Line Listing Report Time run: 30/11/2022 15:16:33

| 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]) | C: A: (II |
|-----------------------|----------------------------------|-------------|------------------------------------|---|----------------------|-------------------------|--|----------------|--|---|--|-----------|
| EU-EC- 10013021610 | 18/07/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | | Not Specified | Male | No | Pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | N |
| | | | | | | | | | | Swelling (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Vaccination site pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 0013021693 | 18/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | | Not Specified | Female | No | Headache (2d - Recovered/Resolved -), Pain in extremity (2d | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use]) | |
| EU-EC- | 19/07/2022 | Spontaneous | Non | European | Not available | 12-17 | Not | Male | No | Recovered/Resolved -) Hypersensitivity (n/a | COMIRNATY [TOZINAMERAN] (S | N |
| 10013021850 | 10/07/2022 | Spontaneous | Healthcare Professional | Economic Area | Nut available | | Specified | inaje | NO | - Not Recovered/Not Resolved -), Lymphadenopathy | - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular use]) | . |
| | | | | | | | | | | (10d - Recovered/Resolved -), Nasopharyngitis (n/a | | |
| | | | | | | | | | | - Not Recovered/Not Resolved -), Pyrexia (3d - | | |
| EU-EC- 10013022112 | 18/07/2022 | Spontaneous | | Non European | Not available | | Not Specified | Male | No | Recovered/Resolved -) Pericarditis (n/a - Unknown - Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | i N |
| | | | | Economic Area | | | | | | Medically Important Condition) | applicable - [1d - n/a - n/a]) | _ |
| EU-EC- 10013022733 | 18/07/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | | Not Specified | Male | Yes | Axillary pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | i N |
| | | | | | | | | | Dehydration (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Unknown | | | |
| | | | | | | | | | | - Other Medically Important Condition) | | _ |
| EU-EC- 10013022815 | 18/07/2022 | Spontaneous | Non Healthcare Professional | Economic | 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]) | N |
| 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]) | N |
| EU-EC- 10013023177 | 18/07/2022 | Spontaneous | Healthcare | European Economic Area | Not available | | Not Specified | Male | No | Fatigue (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Rash (n/a - Not Recovered/Not Resolved -) | | |
| EU-EC- 10013023375 | 18/07/2022 | Spontaneous | | Non European Economic Area | Not available | | Not Specified | Male | No | Asthma (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | N |
| | | | | Alea | | | | | | 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 | | |
| EU-EC- | | Spontaneous | | Non | Not available | 12-17 | Not | Female | No | Condition) Product use issue | COMIRNATY [TOZINAMERAN] (S | N |

| | | | | | | | | | | | PDM09-LIKE STRAIN USED (NIB- |
|-----------|------------|-------------|--------------|------------------|----------------|-------|--------------|------|----|---|--|
| | | | | | | | | | | Condition), | 74XP) DERIVED FROM A/CHRISTCHURCH/16/2010, |
| | | | | | | | | | | Syncope (n/a - Unknown - Other | B/PHUKET/3073/2013-LIKE STRAIN, |
| | | | | | | | | | | Medically Important Condition) | 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) |
| | | | | | | | | | | | 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 |
| | | | | | | | | | | | - LIKÉ VIRUS (B/WASHINGTON/02/2019, WILI |
| | | | | | | | | | | | TYPE), A/HONG KONG/2671/201 (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 |
| -EC- | 18/07/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | ' Adolescent | Male | No | Aneurysm (n/a - | applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S |
| 13025559 | 10/0//2022 | эропшисоцз | Professional | Economic Area | TWO CAVAILABLE | Years | | Maic | | Recovered/Resolved - Caused/Prolonged | - COVID-19 immunisation - Not applicable - [1d - 1{DF} - |
| | | | | 7.1.60 | | | | | | Hospitalisation), | Intramuscular use]) |
| | | | | | | | | | | Arthralgia (n/a - Recovered/Resolved | |
| | | | | | | | | | | - Caused/Prolonged Hospitalisation), | |
| | | | | | | | | | | Thrombosis (n/a - | |
| | | | | | | | | | | Recovered/Resolved - Caused/Prolonged | |
| -EC- | 18/07/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | ' Adolescent | Male | No | Hospitalisation) Abdominal pain (n/a | COMIRNATY [TOZINAMERAN] (S |
| 013025664 | , , | | Professional | | | Years | | | | - Recovering/Resolving | - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use] |
| | | | | | | | | | | - Caused/Prolonged Hospitalisation, | |
| | | | | | | | | | | Other Medically Important | |
| | | | | | | | | | | Condition), | |
| | I . | l | | 1 | I. | 1 | 1 | 1 | 1 | Disturbance in | I . |

