN [MELATONIN] (C - Anxiety, Depression - n/a - [n/a - 2mg - n/a]), [ESCITALOPRAM, ESCITALOPRAM OXALATE] (C - Anxiety, Depression - n/a - [n/a - 10mg - n/a])	ICSR
EU-EC-10010576411	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (n/a - Recovering/Resolving -), Myocarditis (20d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	[LORATADINE] (C - Hypersensitivity - n/a -)	ICSR
EU-EC-10010576671	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cold sweat (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (10s - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010576871	08/11/2021	Spontaneous	Non Healthcare	Non European	Not available	12-17 Years	Not Specified	Female	No	Bell's palsy (n/a - Recovering/Resolving	TOZINAMERAN [TOZINAMERAN] (S -	Not reported	ICSR

			Professional Area	Economic Area							- Disabling, Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [1d - n/a - n/a]		
EU-EC-10010576877	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary mass (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vaccination site erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Parenteral])	Not reported	ICSR	
EU-EC-10010576934	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010576959	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Acute stress disorder (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-10010576963	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Conversion disorder (534min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Crying (9h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hyperventilation (9h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Status epilepticus (8h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010576976	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Joint stiffness (n/a - Recovered/Resolved - Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved -), Pain in jaw (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR	
EU-EC-10010577359	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Confusional state (n/a - Recovered/Resolved -), Eye injury (n/a - Not Recovered/Not Resolved -), Eye swelling (n/a - Not Recovered/Not Resolved -), Feeling abnormal (n/a - Recovered/Resolved -), Limb injury (n/a - Not Recovered/Not Resolved -), Muscular weakness (n/a -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR	

										Recovered/Resolved -), Syncope (n/a - Recovered/Resolved -)			
EU-EC-10010577432	08/11/2021	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 -), Fatigue (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Somnolence (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010578402	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Inappropriate schedule of product administration (n/a - Unknown -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010578624	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Recovered/Resolved -), Heart rate increased (n/a - Recovered/Resolved -), Heart rate irregular (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010579359	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Unknown -), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010579412	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Unknown - Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Unknown -), Syncope (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-10010580133	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epilepsy (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010580273	08/11/2021	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 -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Menstruation irregular (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 -)			
EU-EC-10010580467	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (1d - Unknown - Other Medically Important Condition), Pallor (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Somnolence (1d - Unknown - Other Medically Important Condition), Tremor (1d - Unknown - Other Medically Important Condition), Vomiting (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010580476	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010580492	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Diarrhoea (2d - Recovered/Resolved - Other Medically Important Condition), Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010580519	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Unknown -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010580990	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010581048	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest discomfort (n/a - Recovered/Resolved -), Erythema (40h - Recovered/Resolved - Other Medically Important Condition), Lip swelling (40h - Recovered/Resolved - Other Medically Important Condition), Malaise (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Other Medically Important Condition), Pain (0d - Recovered/Resolved -), Pruritus (40h - Recovered/Resolved - Other Medically Important Condition), Rash (40h - Recovered/Resolved - Other Medically Important Condition), Swelling face (2d - Recovered/Resolved -), Vaccination site pruritus (40h - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10010581060	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Altered state of consciousness (850min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Epilepsy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fall (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Fatigue (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Heat illness (n/a - Unknown - Caused/Prolonged Hospitalisation), Lactic acidosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Physical deconditioning (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010581377	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	CIRCADIN 2 MG PROLONGED-RELEASE TABLETS [MELATONIN] (C - Sleep disorder - n/a - [n/a - 2mg - n/a])	ICSR
EU-EC-10010581385	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menometrorrhagia (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010581566	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Vaccination failure (n/a - Unknown - Other Medically Important Condition)			
EU-EC-10010581745	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Body temperature increased (1d - Recovered/Resolved -), Breast mass (2wk - Recovered/Resolved -), Chills (1d - Recovered/Resolved -), Injection site erythema (4d - Recovered/Resolved -), Injection site inflammation (4d - Recovered/Resolved -), Injection site pain (4d - Recovered/Resolved -), Injection site swelling (4d - 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-10010581886	08/11/2021	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 - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010581935	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immune thrombocytopenia (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [43d - 2{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010581973	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Mixed liver injury (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010581989	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Generalised tonic-clonic seizure (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582058	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582072	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (15min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1umol - Intramuscular])	Not reported	ICSR
EU-EC-10010582079	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (15d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582110	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Monoplegia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582122	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pruritus (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582133	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010582184	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010582202	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582258	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Eyelid oedema (n/a - Not Recovered/Not Resolved -), Lymphadenitis (n/a - Not Recovered/Not Resolved -), Tonsillitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-	08/11/2021	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Female	No	Amnesia fugax	COMIRNATY	Not reported	ICSR

