

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])	Con Adm (Dru PT – [Dur Rou])
EU-EC-10013021610	18/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain (n/a – Recovering/Resolving – Caused/Prolonged Hospitalisation), Swelling (n/a – Recovering/Resolving – Caused/Prolonged Hospitalisation), Vaccination site pain (n/a – Recovering/Resolving – Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S – COVID-19 immunisation – Not applicable – [1d – n/a – Intramuscular use])	Not
EU-EC-10013021693	18/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (2d – Recovered/Resolved –), Pain in extremity (2d – Recovered/Resolved –)	COMIRNATY [TOZINAMERAN] (S – COVID-19 immunisation – n/a – [n/a – 1{DF} – Intramuscular use])	Not
EU-EC-10013021850	18/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypersensitivity (n/a – Not Recovered/Not Resolved –), Lymphadenopathy (10d – Recovered/Resolved –), Nasopharyngitis (n/a – Not Recovered/Not Resolved –), Pyrexia (3d – Recovered/Resolved –)	COMIRNATY [TOZINAMERAN] (S – COVID-19 immunisation – n/a – [n/a – .3mL – Intramuscular use])	Not
EU-EC-10013022112	18/07/2022	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 – [1d – n/a – n/a])	Not
EU-EC-10013022733	18/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	Yes	Axillary pain (n/a – Not Recovered/Not Resolved – Other Medically Important Condition), Dehydration (n/a – Unknown – Other Medically Important Condition), Pain (n/a – Unknown – Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S – COVID-19 immunisation – Not applicable – [1d – n/a – n/a])	Not
EU-EC-10013022815	18/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a – Recovered/Resolved –)	COMIRNATY [TOZINAMERAN] (S – n/a – n/a – [n/a – n/a – n/a])	Not
EU-EC-10013022816	18/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a – Recovered/Resolved –)	COMIRNATY [TOZINAMERAN] (S – n/a – n/a – [n/a – n/a – n/a])	Not
EU-EC-10013023177	18/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a – Not Recovered/Not Resolved –), Rash (n/a – Not Recovered/Not Resolved –)	COMIRNATY [TOZINAMERAN] (S – Immunisation – n/a – [n/a – n/a – n/a])	Not
EU-EC-10013023375	18/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (n/a – Not Recovered/Not Resolved –), Chest pain (n/a – Not Recovered/Not Resolved –), Costochondritis (n/a – Not Recovered/Not Resolved –), Lymphadenopathy (n/a – Not Recovered/Not Resolved –), Presyncope (n/a – Not Recovered/Not Resolved –), Swelling (n/a – Not Recovered/Not Resolved –), Syncope (n/a – Not Recovered/Not Resolved – Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S – COVID-19 immunisation – Not applicable – [1d – n/a – n/a])	Not
EU-EC-10013024373	18/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Product use issue (n/a – Unknown –), Seizure (n/a – Unknown – Other	COMIRNATY [TOZINAMERAN] (S – COVID-19 immunisation – Not applicable – [1d – n/a – n/a]), [A/CALIFORNIA/7/2009 (H1N1)]	Not

										Medically Important Condition), Syncope (n/a - Unknown - Other Medically Important Condition)	PDM09-LIKE STRAIN USED (NIB-74XP) DERIVED FROM A/CHRISTCHURCH/16/2010, B/PHUKET/3073/2013-LIKE STRAIN, A/SWITZERLAND/9715293/2013 (H3N2)-LIKE STRAIN (A/SWITZERLAND/9715293/2013, NIB-88), B/BRISBANE/60/2008, A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/TEXAS/50/2012, B/MASSACHUSETTS/02/2012, A/CALIFORNIA/7/2009 (H1N1) PDM09-LIKE STRAIN USED (NIB-74XP) DERIVED FROM A/CHRISTCHURCH/16/2010, B/BRISBANE/60/2008, B/MASSACHUSETTS/02/2012, A/CALIFORNIA/7/2009 (H1N1) PDM09-LIKE STRAIN USED (NIB-74XP) DERIVED FROM A/CHRISTCHURCH/16/2010, A/TEXAS/50/2012 (H3N2) - DERIVED STRAIN USED (NYMC X-223A), B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012 - DERIVED STRAIN USED (NYMC BX-51B), A/VICTORIA/361/2011 (H3N2)-LIKE STRAIN USED (NYMC X-223A) DERIVED FROM A/TEXAS/50/2012, A/CALIFORNIA/7/2009 (H1N1) PDM09-LIKE STRAIN USED (NIB-74XP) DERIVED FROM A/CHRISTCHURCH/16/2010, B/BRISBANE/60/2008-LIKE VIRUS, B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/GUANGDONG-MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE VIRUS (A/GUANGDONG-MAONAN/SWL1536/2019, CNIC-1909), B/WASHINGTON/02/2019 - LIKE VIRUS (B/WASHINGTON/02/2019, WILD TYPE), A/HONG KONG/2671/2019 (H3N2) - LIKE VIRUS (A/HONG KONG/2671/2019, NIB-121), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016, NIB-104), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/BRISBANE/60/2008-LIKE STRAIN (B/BRISBANE/60/2008, WILD TYPE), A/MICHIGAN/45/2015 (H1N1)PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B), B/PHUKET/3073/2013-LIKE VIRUS (B/PHUKET/3073/2013, WILD TYPE), B/COLORADO/06/2017-LIKE VIRUS (B/VICTORIA/2/87 LINEAGE) (B/MARYLAND/15/2016, NYMC BX-69A), A/BRISBANE/02/2018 (H1N1)PDM09-LIKE VIRUS (A/BRISBANE/02/2018, IVR-190), A/KANSAS/14/2017 (H3N2)-LIKE VIRUS (A/KANSAS/14/2017, NYMC X-327)) (S - n/a - Not applicable - [1d - n/a - n/a])	
EU-EC-10013025559	18/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Aneurysm (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Arthralgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Thrombosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10013025664	18/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disturbance in	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use])	Not

										attention (n/a - Not Recovered/Not Resolved -), General physical health deterioration (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Insomnia (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Parosmia (n/a - Recovered/Resolved -), Taste disorder (n/a - Not Recovered/Not Resolved -), Urticaria (n/a - Unknown -), Walking disability (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC-10013025750	18/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10013025794	18/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10013025853	18/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Decreased appetite (n/a - Recovering/Resolving -), Influenza like illness (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10013025913	18/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (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 use])	Not
EU-EC-10013025947	18/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10013025951	18/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Heavy menstrual bleeding (4wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10013025959	18/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10013026142	18/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d - .3mL - Intramuscular use])	Not
EU-EC-10013026325	18/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Recovered/Resolved -), Vertigo (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10013026399	18/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (n/a - Not Recovered/Not Resolved -), Rash macular (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10013026524	18/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Presyncope (15min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular use])	Not

EU-EC-10013027227	18/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10013028088	18/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Gastroesophageal reflux disease (n/a - Unknown - Caused/Prolonged Hospitalisation), Inappropriate schedule of product administration (n/a - Unknown - Caused/Prolonged Hospitalisation), Merycism (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10013028096	18/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (7d - Recovered/Resolved -), COVID-19 (n/a - Unknown - Other Medically Important Condition), Dizziness (7d - Recovered/Resolved -), Dyspnoea (7d - Recovered/Resolved -), Feeling cold (7d - Recovered/Resolved -), Headache (7d - Recovered/Resolved -), Oropharyngeal pain (7d - Recovered/Resolved -), Rhinorrhoea (7d - Recovered/Resolved -), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10013028103	18/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood iron decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Feeling abnormal (n/a - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Recovered/Resolved -), Serum ferritin decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Syncope (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10013028661	18/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Albumin globulin ratio decreased (n/a - Unknown -), Anxiety (n/a - Unknown -),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not

										<p>C-reactive protein increased (n/a - Unknown -),</p> <p>Complement factor C3 (n/a - Unknown -),</p> <p>Diarrhoea (n/a - Unknown -),</p> <p>Endoscopy abnormal (n/a - Unknown -),</p> <p>Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Fear of disease (n/a - Recovered/Resolved -),</p> <p>Flatulence (n/a - Unknown -),</p> <p>Frequent bowel movements (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Frequent bowel movements (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Gastrointestinal inflammation (n/a - Unknown -),</p> <p>Haematochezia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Hyponatraemia (n/a - Unknown -),</p> <p>Malnutrition (n/a - Recovered/Resolved -),</p> <p>Pyrexia (n/a - Unknown -),</p> <p>Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Weight decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)</p>		
EU-EC-10013028947	18/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	<p>COVID-19 (n/a - Unknown - Other Medically Important Condition),</p> <p>Vaccination failure (n/a - Unknown - Other Medically Important Condition)</p>	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10013029049	18/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	<p>Contusion (n/a - Unknown -),</p> <p>Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Platelet count decreased (n/a - Unknown - Other Medically Important Condition)</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[DE] n/a n/a]
EU-EC-10013029080	18/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not
EU-EC-	18/07/2022	Spontaneous	Non	Non	Not available	12-17	Not	Male	No	Lymphadenopathy	COMIRNATY [TOZINAMERAN] (S	Not