| | | | | | | | | | | 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 | Healthcare | 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | Not |
| | | | | | | | | | | Influenza like illness (n/a - Recovering/Resolving -) | | |
| EU-EC- 10013025913 | 18/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Influenza like illness (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | Not |
| | | | | | | | | | | Vaccination site pain (n/a - Not Recovered/Not Resolved -) | | |
| 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 | Healthcare | 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), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [29d3mL - Intramuscular use]) | Not |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | |
| 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 | Not available | 12-17 Years | Adolescent | Male | No | -) Headache (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |
| | | | | Area | | | | | | Resolved -), Rash macular (n/a - Not Recovered/Not Resolved -), | applicable = [1d - 1{DF} - Intramuscular use]) | |
| | | | | | | | | | | Vomiting (n/a - Not | | |
| EU-EC- | 1010 | Spontaneous | | European | Not available | 12-17 | Adolescent | | No | Recovered/Not Resolved -) Presyncope (15min - | COMIRNATY [TOZINAMERAN] (S | Not |

| | 15.34 | | | | | | _ | eport | | | | |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|---|---|----|
| EU-EC- 10013027227 | 18/07/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | No |
| EU-EC- 10013028088 | 18/07/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | - Caused/Prolonged Hospitalisation) Gastrooesophageal reflux disease (n/a - Unknown - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | No |
| | | | | | | | | | | 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 | | |
| EU-EC- 10013028096 | 18/07/2022 | Spontaneous | | European Economic | Not available | 12-17 Years | Not Specified | Female | No | - Caused/Prolonged Hospitalisation) Back pain (7d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | No |
| 10013028090 | | | Professional | | | Tears | эрестеч | | | -), COVID-19 (n/a - Unknown - Other Medically Important Condition), | applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | 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) | | |
| EU-EC- 10013028103 | 18/07/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blood iron decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | No |
| | | | | | | | | | | 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 -), | | |
| | | 1 | | | | | | | | Serum ferritin | | |
| | | | | | | | | | | decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Recovered/Resolved - Caused/Prolonged | | |

| 0.11.2022 | 15.34 | | | | R | Run Line L | isting Re | eport | | | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|-----------------|----|--|---|---------------------|
| | | | | | | | | | | C-reactive protein increased (n/a - Unknown -), | | |
| | | | | | | | | | | Complement factor C3 (n/a - Unknown -), | | |
| | | | | | | | | | | Diarrhoea (n/a - Unknown -), | | |
| | | | | | | | | | | Endoscopy abnormal (n/a - Unknown -), | | |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Fear of disease (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Flatulence (n/a - Unknown -), | | |
| | | | | | | | | | | Frequent bowel movements (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Frequent bowel movements (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Gastrointestinal inflammation (n/a - Unknown -), | | |
| | | | | | | | | | | Haematochezia (n/a - Recovering/Resolving | | |
| | | | | | | | | | | - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Hyponatraemia (n/a - Unknown -), | | |
| | | | | | | | | | | Malnutrition (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Pyrexia (n/a - Unknown -), | | |
| | | | | | | | | | | Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Weight decreased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | |
| EU-EC- 10013028947 | 18/07/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Fema l e | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| | | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10013029049 | 18/07/2022 | Spontaneous | Non Healthcare Professional | | Not available | 12-17 Years | Not Specified | Ma l e | No | Contusion (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | [DEX n/a n/a] |
| | | | | Area | | | | | | Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | |
| | | | | | | | | | | Platelet count decreased (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10013029080 | 18/07/2022 | Spontaneous | Healthcare Professional | | 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- | | Spontaneous | | Non | Not available | 12-17 | Not | Male | No | Lymphadenopathy | | Not |