10010582268			Professional	Economic Area		Years				(5min - Recovered/Resolved -), Deafness bilateral (5min - Recovered/Resolved -)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])		
EU-EC-10010582296	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582301	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Recovered/Resolved -), Polymenorrhoea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582309	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Breast pain (n/a - Recovering/Resolving -), Intermenstrual bleeding (n/a - Recovering/Resolving -), Pelvic pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582318	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582333	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Gastrointestinal disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582503	08/11/2021	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 - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582505	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582524	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ecchymosis (14d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582542	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -), Pain in extremity (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010582671	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Deafness unilateral (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010582682	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Enterocolitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ileus paralytic (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010582737	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010583295	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Troponin increased (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010583457	08/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Headache (n/a - Not Recovered/Not Resolved -), Vision blurred (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	[ISOTRETINOIN] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010583633	08/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angina pectoris (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (n/a	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

EU-EC-10010584956	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hypoaesthesia (n/a - Recovering/Resolving - Other Medically Important Condition), Paraesthesia (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-10010585075	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Unknown -), Constipation (n/a - Unknown -), Lymphadenitis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown])	Not reported	ICSR	
EU-EC-10010585093	08/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown])	Not reported	ICSR	
EU-EC-10010585338	08/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Hypophagia (n/a - Unknown -), Nausea (n/a - Unknown -), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010574074	07/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Injection site haematoma (n/a - Recovering/Resolving -), Injection site inflammation (n/a - Recovering/Resolving -), Injection site pain (n/a - Recovering/Resolving -), Injection site warmth (n/a - Recovering/Resolving -), Malaise (0d - 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-10010574402	07/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010574494	07/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cyanosis (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Epistaxis (n/a - Recovered/Resolved -), Influenza like illness (8d - Recovered/Resolved -), Limb discomfort (n/a - Recovered/Resolved -), Urticaria (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-10010574618	07/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Dysphoria (n/a - Recovering/Resolving - Other Medically Important Condition), Pallor (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010574743	07/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving -), Intermenstrual bleeding (n/a - Recovering/Resolving -), Menstruation delayed (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010574812	07/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Myalgia (2d - 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-10010571555	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010571600	06/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010571764	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Burning sensation (n/a - Not Recovered/Not Resolved -), Erythema (n/a - Not Recovered/Not Resolved -), Hypersensitivity (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Subcutaneous])	[KETOPROFEN LYSINE] (C - n/a - n/a - [n/a - 80ug - Oral])	ICSR
EU-EC-10010571988	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Epistaxis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010572102	06/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving -), Troponin increased (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010572295	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010572300	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010572322	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010572323	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovering/Resolving -), 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

											Taste disorder (0d - Recovered/Resolved -)			
EU-EC-10010572334	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10010572366	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10010572372	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10010572381	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10010572383	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Nausea (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10010572461	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Injection site pain (2d - Recovered/Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10010572488	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (3d - Recovered/Resolved -), Injection site haematoma (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-10010572726	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Cough (n/a - Recovering/Resolving -), Dark circles under eyes (n/a - Recovering/Resolving -), Eye irritation (n/a - Recovering/Resolving -), Feeling cold (n/a - Recovered/Resolved -), Influenza like illness (n/a - Recovering/Resolving -), Rhinorrhoea (n/a - Recovering/Resolving -), Throat irritation (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Recovered/Resolved -), Vaccination site reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010572763	06/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR	
EU-EC-10010572941	06/11/2021	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 -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	