10013029859			Healthcare Professional	European Economic Area		Years	Specified			(n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	- COVID-19 immunisation - Not applicable - [1d - n/a - n/a]]	
EU-EC-10013019374	17/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hyperhidrosis (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vision blurred (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10013016978	16/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chills (1d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Pyrexia (1d - Recovered/Resolved -), Vaccination site lymphadenopathy (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not
EU-EC-10013005237	15/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Hsu, T.. Acute Genital Ulceration After Severe Acute Respiratory Syndrome Coronavirus 2 Vaccination and Infection, The Journal of Pediatrics, 2022;246:271-273. doi:10.1016/j.jpeds.2022.04.005	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), [COVID-19 VACCINE] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10013005543	15/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chills (n/a - Unknown -), Cough (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Incorrect route of product administration (n/a - Unknown -), Multisystem inflammatory syndrome in children (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Nausea (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pain (n/a - Unknown -), Pulmonary pain (n/a - Unknown -), Pyelonephritis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intravenous use])	Not
EU-EC-10013006225	15/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10013006453	15/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Unknown -), Anxiety (n/a - Unknown -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not

EU-EC-10013006744	15/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Chest pain (n/a - Unknown -), Asthenia (n/a - Recovered/Resolved -), Pyrexia (24h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10013006763	15/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Pruritus (n/a - Unknown -), Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10013007153	15/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Asthenia (n/a - Unknown -), Hypotension (n/a - Recovered/Resolved -), Lacrimation increased (n/a - Unknown -), Loss of consciousness (15s - Recovered/Resolved - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10013007449	15/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Depressed level of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not
EU-EC-10013007628	15/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Vaccination site erythema (n/a - Unknown -), Vaccination site swelling (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular use])	Not
EU-EC-10013007769	15/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10013008169	15/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (12d - Recovered/Resolved - Other Medically Important Condition), COVID-19 (12d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (12d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10013008853	15/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not
EU-EC-10013008899	15/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not
EU-EC-10013009096	15/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (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 - n/a])	Not

											Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Electrocardiogram abnormal (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved -)		
EU-EC-10013009116	15/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a])	Not	
EU-EC-10013009224	15/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Cough (n/a - Unknown -), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Encephalitis post immunisation (n/a - Fatal - Results in Death, Other Medically Important Condition), Malaise (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not	
EU-EC-10013009689	15/07/2022	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 - Immunisation - n/a - [n/a - n/a - n/a])	Not	
EU-EC-10013009703	15/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Unknown -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not	
EU-EC-10013010146	15/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Discomfort (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Dyspepsia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pericarditis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not	
EU-EC-10013010834	15/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Chronic fatigue syndrome (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not	
EU-EC-10013011089	15/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deafness neurosensory (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not	

											Important Condition), Tinnitus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition)		
EU-EC-10013014058	15/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood fibrinogen increased (n/a - Recovering/Resolving -), Blood glucose increased (n/a - Recovering/Resolving -), Dyspnoea (n/a - Recovering/Resolving -), Fibrin D dimer increased (n/a - Recovering/Resolving -), Heart rate increased (n/a - Recovering/Resolving -), Hyperpyrexia (2d - Recovering/Resolving - Other Medically Important Condition), Platelet count increased (n/a - Recovering/Resolving -), Respiratory rate increased (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not	
EU-EC-10013014084	15/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), Fibula fracture (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10013014851	15/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymph node pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lymphadenopathy (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10013015001	15/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Swelling (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not	
EU-EC-10013015047	15/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Alopecia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a])	Not	
EU-EC-10013015166	15/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Bell's palsy (1d - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use - More in ICSR])	Not	
EU-EC-10013015567	15/07/2022	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 - 1{DF} - n/a])	Not	
EU-EC-10012994679	14/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Insomnia (n/a - Recovered/Resolved - Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not	

										Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Movement disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vision blurred (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Visual impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)		
EU-EC-10012994753	14/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	[FLL PRO SALI FLU' PRO SALI XIN/ - n/ε [MO MO] (C - - n/ε
EU-EC-10012994800	14/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Dyspnoea (12h - Recovered/Resolved -), Headache (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012995778	14/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cystitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Haematuria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), IgA nephropathy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Proteinuria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012995830	14/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Altered state of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (19d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Cytotoxic lesions of corpus callosum (412h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Disorientation (414h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Encephalitis (412h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not

											Important Condition), Encephalopathy (414h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (19d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (19d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rhinorrhoea (19d - Recovered/Resolved - Caused/Prolonged Hospitalisation)		
EU-EC-10012996162	14/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not	
EU-EC-10012996111	14/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Dizziness (n/a - Unknown -), Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .6mL - Intramuscular use])	Not	
EU-EC-10012996701	14/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Thrombophlebitis (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not	
EU-EC-10012997107	14/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Arthralgia (n/a - Unknown -), Asthenia (n/a - Unknown -), Decreased appetite (n/a - Unknown -), Myalgia (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not	
EU-EC-10012997847	14/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Pyrexia (24h - Recovered/Resolved -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not	
EU-EC-10012998115	14/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown -), Throat irritation (n/a - Unknown -), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	COS (SEC Ank) n/a REM (C - n/a)	
EU-EC-10012998737	14/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Decreased appetite (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Insomnia (n/a - Unknown -), Peripheral swelling (n/a - Recovered/Resolved -), Sleep disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not	
EU-EC-10012999949	14/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not	
EU-EC-10013000415	14/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not	
EU-EC-10013000759	14/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Chest pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not	
EU-EC-10013001114	14/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), [SARS-COV-2, STRAIN HB02,	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]),	Not	

										Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Fibrin D dimer increased (n/a - Unknown -), Interchange of vaccine products (n/a - Fatal - Results in Death), Off label use (n/a - Fatal - Results in Death)	BETA-PROIOLACTONE INACTIVATED] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	
EU-EC-10013001169	14/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10013001170	14/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	CSF test abnormal (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Mental disorder (n/a - Unknown -), Nausea (n/a - Unknown -), Physical deconditioning (n/a - Unknown -), Visual acuity reduced (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Visual impairment (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10013001706	14/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cardiac discomfort (n/a - Unknown - Disabling, Other Medically Important Condition), Cardiomegaly (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Chest pain (n/a - Unknown - Disabling, Other Medically Important Condition), Chillblains (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Condition aggravated (n/a - Unknown - Disabling, Other Medically Important Condition), Cyanosis (n/a - Unknown - Disabling, Other Medically Important Condition), Discomfort (n/a - Unknown - Disabling, Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Dyspnoea (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Disabling, Other	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not

										Medically Important Condition), Malaise (n/a - Recovering/Resolving - Disabling, Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Poor peripheral circulation (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Postural orthostatic tachycardia syndrome (n/a - Unknown - Disabling, Other Medically Important Condition), Rales (n/a - Unknown - Disabling, Other Medically Important Condition), Raynaud's phenomenon (n/a - Unknown - Disabling, Other Medically Important Condition), Syncope (n/a - Unknown - Disabling, Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)		
EU-EC-10013002406	14/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling abnormal (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	[CE] DIH' Mult [n/a] [LOf Rhin [n/a] [MO FUR - n/i use] [SEF SER' HYD Anxi - [n]
EU-EC-10013002459	14/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthma (n/a - Not Recovered/Not Resolved -), Chest pain (n/a - Not Recovered/Not Resolved -), Costochondritis (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Presyncope (n/a - Not Recovered/Not Resolved -), Swelling (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Product used for unknown indication - Unknown - [n/a - 1{DF} - n/a]), SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX-024414)] (S - COVID-19 prophylaxis - Unknown - [n/a - 1{DF} - n/a])	Not
EU-EC-10013003063	14/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown -), Immune system disorder (52d - Recovered/Resolved With Sequelae -), Lymphadenopathy (52d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not