										-), Myalgia (n/a - Not Recovered/Not Resolved -), Neck pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)			
EU-EC-10010572989	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (1d - Recovered/Resolved -), Body temperature increased (1d - Recovered/Resolved -), Chills (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC-10010573043	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Unknown -), Chills (1d - Recovered/Resolved -), Headache (0d - 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 -), Injection site warmth (2d - Recovered/Resolved -), Myalgia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010573057	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Fatigue (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovered/Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Puncture site pain (n/a - Recovered/Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Rhinorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010573207	06/11/2021	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 -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (1d - Recovered/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-10010573525	06/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010573539	06/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010573570	06/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ear inflammation (n/a - Recovering/Resolving -), Oropharyngeal pain (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Sinusitis (n/a - Recovering/Resolving -)	AMBIRIX SUSPENSION FOR INJECTION [HEPATITIS A VIRUS (INACTIVATED), HEPATITIS B SURFACE ANTIGEN (RDNA)] (S - n/a - n/a - [n/a - n/a - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010573849	06/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010560768	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pain in extremity (n/a - Recovering/Resolving -), Vertigo (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010561145	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010561198	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Seizure (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010561282	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pruritus (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010561430	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -), Chest pain (n/a - Not Recovered/Not Resolved -), Dyspnoea (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 -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010561689	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition), Tremor (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-10010561719	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010561823	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain in extremity (7d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Rash erythematous (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010561838	05/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cold sweat (n/a - Recovered/Resolved - Other Medically Important Condition), Malaise (n/a - Recovered/Resolved - Other Medically Important Condition), Oxygen saturation decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Presyncope (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-10010561861	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Muscle tightness (n/a - Not Recovered/Not Resolved -), Pain in extremity (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-10010562151	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010562157	05/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Erythema (n/a - Unknown -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Pruritus (n/a - Recovered/Resolved -), Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010562295	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inflammation (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Intracranial pressure increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Musculoskeletal stiffness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neck pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oropharyngeal pain (24h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) [DYDROGESTERONE] (C - Heavy menstrual bleeding - n/a - [n/a - 20mg - Oral]), [MEDROXYPROGESTERONE ACETATE] (C - Heavy menstrual bleeding - n/a - [n/a - 20mg - Oral])	Not reported	ICSR

										Papilloedema (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Rhinitis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10010562333	05/11/2021	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), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Pyrexia (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-10010562345	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Ear infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Ear pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Epistaxis (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-10010562367	05/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Bronchitis (n/a - Not Recovered/Not Resolved -), Chest pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010562372	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blister (n/a - Unknown - Other Medically Important Condition), Rash papular (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-10010562379	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cold sweat (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pallor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010562398	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (3d - Recovered/Resolved - Other Medically Important Condition), Constipation (2d - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[MEBEVERINE] (C - Irritable bowel syndrome - n/a - [n/a - n/a - n/a])	ICSR

										Headache (3d - Recovered/Resolved - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition), Peripheral swelling (n/a - Recovering/Resolving - Other Medically Important Condition)			
EU-EC-10010562532	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Administration site erythema (4d - Recovered/Resolved -), Administration site oedema (3d - Recovered/Resolved -), Administration site pain (4d - Recovered/Resolved -), Body temperature increased (4d - Recovered/Resolved -), Decreased appetite (2d - Recovered/Resolved -), Fatigue (4d - Recovered/Resolved -), Irritability (4d - Recovered/Resolved -), Loss of consciousness (1min - Recovered/Resolved -), Mood altered (4d - Recovered/Resolved -), Vertigo (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010562703	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010562873	05/11/2021	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 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 -), 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-10010563096	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypertension (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010563251	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Appendicitis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

EU-EC-10010563262	05/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Medically Important Condition) Generalised tonic-clonic seizure (2min - Recovered/Resolved - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010563330	05/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fall (0d - Recovered/Resolved -), Feeling abnormal (0d - Recovered/Resolved -), Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Presyncope (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010563371	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010563458	05/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Flushing (n/a - Recovered/Resolved -), Flushing (n/a - Unknown -), Peripheral coldness (n/a - Unknown -), Rash (n/a - Unknown -), Rash macular (n/a - Recovered/Resolved -), Somnolence (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010563531	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving -), Intermenstrual bleeding (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 AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010563817	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010563877	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010564266	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010564512	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pityriasis rosea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010564688	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Intermenstrual bleeding (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-10010564822	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (2d - Recovered/Resolved -), Peripheral swelling (2d -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved -), Skin disorder (2d - Recovered/Resolved -), Urticaria (2d - Recovered/Resolved -)			
EU-EC-10010565248	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diabetes mellitus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Polydipsia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010565281	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Heart rate increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010565434	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Heart rate increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Musculoskeletal chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paraesthesia oral (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Dysmenorrhoea - n/a - [n/a - n/a - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Depression - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010565438	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010565536	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pallor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)			
EU-EC-10010565540	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010566125	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthma (n/a - Recovered/Resolved -), Dyspnoea (n/a - Recovered/Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[SALBUTAMOL] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010566131	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Unknown -), Menstruation irregular (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[PANTOPRAZOLE SODIUM SESQUIHYDRATE] (C - Gastroesophageal reflux disease - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010566137	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pityriasis rosea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010566150	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Alopecia (n/a - Unknown -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010566642	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Recovered/Resolved -), Application site reaction (n/a - Recovered/Resolved -), Diarrhoea (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010566761	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown - Other Medically Important Condition), Seizure (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10010566919	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Other Medically Important Condition) Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Mental disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Unknown -), Nausea (n/a - Unknown -), Skin reaction (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-10010566970	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010566990	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Troponin T increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	BEXSERO [ALUMINIUM HYDROXIDE, RECOMBINANT NEISSERIA MENINGITIDIS GROUP B NHBA FUSION PROTEIN PRODUCED IN E. COLI CELLS BY RECOMBINANT DNA TECHNOLOGY ADSORBED ON ALUMINIUM HYDROXIDE, RECOMBINANT NEISSERIA MENINGITIDIS GROUP B NADA PROTEIN PRODUCED IN E. COLI CELLS BY RECOMBINANT DNA TECHNOLOGY ADSORBED ON ALUMINIUM HYDROXIDE, RECOMBINANT NEISSERIA MENINGITIDIS GROUP B FHBP FUSION PROTEIN PRODUCED IN E. COLI CELLS BY RECOMBINANT DNA TECHNOLOGY ADSORBED ON ALUMINIUM HYDROXIDE, OUTER MEMBRANE VESICLES (OMV) FROM NEISSERIA MENINGITIDIS GROUP B STRAIN NZ98/254 MEASURED AS AMOUNT OF TOTAL PROTEIN CONTAINING THE PORA P1.4 ADSORBED ON ALUMINIUM HYDROXIDE, RECOMBINANT NEISSERIA MENINGITIDIS GROUP B NHBA FUSION PROTEIN PRODUCED IN E. COLI CELLS BY RECOMBINANT DNA TECHNOLOGY ADSORBED ON ALUMINIUM HYDROXIDE, RECOMBINANT NEISSERIA MENINGITIDIS GROUP B NADA PROTEIN PRODUCED IN E. COLI CELLS BY RECOMBINANT DNA TECHNOLOGY ADSORBED ON ALUMINIUM HYDROXIDE, RECOMBINANT NEISSERIA MENINGITIDIS GROUP B FHBP FUSION PROTEIN PRODUCED IN E. COLI CELLS BY RECOMBINANT DNA TECHNOLOGY ADSORBED ON ALUMINIUM HYDROXIDE, OUTER MEMBRANE VESICLES (OMV) FROM NEISSERIA MENINGITIDIS GROUP B STRAIN NZ98/254 MEASURED AS AMOUNT OF TOTAL PROTEIN CONTAINING THE PORA P1.4 ADSORBED ON ALUMINIUM HYDROXIDE] (S - n/a - n/a - [1d - n/a - Intramuscular]), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010567073	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vomiting (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR

EU-EC-10010567371	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deafness neurosensory (n/a - Unknown - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010567377	05/11/2021	Spontaneous	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), Asthma (n/a - Recovered/Resolved -), Disease recurrence (n/a - Recovering/Resolving - Other Medically Important Condition), Eczema (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010567378	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (10d - Recovered/Resolved - Other Medically Important Condition), Dry skin (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Erythema (n/a - Unknown - Other Medically Important Condition), Periorbital swelling (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Skin irritation (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-10010567447	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspepsia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Eye movement disorder (n/a - Unknown - Other Medically Important Condition), Seizure (1d - Recovered/Resolved - Other Medically Important Condition), Syncope (1d - Recovered/Resolved - Other Medically Important Condition), Tinnitus (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010567726	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lichen planus (n/a - 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-10010567815	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010567989	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	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-10010568080	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010568141	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Epistaxis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010568169	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Gastrointestinal disorder (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010568193	05/11/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Presyncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S -)	Not reported	ICSR