EU-EC-10013003158	14/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10013003285	14/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Incorrect route of product administration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Neuralgic amyotrophy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intraarticular use])	Not
EU-EC-10013003809	14/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Odynophagia (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not
EU-EC-10013004555	14/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Hsu, T.. Acute Genital Ulceration After Severe Acute Respiratory Syndrome Coronavirus 2 Vaccination and Infection. Journal of Pediatrics. 2022;246:271-273. doi:10.1016/j.jpeds.2022.04.005	12-17 Years	Not Specified	Female	No	Genital ulceration (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012984171	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Abdominal pain (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Pyrexia (24h - Recovered/Resolved -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012984736	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chest pain (0d - Recovered/Resolved -), Palpitations (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012984734	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012985071	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Blood pressure decreased (n/a - Recovered/Resolved -), Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012985270	13/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - Other Medically Important Condition), Asthenia (n/a - Unknown - Other Medically Important Condition), Hallucination (n/a - Unknown - Other Medically Important Condition), Hyperhidrosis (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Night sweats (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not

										Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - Other Medically Important Condition)		
EU-EC-10012985528	13/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012985551	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (48h - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012985744	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Auditory disorder (n/a - Recovered/Resolved -), Hypotonic-hyporesponsive episode (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Visual impairment (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012985968	13/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition), Anaphylactic shock (n/a - Recovered/Resolved - Other Medically Important Condition), Depressed level of consciousness (n/a - Unknown - Other Medically Important Condition), Hypopnoea (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved -), Respiratory rate increased (n/a - Recovered/Resolved -), Speech disorder (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10012986024	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	[FLL PRO SALI FLU' PRO SALI XIN - n/i [MO MO' (C - n/i]
EU-EC-10012986194	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Pyrexia (24h - Recovered/Resolved -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012986540	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Nipple swelling (3d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not

											Vaccination site pain (3d - Recovered/Resolved -)	applicable - [n/a - .3mL - Intramuscular use]	
EU-EC-10012987065	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not	
EU-EC-10012987203	13/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Asthenia (n/a - Not Recovered/Not Resolved -), Loss of personal independence in daily activities (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not	
EU-EC-10012987427	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Decreased appetite (9h - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	CELI [MY] MOF), [DR] SULI [n/a] [ME] (C - - Or [PAM] SESI n/a Oral [SUI] TRII - n/i [TAC] TACI MOI - n/i	
EU-EC-10012987727	13/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Skin disorder (30min - Recovered/Resolved -), Urticaria (30min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012988016	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Loss of consciousness (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 - .3mL - Intramuscular use])	Not	
EU-EC-10012988070	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not	
EU-EC-10012988350	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular use])	Not	
EU-EC-10012988644	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Asthenia (n/a - Not Recovered/Not Resolved -), Pruritus (n/a - Not Recovered/Not Resolved -), Rash morbilliform (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not	
EU-EC-10012989727	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not	
EU-EC-10012990115	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), Hypotonic-hyporesponsive episode (n/a - Unknown - Caused/Prolonged Hospitalisation), Presyncope (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not	

											Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC-10012990398	13/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Feeling hot (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012990414	13/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Physical deconditioning (n/a - Unknown -), Pyrexia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012992254	13/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -), Dyspnoea exertional (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Palpitations (n/a - Recovering/Resolving -), Pericardial effusion (n/a - Recovering/Resolving - Other Medically Important Condition), Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Troponin I increased (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not	
EU-EC-10012992268	13/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Unknown -), Myalgia (n/a - Unknown -), Respiratory tract congestion (n/a - Unknown -), Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	[CE] n/a [DIH] n/a [GU] n/a	
EU-EC-10012992728	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not	
EU-EC-10012992753	13/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not	

											Vomiting (n/a - Recovering/Resolving -)		
EU-EC-10012994053	13/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), Headache (4d - Recovered/Resolved -), Pyrexia (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012994105	13/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Productive cough (n/a - Not Recovered/Not Resolved -), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012971391	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Arthralgia (n/a - Recovering/Resolving -), Blood pressure decreased (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Presyncope (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not	
EU-EC-10012972378	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Epistaxis (n/a - Recovered/Resolved -), Hypoesthesia (n/a - Recovered/Resolved -), Vaccination site reaction (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not	
EU-EC-10012973028	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Hypoesthesia (n/a - Unknown -), Malaise (n/a - Unknown -), Palpitations (n/a - Unknown -), Pyrexia (72h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not	
EU-EC-10012973439	12/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012973604	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Lymph node pain (n/a - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a])	Not	

EU-EC-10012974194	12/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenopathy (n/a - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Myocarditis (1530min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myopericarditis (1530min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pericarditis (1530min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012974294	12/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Dysstasia (n/a - Unknown -), Eyelid ptosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Gait inability (n/a - Unknown -), Movement disorder (n/a - Unknown -), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation), Quality of life decreased (n/a - Unknown -), Visual impairment (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012974613	12/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10012974659	12/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Seizure (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not

EU-EC-10012975717	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Body temperature increased (1d - Recovered/Resolved -), Lymphadenitis (3d - Recovered/Resolved -), Lymphadenopathy (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012975860	12/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Somnolence (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012975861	12/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -), Myalgia (n/a - Unknown -), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012976248	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Headache (30min - Recovered/Resolved -), Hypoesthesia (30min - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012976714	12/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Immune system disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012976741	12/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012976795	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Erythema (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012976804	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Injection site erythema (n/a - Not Recovered/Not Resolved -), Product preparation error (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 use])	Not
EU-EC-10012976843	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Medication error (n/a - Unknown -), Wrong product administered (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012976983	12/07/2022	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), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012977605	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012978088	12/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Limb discomfort (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - n/a])	Not

											Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Presyncope (1d - Recovered/Resolved -)		
EU-EC-10012978426	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Expired product administered (n/a - Unknown -), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	[FLL PRO SALI FLU PRO SALI XIN/ - n/i [MO MOI (C - n/a	
EU-EC-10012978812	12/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not	
EU-EC-10012979843	12/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Loss of consciousness (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tunnel vision (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not	
EU-EC-10012979945	12/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Ageusia (2d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012980077	12/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Menstruation delayed (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular use])	Not	
EU-EC-10012980582	12/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not	
EU-EC-10012981348	12/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain lower (n/a - Unknown -), Vaginal haemorrhage (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not	
EU-EC-10012955413	11/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Ridolfi, A.. Lipshutz's acute vulvar ulceration and SARS-CoV-2: possible correlation?.. Swiss Medical Weekly, 2022;152 (SUPPL 258):275	12-17 Years	Not Specified	Female	No	Vulval ulceration (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-	11/07/2022	Spontaneous	Healthcare	European	Not available	12-17	Not	Female	No	Infectious	COMIRNATY [TOZINAMERAN] (S	Not	

10012957245			Professional	Economic Area		Years	Specified				mononucleosis (n/a - Unknown -)	- COVID-19 immunisation - Not applicable - [1d - n/a - n/a]]	
EU-EC-10012960133	11/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No		Pruritus (n/a - Unknown -), Rash morbilliform (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012961577	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No		Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	NOT n/a [IBL n/a]
EU-EC-10012961592	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Malaise (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not
EU-EC-10012961853	11/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Truong, D.. Clinically Suspected Myocarditis Temporarily Related to COVID-19 Vaccination in Adolescents and Young Adults. Circulation, 2021;10.1161/CIRCULATIONAHA.121.056583 doi:10.1161/CIRCULATIONAHA.121.056583 Truong, D.. Clinically Suspected Myocarditis Temporarily Related to COVID-19 Vaccination in Adolescents and Young Adults: Suspected Myocarditis After COVID-19 Vaccination.. Circulation, 2022;145(5):345-356, doi:10.1161/CIRCULATIONAHA.121.056583	12-17 Years	Not Specified	Male	No		Myocarditis (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012962228	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Burning sensation (n/a - Not Recovered/Not Resolved - Disabling), Pain in extremity (n/a - Not Recovered/Not Resolved - Disabling), Peripheral swelling (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012962738	11/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No		Vaccination site lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not
EU-EC-10012962831	11/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No		Asthenia (n/a - Unknown -), Dizziness (n/a - Unknown -), Malaise (n/a - Unknown -), Pyrexia (24h - Recovered/Resolved -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular use])	Not
EU-EC-10012963090	11/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No		Axillary pain (n/a - Unknown -), Lymph node pain (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 3mL - Intramuscular use])	Not
EU-EC-10012963137	11/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No		Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10012963515	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No		Dyspnoea (n/a - Recovering/Resolving -), Immunisation reaction (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012963588	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No		Abdominal pain (1wk - Recovered/Resolved -), Heavy menstrual bleeding (1wk - Recovered/Resolved -), Vomiting (1wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012963601	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No		Amenorrhoea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [365d - 1{DF} - Intramuscular use])	Not