				Area)			
EU-EC-10010568213	05/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Unknown - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Troponin I increased (n/a - Unknown - Caused/Prolonged Hospitalisation)	COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]	Not reported	ICSR
EU-EC-10010568244	05/11/2021	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 - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010568260	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Vertigo (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010568270	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nausea (n/a - Not Recovered/Not Resolved -), Pallor (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010568271	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (10d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010568272	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Ophthalmic herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010568280	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Herpes zoster (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010568285	05/11/2021	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 - Unknown - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010568442	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Nasopharyngitis (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010568464	05/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Body temperature increased (0d - Recovered/Resolved -), Epilepsy (n/a - Unknown - Other Medically Important Condition), Generalised tonic-clonic seizure (0d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR

EU-EC-10010568484	05/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (n/a - Recovering/Resolving - Other Medically Important Condition), Lip swelling (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010568598	05/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010569018	05/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Depressed level of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Muscle spasms (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other Medically Important Condition), Peripheral circulatory failure (n/a - Unknown - Other Medically Important Condition), Rash (n/a - Unknown - Other Medically Important Condition), Rash erythematous (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - Other Medically Important Condition), Stridor (0d - Recovered/Resolved - Other Medically Important Condition), Stridor (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	FLUENZ TETRA [A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE STRAIN (A/HAWAII/66/2019, MEDI 326775), A/HONG KONG/2671/2019 (H3N2) - LIKE STRAIN (A/HONG KONG/2671/2019, MEDI 325078), B/PHUKET/3073/2013 - LIKE STRAIN (B/PHUKET/3073/2013, MEDI 306444), B/WASHINGTON/02/2019 - LIKE STRAIN (B/WASHINGTON/02/2019, MEDI 323797), A/TEXAS/50/2012 (H3N2)- LIKE STRAIN (A/TEXAS/50/2012, MEDI 237514), B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/MASSACHUSETTS/2/2012, MEDI 237751), A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (A/CALIFORNIA/7/2009, MEDI 228029), B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), A/CALIFORNIA/7/2009 (H1N1)PDM09-LIKE STRAIN (A/BOLIVIA/559/2013, MEDI 255962), B/PHUKET/3073/2013 (YAMAGATA LINEAGE)-LIKE STRAIN (B/PHUKET/3073/2013, MEDI 254977), A/HONG KONG/4801/2014 (H3N2)- LIKE STRAIN (A/NEW CALEDONIA/71/2014, MEDI 263122), B/PHUKET/3073/2013 (YAMAGATA LINEAGE)-LIKE STRAIN (B/PHUKET/3073/2013, MEDI 254977), A/MICHIGAN/45/2015 (H1N1)PDM09 - LIKE STRAIN (A/SLOVENIA/2903/2015, MEDI 279432), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, MEDI 291690), B/COLORADO/06/2017-LIKE STRAIN (B/COLORADO/06/2017, MEDI 293454)] (C - Influenza immunisation - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10010569087	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (7d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010570207	05/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Neuropathy peripheral (n/a - Unknown - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Paralysis (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10010570380	05/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Discomfort (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-10010570841	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash (n/a - Recovering/Resolving -)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010571138	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010571182	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Administration site joint pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10010571208	05/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Nausea (2d - Recovered/Resolved -), Pyrexia (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10010549365	04/11/2021	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), Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling cold (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Hot flush (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Recovered/Resolved - Other Medically Important Condition), Poor quality sleep (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-10010549478	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010549908	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	[LOMERIZINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010549950	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-	04/11/2021	Spontaneous	Non	Non	Not available	12-17	Not	Female	No	Rash (n/a -	COMIRNATY	Not reported	ICSR

10010550002			Healthcare Professional	European Economic Area		Years	Specified			Recovering/Resolving - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		
EU-EC-10010550065	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure increased (118min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - intramuscular])	Not reported	ICSR
EU-EC-10010550332	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Angina pectoris (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown -), Vaccination site swelling (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010550699	04/11/2021	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 -), 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-10010550701	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010550707	04/11/2021	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 -), Hyperpyrexia (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])	[PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010550708	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010550709	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010550858	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Palpitations (2d - Recovered/Resolved - Other Medically Important Condition), Tremor (1d - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010550921	04/11/2021	Spontaneous	Non Healthcare Professional	Non 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 - 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-10010550960	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Electrocardiogram abnormal (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