EU-EC-10012963625	11/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pigmentation disorder (10d - Recovered/Resolved -), Urticaria (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012963680	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012963684	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012963685	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Pain (n/a - Recovered/Resolved With Sequelae -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012963689	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012963690	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012963691	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Immunisation reaction (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012964059	11/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Lymph node pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular use])	Not
EU-EC-10012964292	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anxiety (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012964400	11/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Not Recovered/Not Resolved -), Feeling hot (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012964414	11/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Electrocardiogram ST segment elevation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10012965095	11/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Asthenia (n/a - Recovered/Resolved -), Feeling hot (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not

EU-EC-10012965193	11/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012965303	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (1d - Recovering/Resolving -), Vomiting (1d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012965310	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Balance disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tremor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012965328	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ear pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Feeling cold (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pallor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012965331	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Diarrhoea (1d - Recovering/Resolving -), Dizziness (1d - Recovering/Resolving -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not

										Fatigue (2d - Recovering/Resolving -), Vomiting (1d - Recovering/Resolving -)		
EU-EC-10012965332	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Axonal and demyelinating polyneuropathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Dizziness (n/a - Unknown -), Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Headache (n/a - Not Recovered/Not Resolved -), Hypoesthesia (n/a - Not Recovered/Not Resolved -), Nerve injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tremor (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a])	Not
EU-EC-10012965444	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Headache (n/a - Recovering/Resolving - Disabling), Injection site movement impairment (n/a - Recovering/Resolving - Disabling), Injection site pain (n/a - Recovering/Resolving - Disabling), Myalgia (n/a - Recovering/Resolving - Disabling), Neck pain (n/a - Recovering/Resolving - Disabling), Pain in extremity (n/a - Recovering/Resolving - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012965466	11/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Truong, D.. Clinically Suspected Myocarditis Temporally Related to COVID-19 Vaccination in Adolescents and Young Adults. Circulation, 2021;doi:10.1161/CIRCULATIONAHA.121.056583 Truong, D.. Clinically Suspected Myocarditis Temporally Related to COVID-19 Vaccination in Adolescents and Young Adults: Suspected Myocarditis After COVID-19 Vaccination. Circulation, 2022;145:345-356. doi:10.1161/CIRCULATIONAHA.121.056583	12-17 Years	Not Specified	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition), Oedema due to cardiac disease (n/a - Unknown -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012966524	11/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Paparella, R.. Chilblain-like lesions onset during SARS-CoV-2 infection in a COVID-19-vaccinated adolescent: Case report and review of literature. Research Square. 2022;10.21203/rs.3.rs-1587115/v1. doi:10.21203/rs.3.rs-1587115/v1 Paparella, R.. Chilblain-like lesions onset during SARS-CoV-2 infection in a COVID-19-vaccinated adolescent: Case report and review of literature. Italian Journal of Pediatrics, 2022;48(93):10.1186/s13052-022-01296-5. doi:10.1186/s13052-022-01296-5 Paparella, R.. Chilblain-like lesions onset during SARS-CoV-2 infection in a COVID-19-vaccinated adolescent: Case report and review of literature. Italian Journal of Pediatrics, 2022;48(1):10.1186/s13052-022-01296-5. doi:10.1186/s13052-022-01296-5	12-17 Years	Not Specified	Male	No	Asymptomatic COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Gait disturbance (n/a - Unknown -), Pernio-like erythema (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not

											Condition),		
EU-EC-10012968364	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal pain upper (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Cough (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Dysphagia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Movement disorder (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not	
EU-EC-10012969502	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not	
EU-EC-10012970087	11/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dizziness (n/a - Not Recovered/Not Resolved -), Dysphagia (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Infection susceptibility increased (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a]), [DICLOXACILLIN] (S - Skin infection - Not applicable - [10d - 500mg - Oral use])	GAR PAP: 31 L ADS FOR PAR' YEA: (SAC CER 5 (S RDN PAP: 33 L ADS FOR PAR' YEA: (SAC CER 5 (S RDN PAP: 45 L ADS FOR PAR' YEA: (SAC CER 5 (S RDN PAP: 52 L ADS FOR PAR' YEA: (SAC CER 5 (S RDN PAP: 58 L ADS FOR PAR' YEA: (SAC CER 5 (S RDN PAP: 11 L ADS FOR PAR' YEA: (SAC CER 5 (S RDN PAP: 16 L ADS FOR PAR' YEA: (SAC CER 5 (S RDN PAP:	

													18 L ADS FOR PAR YEA (SAC CER 5 (S RDN PAP L1 P - IN VIRI PRO CELI CER 5 (S RDN ALU SULI papi imm - n/i
EU-EC-10012970189	11/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Inappropriate schedule of product administration (n/a - Unknown -), Tremor (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not	
EU-EC-10012949180	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular use])	Not	
EU-EC-10012949510	08/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown -), Haematemesis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Malaise (n/a - Fatal - Results in Death), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not	
EU-EC-10012949565	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Diarrhoea (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not	
EU-EC-10012949574	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Headache (n/a - Unknown -), Loss of consciousness (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 - .3mL - Intramuscular use])	Not	
EU-EC-10012949607	08/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Interstitial lung disease (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pneumomediastinum (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pneumothorax (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not	
EU-EC-10012950205	08/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	Yes	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Epistaxis (n/a - Not Recovered/Not Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	

											Headache (n/a - Not Recovered/Not Resolved -)		
EU-EC-10012950210	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012950234	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Body temperature abnormal (n/a - Unknown -), Decreased appetite (n/a - Unknown -), Dizziness (n/a - Unknown -), Eruetation (n/a - Unknown -), Insomnia (n/a - Unknown -), Myalgia (n/a - Unknown -), Nausea (n/a - Unknown -), Night sweats (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Spinal pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not	
EU-EC-10012951493	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Parotid gland enlargement (n/a - Recovering/Resolving - Other Medically Important Condition), Rash (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not	
EU-EC-10012951574	08/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Decreased activity (n/a - Unknown -), Dizziness exertional (n/a - Recovering/Resolving -), Educational problem (n/a - Unknown -), Fatigue (n/a - Recovering/Resolving -), General physical health deterioration (n/a - Unknown -), Headache (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	[PO AM CAL POT - n/i n/a]	
EU-EC-10012951820	08/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain in extremity (n/a - Unknown - Disabling), Vomiting (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012951982	08/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (1d - Recovered/Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Peripheral coldness (1d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012952149	08/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hyperthermia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	

											- Caused/Prolonged Hospitalisation)		
EU-EC-10012952288	08/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Cardiac arrest (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not	
EU-EC-10012952516	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (9mo - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not	
EU-EC-10012952576	08/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Chest pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not	
EU-EC-10012952630	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (3h - Recovered/Resolved -), Abdominal pain upper (3h - Recovered/Resolved -), Nausea (3h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not	
EU-EC-10012952856	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Chest discomfort (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Electrocardiogram abnormal (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Fatigue (n/a - Unknown -), Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), N-terminal prohormone brain natriuretic peptide increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pain in extremity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Troponin T increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	KAF ELE IVAC n/a KAL (C - - n/i	
EU-EC-10012953225	08/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site lymphadenopathy (6d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not	
EU-EC-10012953237	08/07/2022	Spontaneous	Non 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 use])	Not	
EU-EC-10012953673	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Skin reaction (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012953737	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site erythema (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012953911	08/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fibrin D dimer increased (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012937920	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lip swelling (n/a - Recovered/Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -), Peripheral swelling (n/a - Recovered/Resolved -), Pruritus (n/a - Not Recovered/Not Resolved -), Swollen tongue (n/a -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	

EU-EC-10012937983	07/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Recovering/Resolving -) Epiglottic oedema (n/a - Unknown - Other Medically Important Condition), Laryngeal oedema (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012938300	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hypersensitivity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash rubelliform (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Urticaria (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012938341	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site reaction (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012938427	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Asthenia (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Pyrexia (n/a - Unknown -), Vaccination site reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012938627	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Chest pain (n/a - Recovered/Resolved -), Troponin abnormal (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012939054	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Dizziness (n/a - Unknown -), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use - More in ICSR])	Not
EU-EC-10012939301	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Headache (7d - Recovered/Resolved -), Oropharyngeal pain (7d - Recovered/Resolved -), Pyrexia (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012940094	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Facial paresis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 30ug - n/a])	Not
EU-EC-10012940594	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Pyrexia (48h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012940609	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Presyncope (n/a - Unknown -), Pyrexia (24h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .5mL - Intramuscular use])	Not
EU-EC-10012940731	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure measurement (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), Hyperventilation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Loss of consciousness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not

											Important Condition), Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC-10012941203	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Extensive swelling of vaccinated limb (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012941279	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cold sweat (275d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (275d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (233d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (275d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Extrasystoles (275d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Fatigue (275d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Headache (275d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Malaise (275d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tachycardia (91d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tension headache (275d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tinnitus (275d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not	
EU-EC-10012941338	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not	

											Recovered/Not Resolved - Caused/Prolonged Hospitalisation)		
EU-EC-10012941557	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Infectious mononucleosis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not	
EU-EC-10012941588	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not	
EU-EC-10012941884	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Carpal tunnel syndrome (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not	
EU-EC-10012941944	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Hyperthyroidism (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942024	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Arthralgia (n/a - Unknown -), Back pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942031	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942080	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942125	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942126	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942130	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942131	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942132	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942133	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942135	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Myalgia (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942136	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942138	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (4d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942140	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [7d - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942142	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not	
EU-EC-10012942191	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (n/a - Recovered/Resolved -), Incorrect dose administered (1d - Recovered/Resolved -), Vaccination site oedema (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 4{DF} - Intramuscular use])	Not	
EU-EC-10012942300	07/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abnormal behaviour (n/a - Unknown -), Encephalitis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not	

											Hospitalisation, Other Medically Important Condition), Nausea (n/a - Recovered/Resolved With Sequelae -), Pyrexia (n/a - Recovered/Resolved With Sequelae -), Respiratory arrest (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC-10012942581	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (6d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not	
EU-EC-10012942586	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (32d - Recovered/Resolved -), Paraesthesia (32d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not	
EU-EC-10012942912	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Erythema (n/a - Unknown -), Incorrect route of product administration (n/a - Unknown -), Vaccination site pain (n/a - Unknown -), Vaccination site swelling (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012943077	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Administration site reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not	
EU-EC-10012943094	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Administration site reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not	
EU-EC-10012943299	07/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Hyperpyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012943300	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Administration site reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not	
EU-EC-10012943588	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Ear pain (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012943589	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Injection site erythema (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012943613	07/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Amenorrhoea (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012944168	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Nausea (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012944202	07/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Body temperature increased (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Pain in extremity (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[EX] GEN VER COM CUT, RUB FLO CUT EXTI ETH GEN ROC COM PRI CAL FLO GEN SAM VER	

																					VER FLO: PRI GAR VER SAM ROC COM PRI CAL' [n/a]
																					[MA' ACH L. H MAR POW HER POW LEA' n/a n/a]
EU-EC-10012944226	07/07/2022	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 - n/a - n/a])		Not								
EU-EC-10012944714	07/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Back pain (40040min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (1160min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (30d - Recovered/Resolved -), Myocarditis (40040min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (30d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		Not								
EU-EC-10012945856	07/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	Yes	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		[EPI n/a] [NO n/a n/a] [PAF Che: n/a]								
EU-EC-10012926814	06/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Altered state of consciousness (60min - Recovered/Resolved - Other Medically Important Condition), Balance disorder (60min - Recovered/Resolved -), Behaviour disorder (60min - Recovered/Resolved -), Headache (24h - Recovered/Resolved -), Memory impairment (60min - Recovered/Resolved -), Motor dysfunction (60min - Recovered/Resolved -), Somnolence (24h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])		Not								
EU-EC-10012927497	06/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lip swelling (n/a - Recovering/Resolving -), Urticaria (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])		Not								
EU-EC-10012927521	06/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Skin discolouration (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])		Not								
EU-EC-10012927533	06/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Uchiyama, Y.. Sibling cases of gross hematuria and newly diagnosed IgA nephropathy following SARS-CoV-2 vaccination. BMC Nephrology, 2022;23(1):216. doi:10.1186/s12882-022-02843-2	12-17 Years	Not Specified	Male	No	Haematuria (6d - Recovered/Resolved - Other Medically Important Condition), IgA nephropathy (n/a - Unknown - Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])		Not								

											Important Condition), Proteinuria (n/a - Not Recovered/Not Resolved -)	
EU-EC-10012927593	06/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Urticaria (2599h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012927824	06/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Tremor (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012928118	06/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Facial paralysis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012928266	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Colitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Crohn's disease (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a])	Not
EU-EC-10012928503	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Seizure (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Urinary incontinence (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Subcutaneous use])	Not
EU-EC-10012930269	06/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Vaccination site pain (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012931651	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vision blurred (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	[ME: n/a
EU-EC-10012931664	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012931876	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012931880	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (5d - Recovered/Resolved -), Insomnia (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012931885	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain (1d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012931887	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012931888	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012932116	06/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (n/a - Not Recovered/Not Resolved -), Paraesthesia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a])	Not
EU-EC-10012932249	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site swelling (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012932275	06/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012932277	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Axillary pain (n/a - Recovering/Resolving -), Pain in extremity	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not

										(n/a - Recovering/Resolving -), Swelling (n/a - Recovering/Resolving -)		
EU-EC-10012933293	06/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (2d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012915706	05/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10012916096	05/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (15min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012916114	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Petechiae (n/a - Unknown -), Thrombocytopenia (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012916803	05/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Jongvilaikasem, P. Minimal change disease and acute interstitial nephritis following SARS-CoV-2 BNT162b2 vaccination, Pediatric Nephrology, 2022;37(6):1419-1421. doi:10.1007/s00467-022-05470-z	12-17 Years	Not Specified	Male	No	Acute kidney injury (n/a - Recovering/Resolving - Other Medically Important Condition), Glomerulonephritis minimal lesion (n/a - Recovering/Resolving - Other Medically Important Condition), Hypertension (n/a - Unknown -), Nephrotic syndrome (n/a - Recovering/Resolving - Other Medically Important Condition), Oedema peripheral (n/a - Unknown -), Tubulointerstitial nephritis (n/a - Recovering/Resolving - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012916846	05/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10012917015	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Rash (n/a - Unknown -), Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012917459	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cough (2d - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pyrexia (n/a - Unknown -), Rhinorrhoea (n/a - Unknown -), Vaccination site reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012917516	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Unknown -), Somnolence (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012917538	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012917598	05/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Menstruation delayed (n/a - Unknown - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a]), IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (S - Premenstrual syndrome - Unknown - [n/a - n/a - n/a]), [IBUPROFEN, IBUPROFEN LYSINE, IBUPROFEN PH. EUR., IBUPROFEN SODIUM, IBUPROFEN SODIUM DIHYDRATE] (S - Product used for unknown indication - Unknown - [3d - n/a - n/a]), [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a])	Not

										Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)		
EU-EC-10012917692	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Hypoaesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Mononeuropathy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012917851	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Mycocarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Subcutaneous use])	Not
EU-EC-10012917984	05/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Hypotension (n/a - Unknown - Other Medically Important Condition), Illness (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012918199	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Not Recovered/Not Resolved -), Nausea (0d - Recovered/Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012918373	05/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Anxiety (n/a - Not Recovered/Not Resolved - Disabling), Chills (n/a - Not Recovered/Not Resolved - Disabling), Decreased appetite (n/a - Not Recovered/Not Resolved - Disabling), Dizziness (n/a - Not Recovered/Not Resolved - Disabling), Eye pain (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Headache (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not

										Recovered/Not Resolved - Disabling), Nausea (n/a - Not Recovered/Not Resolved - Disabling), Pain (n/a - Not Recovered/Not Resolved - Disabling), Pain in extremity (n/a - Not Recovered/Not Resolved - Disabling), Pyrexia (n/a - Not Recovered/Not Resolved - Disabling)		
EU-EC-10012918612	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012918688	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012918851	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Lymph node pain (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -), Swelling (n/a - Unknown -), Vaccination site reaction (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012919376	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Influenza (n/a - Not Recovered/Not Resolved -), Insomnia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012919790	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not
EU-EC-10012920255	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Anxiety (n/a - Recovered/Resolved -), Dizziness (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Vaccination site reaction (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012920522	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Pain in extremity (n/a - Unknown -), Peripheral swelling (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intraocular use])	Not
EU-EC-10012920713	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Malaise (n/a - Recovering/Resolving - Other Medically Important Condition), Tonic clonic movements (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012920722	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Fatigue (48d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypersomnia (48d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012920975	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Bronchitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012920986	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Bronchitis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not

EU-EC-10012921040	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Palpitations (n/a - Recovering/Resolved -), Tremor (n/a - Recovering/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012921163	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Oligomenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012921174	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012921213	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -), Dysmenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012921266	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012921802	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Bell's palsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), Dysaesthesia (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Muscle spasms (n/a - Recovered/Resolved -), Musculoskeletal chest pain (n/a - Recovered/Resolved -), Myalgia intercostal (n/a - Recovered/Resolved -), Off label use (n/a - Unknown -), Product use issue (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012921822	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (2d - Recovered/Resolved -), Dry throat (n/a - Unknown -), Fatigue (6d - Recovered/Resolved -), Headache (1wk - Recovered/Resolved -), Nasal dryness (n/a - Unknown -), Nausea (6d - Recovered/Resolved -), Pain in extremity (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012921862	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Illness (n/a - Unknown -), Pyrexia (n/a - Unknown -), Somnolence (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012922403	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Vaccination site urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012922417	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Cardiovascular disorder (n/a - Unknown -), Dizziness (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not