										Nausea (n/a - Recovered/Resolved -), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved -)			
EU-EC-10010550977	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[PARACETAMOL] (C - Headache - n/a - [1d - n/a - n/a])	ICSR
EU-EC-10010551480	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Nausea (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-10010551543	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (n/a - Unknown - Disabling, Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Disabling, Other Medically Important Condition), Heart rate increased (24h - Recovered/Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[DROSPIRENONE, ETHINYLESTRADIOL] (C - Heavy menstrual bleeding - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010551545	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (1d - Recovered/Resolved - Other Medically Important Condition), Hypersensitivity (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010551635	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010551800	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Carditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - Disabling), Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[ETHINYLESTRADIOL, LEVONORGESTREL] (C - Heavy menstrual bleeding - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010552243	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -)	Not reported	ICSR

										Heavy menstrual bleeding (n/a - Recovering/Resolved -), Nausea (n/a - Recovering/Resolved -)	Not applicable - [n/a - 1{DF} - n/a]		
EU-EC-10010552533	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Deep vein thrombosis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	Not reported	ICSR
EU-EC-10010552631	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pruritus (4d - Recovered/Resolved -), Rash papular (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010552734	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010552924	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolved -), Diarrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010552960	04/11/2021	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 -), Hypersomnia (n/a - Unknown -), Impaired quality of life (n/a - Unknown -), Photophobia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010552995	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown -), Mood swings (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010553218	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Discomfort (n/a - Unknown -), Hepatitis (n/a - Unknown - Other Medically Important Condition), Hepatomegaly (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010553428	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure systolic decreased (n/a - Recovered/Resolved -), Feeling abnormal (n/a - Recovered/Resolved -), Shock (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not reported	ICSR
EU-EC-10010553433	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Peripheral swelling (4d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010553447	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010553448	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Appendicitis (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010553449	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Immunisation (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S -)	Not reported	ICSR

			Professional	Economic Area						Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Off label use (n/a - Unknown -), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)	COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]		
EU-EC-10010553465	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Lymph node pain (n/a - Recovering/Resolving - Other Medically Important Condition), Lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Pain (n/a - Recovering/Resolving - Other Medically Important Condition), Peripheral swelling (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination site swelling (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-10010553536	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), Swelling face (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (C - n/a - n/a - [n/a - n/a - n/a]), [COLCHICINE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR

										Tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)			
EU-EC-10010553545	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved - Other Medically Important Condition), Fatigue (1d - Recovered/Resolved - Other Medically Important Condition), Insomnia (n/a - Unknown - Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (1d - Recovered/Resolved - Other Medically Important Condition), Peripheral swelling (n/a - Unknown - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (1d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010553564	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Influenza like illness (n/a - Unknown - Other Medically Important Condition), Migraine (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nasal congestion (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tremor (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-10010553588	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Presyncope (1d - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010553926	04/11/2021	Spontaneous	Healthcare Professional	European Economic	Not available	12-17 Years	Adolescent	Female	No	Deep vein thrombosis (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - n/a -)	Not reported	ICSR

EU-EC-10010553948	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Other Medically Important Condition) Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	Drug withdrawn - [n/a - n/a - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010554019	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (2d - Recovered/Resolved -), Disturbance in attention (n/a - Not Recovered/Not Resolved -), Eye pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Injection site pain (3d - Recovered/Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (2d - Recovered/Resolved -), Weight bearing difficulty (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010554037	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Malaise (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pruritus (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Sensation of foreign body (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Somnolence (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Urticaria (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010554041	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Feeling cold (n/a - Recovered/Resolved - Other Medically Important Condition), Gastrointestinal pain (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Infection (n/a - Recovered/Resolved - Other Medically Important Condition), Limb discomfort (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR

										Other Medically Important Condition), Tremor (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)			
EU-EC-10010554111	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovered/Resolved -), Incorrect dosage administered (n/a - Unknown -), Underdose (n/a - Unknown -), Vaccination site thrombosis (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .1mL - Intramuscular])	Not reported	ICSR
EU-EC-10010554119	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Pericarditis (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-10010554128	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (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-10010554393	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Decreased appetite (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Sleep disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010554500	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chills (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Feeling cold (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Rash (n/a - Recovered/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 - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010554510	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Mydriasis (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[COLLAGEN] (C - n/a - n/a - [n/a - n/a - n/a]), [DOCONEXENT, ICOSAPENT, FISH OIL, OMEGA-3-ACID ETHYL ESTERS 90] (C - n/a - n/a - [n/a - n/a - n/a]), [FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010554543	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chest discomfort (n/a - Recovering/Resolving -), Vaccination site movement impairment (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR

										-), Vaccination site pain (n/a - Recovering/Resolving -)			
EU-EC-10010554598	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Alopecia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010554605	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cardiovascular disorder (n/a - Not Recovered/Not Resolved -), Chills (n/a - Recovered/Resolving -), Dizziness (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Hyperhidrosis (n/a - Recovered/Resolving -), Tinnitus (n/a - Recovered/Resolving -), Visual impairment (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010554609	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (72h - Recovered/Resolving -), Myalgia (72h - Recovered/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010554612	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (72h - Recovered/Resolving -), Fatigue (n/a - Not Recovered/Not Resolved -), Vaccination site movement impairment (48h - Recovered/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010554614	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Recovered/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010554628	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Axillary pain (n/a - Recovering/Resolving -), Back pain (n/a - Recovering/Resolving -), Localised oedema (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010554636	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Eczema (1h - Recovered/Resolving - Caused/Prolonged Hospitalisation), Seizure (1h - Recovered/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[WARFARIN POTASSIUM] (C - n/a - n/a - [n/a - 1g - n/a])	ICSR
EU-EC-10010554678	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash papular (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a])	[FLUTICASONE PROPIONATE] (C - Asthma - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010554697	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010554817	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Oligomenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-	04/11/2021	Spontaneous	Healthcare	European	Not available	12-17	Not	Female	No	Myopericarditis (n/a -	COMIRNATY	Not reported	ICSR

1001055575			Professional	Economic Area		Years	Specified			Recovering/Resolving - Other Medically Important Condition)	[TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])		
EU-EC-10010555883	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling cold (1d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010555926	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Tachycardia (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010556003	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased appetite (5d - Recovered/Resolved -), Flat affect (5d - Recovered/Resolved -), Headache (5d - Recovered/Resolved -), Nausea (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010556456	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (33d - Recovered/Resolved -), Fatigue (33d - Recovered/Resolved -), Oropharyngeal pain (33d - Recovered/Resolved -), Pyrexia (33d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010556677	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Neuropathy peripheral (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010556827	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[INFLUENZA VIRUS] (C - Immunisation - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010556997	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling), Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Menstrual disorder (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010557163	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010557341	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myopericarditis (46d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation -)	Not reported	ICSR

EU-EC-10010557344	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myalgia (n/a - Recovered/Resolved - Other Medically Important Condition), Troponin increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	Not applicable - [1d - 1{DF} - Intramuscular]	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010557450	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Presyncope (1h - Recovered/Resolved -), Vomiting (1h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010557472	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010557601	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oedema peripheral (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010557626	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not reported	ICSR	
EU-EC-10010557636	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Gastrointestinal disorder (n/a - Recovering/Resolving -), Influenza like illness (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intradermal])	Not reported	ICSR	
EU-EC-10010558001	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Syncope (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])	Not reported	ICSR	
EU-EC-10010558066	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (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-10010558102	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovering/Resolving -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Listless (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Oligomenorrhoea (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-10010558117	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10010558440	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (4d - Not Recovered/Not Resolved -), Influenza like illness (4d - Not Recovered/Not Resolved -), Vomiting (4d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR	
EU-EC-10010558563	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (4d - Recovered/Resolved -), Injection site haematoma (7d - Recovered/Resolved -), Injection site pain (7d - Recovered/Resolved -), Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -), Myalgia (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not reported	ICSR	
EU-EC-10010558915	04/11/2021	Spontaneous	Healthcare Professional	Non European	Not available	12-17 Years	Not Specified	Male	No	Abdominal discomfort (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S -	Not reported	ICSR	