											Pyrexia (n/a - Unknown -)		
EU-EC-10012922419	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Vaccination site pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012922446	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Alopecia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012922491	05/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Unknown -), Chest discomfort (n/a - Unknown -), Chest pain (n/a - Recovered/Resolved -), Dyspnoea (n/a - Unknown -), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not	
EU-EC-10012922972	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovered/Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012922984	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hypersensitivity (n/a - Recovered/Resolved -), Urticaria (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012922993	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Diarrhoea (n/a - Unknown -), Headache (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Vomiting (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012923005	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash pruritic (n/a - Recovered/Resolved -), Urticaria (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012923027	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	Yes	Epistaxis (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012923220	05/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Alopecia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dry mouth (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dry skin (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Joint range of motion decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Myositis (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not	

											Caused/Prolonged Hospitalisation), Pain in jaw (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Rash (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Raynaud's phenomenon (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)		
EU-EC-10012924264	05/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not	
EU-EC-10012902547	04/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Gastric infection (n/a - Not Recovered/Not Resolved -), Gastritis (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved -)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012903310	04/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Headache (2d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012903505	04/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Dyspnoea (n/a - Not Recovered/Not Resolved - Disabling), Educational problem (n/a - Unknown -), Fatigue (n/a - Recovering/Resolving - Disabling), Headache (n/a - Not Recovered/Not Resolved - Disabling), Impaired quality of life (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not	
EU-EC-10012903921	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Headache (n/a - Unknown -), Myalgia (n/a - Unknown -), Pyrexia (72h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not	
EU-EC-10012904095	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not	
EU-EC-10012904257	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Myocarditis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not	
EU-EC-10012904300	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epistaxis (3d - Recovered/Resolved -), Pain in extremity (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3{DF} - n/a])	Not	
EU-EC-10012906041	04/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Arthralgia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Myalgia (n/a - Fatal -	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not	

										Results in Death, Caused/Prolonged Hospitalisation), Pyrexia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Vomiting (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)		
EU-EC-10012907687	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Autoimmune thyroiditis (n/a - Not Recovered/Not Resolved -), Goitre (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012908232	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Lymphadenitis (0d - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012908488	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012908745	04/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	Not
EU-EC-10012909713	04/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (n/a - Unknown -), Fall (n/a - Unknown -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012909781	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012909858	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dyspnoea (5d - Recovered/Resolved -), Headache (5d - Recovered/Resolved -), Pain in extremity (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012910210	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012910544	04/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (3d - Recovered/Resolved -), Heavy menstrual bleeding (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012910610	04/07/2022	Spontaneous	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 - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012910630	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Urticaria (5d - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012910632	04/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Recovering/Resolving	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not	Not

			Professional	Area							-)	applicable - [1d - 1{DF} - Intramuscular use]	
EU-EC-10012910730	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Menstrual disorder (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not	
EU-EC-10012910912	04/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Cough (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not	
EU-EC-10012910913	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angioedema (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not	
EU-EC-10012911041	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Asthenia (n/a - Unknown -), Depressed mood (n/a - Unknown -), Palpitations (n/a - Unknown -), Tachycardia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not	
EU-EC-10012911535	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not	
EU-EC-10012912169	04/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Death (n/a - Fatal - Results in Death)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012912642	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Epilepsy (n/a - Unknown - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not	
EU-EC-10012913002	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (5d - Recovered/Resolved -), Burning sensation (4d - Recovered/Resolved -), Chest discomfort (n/a - Recovering/Resolving -), Chills (5d - Recovered/Resolved -), Eczema (2wk - Recovered/Resolved -), Erythema (1d - Recovered/Resolved -), Erythema (2wk - Recovered/Resolved -), Hypersensitivity (2wk - Recovered/Resolved -), Peripheral swelling (2wk - Recovered/Resolved -), Pruritus (4d - Recovered/Resolved -), Pyrexia (5d - Recovered/Resolved -), Swelling face (2wk - Recovered/Resolved -), Urticaria (2wk - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - .3mL - n/a])	Not	
EU-EC-10012913091	04/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition), Chest pain (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Recovered/Resolved - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	

										Palpitations (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)		
EU-EC-10012913204	04/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Asthenia (n/a - Unknown -), Disturbance in attention (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012913296	04/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (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
EU-EC-10012913528	04/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012913929	04/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	Yes	Anuria (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Compartment syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Enterovirus infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Fatigue (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypertrophy (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -), Malaise (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[EPI n/a] [NO n/a n/a] [PAF Che: n/a]

										<p>Multi-organ disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Myocardial ischaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Myocarditis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Pulseless electrical activity (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Renal failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Rhinovirus infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),</p> <p>Ventricular tachycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)</p>		
EU-EC-10012914351	04/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	<p>Chest discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Cold sweat (n/a - Unknown - Other Medically Important Condition),</p> <p>Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Dizziness (n/a - Unknown - Other Medically Important Condition),</p> <p>Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Fatigue (n/a - Unknown - Other Medically Important Condition),</p> <p>Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),</p> <p>Inappropriate</p>	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CHI MAL [3d

										schedule of product administration (n/a - Unknown - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition)		
EU-EC-10012914560	04/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Vaccination site inflammation (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not
EU-EC-10012914632	04/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Unknown - Other Medically Important Condition), Overdose (n/a - Unknown - Other Medically Important Condition), Product preparation error (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - n/a])	Not
EU-EC-10012902089	03/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Deep vein thrombosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])	Not
EU-EC-10012902276	03/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), Rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	[TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a])	[BEC DIP - n/i [FLL PRO Hyp [n/a [LEV Hyp [n/a [PHI PHI (225 PRA PHI POL TIM EXTI Hyp [n/a [TO; - n/i
EU-EC-10012892863	01/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Alopecia areata (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012893261	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	Vaccination site erythema (n/a - Not Recovered/Not Resolved -), Vaccination site induration (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -), Vaccination site pruritus (n/a - Not Recovered/Not Resolved -), Vaccination site warmth (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012893742	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Lymphadenopathy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vaccination site joint movement impairment (n/a -	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not

										Recovered/Resolved - Caused/Prolonged Hospitalisation)		
EU-EC-10012893854	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Hypotonic-hyporesponsive episode (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012893952	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012894026	01/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (3d - Recovered/Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012894425	01/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Upper gastrointestinal haemorrhage (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10012894982	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pyrexia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012895273	01/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10012895284	01/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (2h - Recovered/Resolved -), Loss of consciousness (10min - Recovered/Resolved - Other Medically Important Condition), Myalgia (4h - Recovered/Resolved -), Nausea (4h - Recovered/Resolved -), Vomiting (4h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10012895743	01/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Blood pressure decreased (0d - Recovered/Resolved -), Heart rate decreased (n/a - Recovered/Resolved -), Pallor (n/a - Recovered/Resolved -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012896349	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Facial paresis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012896394	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Gastritis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Migraine (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3{DF} - n/a])	Not
EU-EC-10012897104	01/07/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved - Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[INS HUM Unkn n/a]

EU-EC-10012897972	01/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	Yes	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012897982	01/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Fatigue (n/a - Unknown -), Feeling abnormal (n/a - Unknown -), Headache (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Pruritus (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012898065	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Freise, N.. Acute cardiac side effects after COVID-19 mRNA vaccination: a case series. European Journal of Medical Research. 2022;27(1):10.1186/s40001-022-00695-y, doi:10.1186/s40001-022-00695-y	12-17 Years	Not Specified	Female	No	Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012898453	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	Yes	Polyarthritits (7d - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .3mL - Intramuscular use])	Not
EU-EC-10012898696	01/07/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved -), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012904359	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Freise, N.. Acute cardiac side effects after COVID-19 mRNA vaccination: a case series. European Journal of Medical Research. 2022;27(1):10.1186/s40001-022-00695-y, doi:10.1186/s40001-022-00695-y	12-17 Years	Not Specified	Male	No	Chest pain (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myocarditis (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pneumonia mycoplasmal (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012905875	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dermatitis atopic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012905958	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Henoch-Schonlein purpura (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012906672	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Labyrinthitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012906771	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Haemophagocytic lymphohistiocytosis (30d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012906999	01/07/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])	Not
EU-EC-10012907186	01/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Syncope (31min - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10012907440	01/07/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Dizziness (64min - Recovered/Resolved -), Syncope (64min - Recovered/Resolved	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not