				Economic Area						Asthenia (n/a - Unknown -), Hypoesthesia (n/a - Unknown -), Malaise (n/a - Unknown -), Movement disorder (n/a - Unknown - Caused/Prolonged Hospitalisation), Rash (n/a - Unknown -)	COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])		
EU-EC-10010558962	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Blood creatine phosphokinase increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), Fibrin D dimer increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Pneumonia viral (n/a - Unknown - Caused/Prolonged Hospitalisation), Renal failure (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010559192	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a])	COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a])	ICSR
EU-EC-10010559278	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010559314	04/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyspepsia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myopericarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010559709	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Adhesion (n/a - Unknown -), Influenza (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010559716	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pruritus (n/a - Unknown -), Rash maculo-papular (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010559735	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010559774	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010559939	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010559953	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Adhesion (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S -)	Not reported	ICSR

				Area							COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])		
EU-EC-10010559975	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010559987	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010560025	04/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010560211	04/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	AST/ALT ratio abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Back pain (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation), C-reactive protein increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hyperthermia (241h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Inflammation (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Mobility decreased (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010560238	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dry mouth (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	[SOMATROPIN] (C - Growth hormone deficiency - n/a - [796d - n/a - n/a])	ICSR
EU-EC-10010560449	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dysphonia (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010560477	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Chest pain (n/a - Unknown -), Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010560579	04/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Bacterial infection (14d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved -), Herpes zoster (39d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not reported	ICSR
EU-EC-10010536136	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovered/Resolved -), Lymphadenopathy	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR

										(n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Tremor (n/a - Recovered/Resolved -), Vertigo (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)			
EU-EC-10010536138	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash vesicular (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010536182	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (4d - Recovered/Resolved -), Epistaxis (4d - Recovered/Resolved -), Pyrexia (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010536201	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pulmonary embolism (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010536217	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (1d - Recovered/Resolved -), Myalgia (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010536224	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (1d - Recovered/Resolved -), Pain in extremity (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010536226	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Erythema (4d - Recovered/Resolved -), Injection site rash (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular])	Not reported	ICSR
EU-EC-10010536262	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Injection site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010536449	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010536473	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Gastrointestinal disorder (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocardial oedema (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR
EU-EC-10010536481	03/11/2021	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not reported	ICSR
EU-EC-10010536493	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Bundle branch block right (8d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myopericarditis (8d -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not reported	ICSR

EU-EC-10010536611	03/11/2021	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Periorbital swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Swelling face (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010536864	03/11/2021	Spontaneous	Healthcare Professional	Non 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 -), Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010536871	03/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arrhythmia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Chest pain (n/a - Not Recovered/Not Resolved -), Hypertension (n/a - Not Recovered/Not Resolved -), Lethargy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not reported	ICSR
EU-EC-10010536872	03/11/2021	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Febrile neutropenia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Neutrophil count decreased (3d - Recovered/Resolved - Life Threatening), Pyrexia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	GRANISETRON [GRANISETRON] (C - n/a - n/a - [n/a - n/a - n/a]), TISAGENLECLEUCEL [TISAGENLECLEUCEL] (C - n/a - n/a - [n/a - n/a - n/a]), TOCILIZUMAB [TOCILIZUMAB] (C - n/a - n/a - [n/a - n/a - n/a]), [CIPROFLOXACIN, CIPROFLOXACIN HYDROCHLORIDE, CIPROFLOXACIN HYDROCHLORIDE MONOHYDRATE, CIPROFLOXACIN LACTATE] (C - n/a - n/a - [n/a - n/a - n/a]), [CLEMASTINE] (C - n/a - n/a - [n/a - n/a - n/a]), [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - [n/a - n/a - n/a]), [SULFAMETHOXAZOLE, TRIMETHOPRIM] (C - n/a - n/a - [n/a - n/a - n/a])	ICSR
EU-EC-10010536920	03/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (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-10010536922	03/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition), Tinnitus (n/a - Unknown -), Vision blurred (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

Run Line Listing Report

EU-EC-10010537366	03/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (n/a - Recovered/Resolved -), Confusional state (n/a - Recovered/Resolved -), Delirium (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (n/a - Recovered/Resolved -), Lethargy (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR
EU-EC-10010537765	03/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Aphthous ulcer (n/a - Recovering/Resolving -), Urinary retention (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-10010538080	03/11/2021	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Atrioventricular block first degree (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Myocarditis (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Unknown -), Tachycardia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not reported	ICSR

Rows 5001 - 5500

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