EU-EC-10012881486	30/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	- Other Medically Important Condition) COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012881845	30/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use])	Not
EU-EC-10012882458	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Application site pain (n/a - Not Recovered/Not Resolved -), Application site warmth (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012882918	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tinnitus (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a])	Not
EU-EC-10012884961	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Non-Hodgkin's lymphoma (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not
EU-EC-10012885880	30/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Dawoud, N.. The first case report of Pityriasis lichenoides chronica following COVID-19 mRNA vaccination. Dermatologic Therapy, 2022;35(6):10.1111/dth.15445. doi:10.1111/dth.15445	12-17 Years	Not Specified	Male	No	Disease progression (n/a - Recovered/Resolved - Other Medically Important Condition), Parapsoriasis (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012886123	30/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Immune thrombocytopenia (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10012886326	30/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10012886331	30/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])	Not
EU-EC-10012886557	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Chills (10h - Recovered/Resolved -), Heart rate increased (10h - Recovered/Resolved -), Oxygen saturation decreased (10h - Recovered/Resolved -), Pyrexia (10h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012886778	30/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Abdominal pain (n/a - Recovered/Resolved -), Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition), Chills (n/a - Recovered/Resolved -), Confusional state (n/a - Recovered/Resolved - Other Medically Important Condition), Decreased appetite (n/a - Recovered/Resolved -), Diarrhoea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])	Not

											Headache (n/a - Recovered/Resolved -), Myocarditis (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved -), Vertigo (n/a - Recovered/Resolved -)		
EU-EC-10012887009	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Parosmia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012887066	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Abdominal pain upper (n/a - Not Recovered/Not Resolved -), Cough (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012887542	30/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012887760	30/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccine breakthrough infection (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012887848	30/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Rash (90min - Recovered/Resolved - Other Medically Important Condition), Rash erythematous (90min - Recovered/Resolved - Other Medically Important Condition), Rash pruritic (90min - Recovered/Resolved - Other Medically Important Condition), Urticaria (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012887968	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Malaise (n/a - Unknown -), Product quality issue (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012888885	30/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not	
EU-EC-10012888929	30/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Ecchymosis (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [36d - 2{DF} - n/a])	Not	

										Caused/Prolonged Hospitalisation), Paresis (n/a - Unknown - Caused/Prolonged Hospitalisation)		
EU-EC-1001288988	30/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition), Circulatory collapse (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), Tachycardia (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use])	Not
EU-EC-10012889233	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Tinnitus (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not
EU-EC-10012889234	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (5d - Recovered/Resolved -), Vaccination site pain (7d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not
EU-EC-10012889235	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not
EU-EC-10012889236	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Pain (2d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not
EU-EC-10012889238	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not
EU-EC-10012889239	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not
EU-EC-10012889240	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Vaccination site pain (1d - Recovered/Resolved -), Vaccination site swelling (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not
EU-EC-10012889246	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain (1d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not
EU-EC-10012889247	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -), Skin reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not
EU-EC-10012889248	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Pain (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not
EU-EC-10012889249	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Myalgia (1d - Recovered/Resolved -),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not

										Pain (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)		
EU-EC-10012889267	30/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Rash (3d - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012889290	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Adnexa uteri pain (n/a - Recovering/Resolving -), Menstruation delayed (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not
EU-EC-10012889298	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Anaemia (n/a - Not Recovered/Not Resolved -), Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not
EU-EC-10012889325	30/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Menometrorrhagia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [25d - 12{DF} - n/a])	Not
EU-EC-10012889333	30/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dysmenorrhoea (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])	Not
EU-EC-10012889423	30/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Dawoud, N.. The first case report of Pityriasis lichenoides chronica following COVID-19 mRNA vaccination. Dermatologic Therapy, 2022;35(6):10.1111/dth.15445. doi:10.1111/dth.15445	12-17 Years	Not Specified	Male	No	Parapsoriasis (n/a - Recovered/Resolved - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012889820	30/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012891632	30/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Aoki, K.. A Case of Childhood Idiopathic Thoracic Spinal Epidural Haematoma After COVID-19 Vaccination. The 37th Annual Meeting of the Neurospinal Society of Japan. 2022;37th:299	12-17 Years	Not Specified	Female	No	Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Extradural haematoma (14d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), Movement disorder (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Paraplegia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Sensory disturbance (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Spinal epidural haematoma (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	[CE] DJH Rhin Oral
EU-EC-10012869721	29/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Depressed level of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not

											Pyrexia (n/a - Unknown -), Seizure (0d - Recovered/Resolved - Other Medically Important Condition)		
EU-EC-10012870159	29/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Back pain (n/a - Recovered/Resolved -), Body temperature increased (1d - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Headache (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not	
EU-EC-10012870780	29/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Hiccups (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	
EU-EC-10012871064	29/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Antinuclear antibody positive (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Antisynthetase syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), Juvenile polymyositis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 2{DF} - n/a - More in ICSR])	Not	
EU-EC-10012871505	29/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not	
EU-EC-10012871851	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Unknown -), Chills (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Ecchymosis (n/a - Unknown -), Fatigue (n/a - Unknown -), Fibrin D dimer increased (n/a - Unknown -), Headache (n/a - Unknown -), Herpes zoster (n/a - Unknown -), Infectious mononucleosis (n/a - Unknown -), Injection site reaction (n/a - Unknown -), Lymphocyte count (n/a - Unknown -), Myalgia (n/a - Unknown -), Pyrexia (n/a - Unknown -), Skin disorder (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012871914	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest discomfort (n/a - Recovered/Resolved -), Chest pain (n/a - Recovered/Resolved -), Sleep disorder due to general medical condition, insomnia type (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012871933	29/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Back pain (n/a - Recovering/Resolving - Other Medically Important	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	

										Condition), Blood creatine phosphokinase increased (n/a - Unknown -), Bradycardia (n/a - Unknown - Other Medically Important Condition), Chest discomfort (n/a - Unknown -), Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Malaise (n/a - Unknown -), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC-10012872100	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncopal (Od - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012872194	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Herpes zoster (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not
EU-EC-10012872574	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Swelling of eyelid (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not
EU-EC-10012872579	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Dry skin (n/a - Not Recovered/Not Resolved -), Facial pain (n/a - Not Recovered/Not Resolved -), Malaise (2s - Recovered/Resolved -), Myalgia (n/a - Recovered/Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Swelling face (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not
EU-EC-10012872745	29/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Axillary pain (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vaccination site erythema (n/a - Recovered/Resolved -), Vaccination site oedema (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - .3mL - Intramuscular])	Not
EU-EC-10012872917	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	[LEV LEV1 SOD Hyp n/a]
EU-EC-10012873191	29/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Pain in extremity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])	Not
EU-EC-10012874857	29/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition),	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not

											Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition)		
EU-EC-10012875345	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Insomnia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not	
EU-EC-10012875347	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])	Not	
EU-EC-10012875358	29/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Abdominal pain (n/a - Recovering/Resolving - Other Medically Important Condition), Arthralgia (n/a - Recovering/Resolving - Other Medically Important Condition), Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[CR] - [n] [D-A n/a n/a]	
EU-EC-10012875774	29/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Dawoud, N.. The first case report of Pityriasis lichenoides chronica following COVID-19 mRNA vaccination. Dermatologic Therapy. 2022;35(6):10.1111/dth.15445. doi:10.1111/dth.15445	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not	
EU-EC-10012876791	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Arthralgia (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not	
EU-EC-10012877021	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Headache (1d - Recovered/Resolved -), Loss of consciousness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tonic convulsion (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tremor (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not	
EU-EC-10012877297	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (5d - Recovered/Resolved -), Polymenorrhoea (n/a - Not Recovered/Not Resolved -), Vomiting (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular])	Not	
EU-EC-10012877314	29/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Abdominal pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not	
EU-EC-10012877319	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Back pain (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not	

										Recovered/Not Resolved -), Migraine (n/a - Not Recovered/Not Resolved -)		
EU-EC-10012877321	29/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adult	Female	No	Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not
EU-EC-10012877323	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not
EU-EC-10012877327	29/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Female	No	Blister (n/a - Recovering/Resolving -), Papule (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not
EU-EC-10012877330	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (n/a - Not Recovered/Not Resolved -), Insomnia (n/a - Not Recovered/Not Resolved -), Skin reaction (3d - Recovered/Resolved -), Somnolence (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not
EU-EC-10012877331	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Immunisation reaction (3d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not
EU-EC-10012877332	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Immunisation reaction (5d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not
EU-EC-10012877335	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Myalgia (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not
EU-EC-10012877336	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Pain (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not
EU-EC-10012877337	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Diarrhoea (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not
EU-EC-10012877338	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (2d - Recovered/Resolved -), Somnolence (1h - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not
EU-EC-10012877341	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Immunisation reaction (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not
EU-EC-10012877346	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Myalgia (2d - Recovered/Resolved -), Pain (1d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not
EU-EC-10012877347	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Influenza like illness (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not
EU-EC-10012877368	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Influenza like illness (n/a - Recovered/Resolved -), Pain (n/a - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not
EU-EC-10012877920	29/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-	29/06/2022	Spontaneous	Healthcare	Non	Not available	12-17	Not	Female	No	Facial paralysis (n/a -)	COMIRNATY [TOZINAMERAN] (S	Not

10012877947			Professional	European Economic Area		Years	Specified			Recovered/Resolved - Other Medically Important Condition), Pericarditis (n/a - Recovered/Resolved - Other Medically Important Condition)	- COVID-19 immunisation - Not applicable - [1d - n/a - n/a]	
EU-EC-10012878312	29/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Myalgia (n/a - Not Recovered/Not Resolved -), Vaccination site lymphadenopathy (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a])	Not
EU-EC-10012878357	29/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Abdominal discomfort (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), Electrocardiogram abnormal (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a])	Not
EU-EC-10012879070	29/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Angina pectoris (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Cough (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Drug eruption (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Ejection fraction decreased (n/a - Recovered/Resolved - Life Threatening), Electrocardiogram abnormal (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Inflammatory marker increased (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocardial necrosis marker increased (n/a - Recovered/Resolved - Life Threatening), Myocarditis (n/a - Recovered/Resolved - Life Threatening), Oropharyngeal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pharyngitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash maculo-papular (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular])	Not
EU-EC-10012879320	29/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Acute disseminated encephalomyelitis (34d - Recovered/Resolved - Caused/Prolonged Hospitalisation),	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not

										Other Medically Important Condition), Dysaesthesia (34d - Recovered/Resolved -), Gait disturbance (34d - Recovered/Resolved -), Incontinence (34d - Recovered/Resolved -), Muscular weakness (28d - Recovered/Resolved -)		
EU-EC-10012857228	28/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Ageusia (n/a - Recovering/Resolving -), Anosmia (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [DIPHThERIA TOXOID, TETANUS TOXOID, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALGELDRATE, DIPHThERIA TOXOID, TETANUS TOXOID, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN), POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN), POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN), DIPHThERIA TOXOID, TETANUS TOXOID, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALGELDRATE, FILAMENTOUS HAEMAGGLUTININ, DIPHThERIA TOXOID, TETANUS TOXOID, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN), POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN), POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN), ALUMINIUM HYDROXIDE, FILAMENTOUS HAEMAGGLUTININ, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, DIPHThERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALGELDRATE, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, PERTUSSIS PERTACTIN	Not

											<p>ADSORBED ON ALUMINIUM HYDROXIDE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ADSORBED ON ALUMINIUM HYDROXIDE, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALUMINIUM HYDROXIDE, HAEMOPHILUS TYPE B CONJUGATE VACCINE (TETANUS TOXOID CONJUGATE), POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN), PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, PERTUSSIS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, TETANUS TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN), PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, ALGELDRATE] (S - Prophylaxis - Unknown - [n/a - n/a - n/a]),</p> <p>[INFLUENZA VIRUS] (S - Prophylaxis - Not applicable - [1d - n/a - n/a])</p>	
EU-EC-10012857295	28/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	<p>Abdominal pain (n/a - Unknown -),</p> <p>Diarrhoea (n/a - Unknown -),</p> <p>Dysarthria (n/a - Unknown -),</p> <p>Foaming at mouth (n/a - Unknown -),</p> <p>Hyperhidrosis (n/a - Unknown -),</p> <p>Hypoaesthesia (n/a - Unknown -),</p> <p>Loss of consciousness (n/a - Unknown - Other Medically Important Condition),</p> <p>Respiratory rate increased (n/a - Unknown -),</p> <p>Seizure (n/a - Unknown - Other Medically Important Condition),</p> <p>Vomiting (n/a - Unknown -)</p>	<p>COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular])</p>	Not
EU-EC-10012857900	28/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Not Specified	No	<p>Abdominal pain upper (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),</p> <p>Somnolence (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation),</p> <p>Tachycardia (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation),</p> <p>Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)</p>	<p>COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular])</p>	Not
EU-EC-10012857957	28/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	<p>Chest pain (n/a - Unknown - Other Medically Important Condition),</p> <p>Chills (n/a - Unknown -),</p> <p>Myocarditis (n/a - Unknown - Other Medically Important Condition),</p> <p>Pyrexia (n/a -</p>	<p>COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular])</p>	Not

										Unknown -), Tachycardia (n/a - Unknown - Other Medically Important Condition), Troponin I increased (n/a - Unknown - Other Medically Important Condition)		
EU-EC-10012858078	28/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Chest pain (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - n/a - Intramuscular])	Not
EU-EC-10012858357	28/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dizziness (n/a - Unknown -), Pallor (n/a - Unknown -), Syncope (2d - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular])	Not
EU-EC-10012858409	28/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Headache (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypoaesthesia (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Speech disorder (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tunnel vision (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular])	Not
EU-EC-10012858578	28/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Pyrexia (1d - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a - .3mL - Intramuscular])	Not
EU-EC-10012858778	28/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Condition aggravated (n/a - Unknown - Disabling, Other Medically Important Condition), Hiccups (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Loss of personal independence in daily activities (n/a - Unknown - Disabling, Other Medically Important Condition), Pain (n/a - Unknown - Disabling, Other Medically Important Condition), Quality of life decreased (n/a - Unknown - Disabling, Other Medically Important Condition), Sleep disorder (n/a - Unknown - Disabling, Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not
EU-EC-10012858783	28/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Female	No	Collagen disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Poor peripheral circulation (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Raynaud's phenomenon (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012858920	28/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Meningitis aseptic (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	REL [FLL VIL] n/a [SAL SALI (C - - n/i
EU-EC-	28/06/2022	Spontaneous	Healthcare	European	Not available	12-17	Adolescent	Female	No	Amenorrhoea (n/a -	COMIRNATY [TOZINAMERAN] (S	Not

10012858978			Professional	Economic Area		Years				Recovered/Resolved - Other Medically Important Condition)	- COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	
EU-EC-10012859131	28/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Child	Male	No	Immunisation reaction (2d - Recovered/Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular])	Not
EU-EC-10012859206	28/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Rash (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not
EU-EC-10012859235	28/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Amenorrhoea (n/a - Not Recovered/Not Resolved -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular])	Not
EU-EC-10012859301	28/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Aphonia (n/a - Unknown -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not
EU-EC-10012859697	28/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Syncope (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a])	Not
EU-EC-10012859930	28/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Female	Yes	COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012859937	28/06/2022	Spontaneous	Non Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])	Not
EU-EC-10012861032	28/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Arthralgia (n/a - Recovering/Resolving -), Chest pain (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Injection site reaction (n/a - Recovering/Resolving -), Lymphadenopathy (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Oropharyngeal pain (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	[LAI - Un n/a]
EU-EC-10012861113	28/06/2022	Spontaneous	Healthcare Professional	Non European Economic Area	Not available	12-17 Years	Not Specified	Male	No	Dengue fever (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular])	Not
EU-EC-10012861230	28/06/2022	Spontaneous	Non Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Seborrhoeic dermatitis (21d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Type 1 diabetes mellitus (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Vaccination site reaction (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a])	Not
EU-EC-10012862234	28/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Spasiano, A., A RARE CASE OF SECONDARY HAEMOLYTIC UREMIC SYNDROME AFTER ANTI-SARS-COV-2 VACCINATION, Nephrology Dialysis Transplantation, 2022;37 (SUPPL 3):i130-i131. doi:10.1093/ndt/gfac066.096	12-17 Years	Not Specified	Female	No	Haemolytic uraemic syndrome (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically	TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])	Not

										Important Condition), Vitamin B12 deficiency (n/a - Unknown - Life Threatening Caused/Prolonged Hospitalisation, Other Medically Important Condition)		
EU-EC-10012862767	28/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Female	No	Affective disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Sinus tachycardia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular])	Not
EU-EC-10012862838	28/06/2022	Spontaneous	Healthcare Professional	European Economic Area	Not available	12-17 Years	Adolescent	Male	No	Lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition)	COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular])	Not

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