| .11.2022 | 15.34 | | | | Run | Line L | isting Re | eport | | | | |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|---|----------------|------------------|--------|----|---|---|-----|
| 10013029859 | | | Healthcare Professional | | | Years | Specified | | | (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | |
| U-EC- 0013019374 | 17/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Hyperhidrosis (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | Not |
| | | | | | | | | | | Vision blurred (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10013016978 | 16/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chills (1d - Recovered/Resolved -), Fatigue (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | No |
| | | | | | | | | | | Recovering/Resolving -), Malaise (n/a - Recovering/Resolving | | |
| | | | | | | | | | | -), Pyrexia (1d - Recovered/Resolved | | |
| | | | | | | | | | | Vaccination site lymphadenopathy | | |
| | | | | | | | | | | Recovering/Resolving -) | | |
| EU-EC- 10013005237 | 15/07/2022 | Spontaneous | | 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, | 12-17 Years | Not Specified | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), | |
| | | | | | doi:10.1016/j.jpeds.2022.04.005 | | | | | Drug ineffective (n/a - Unknown - Other Medically Important Condition) | [COVID-19 VACCINE] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a]) | |
| EU-EC- 10013005543 | 15/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Chills (n/a - Unknown -), Cough (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intravenous use]) | Not |
| | | | | | | | | | | 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 -) | | |
| EU-EC- 10013006225 | 15/07/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| | | | | | | | | | | Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | |

| | | | | | | | | | | Chest pain (n/a - | | ı |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|------------------|----|---|---|-----|
| EU-EC- 10013006744 | 15/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Not Specified | No | Unknown -) Asthenia (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | Not |
| | | | | | | | | | | Pyrexia (24h - Recovered/Resolved -) | , | |
| EU-EC- 10013006763 | 15/07/2022 | Spontaneous | | 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/a3mL - Intramuscular use]) | Not |
| EU-EC- 10013007153 | 15/07/2022 | Spontaneous | | 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 | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | Not |
| | 15/07/2022 | Spontaneous | | European | Not available | 12-17 | Not | Male | No | consciousness (15s - Recovered/Resolved - Other Medically Important Condition), Rhinorrhoea (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S | Not |
| 10013007449 | | | Professional | Economic Area | | Years | Specified | | | consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important | - n/a - n/a - [n/a - n/a - n/a]) | |
| EU-EC- 10013007628 | 15/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Not Specified | No | Condition) Vaccination site erythema (n/a - Unknown -), Vaccination site swelling (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a5mL - Intramuscular use]) | Not |
| EU-EC- 10013007769 | 15/07/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not |
| | 45/03/2022 | | | | | 10.17 | | | | (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10013008169 | 15/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular use]) | Not |
| | | | | | | | | | | Pyrexia (12d - Recovered/Resolved - Other Medically Important Condition) | | |
| 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), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not |
| | | | | | | | | | | Chest pain (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (1d - Recovered/Resolved | | |
| | 15/07/2022 | Spontaneous | | European | Not available | | Not | Female | No | - Caused/Prolonged Hospitalisation) Blood pressure | COMIRNATY [TOZINAMERAN] (S | Not |
| 10013008899 | | | Healthcare Professional | Economic Area | | Years | Specified | | | increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Palpitations (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10013009096 | 15/07/2022 | Spontaneous | | 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 | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |

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|-----------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|---------------|----|--|--|-----|
| EU-EC- 10013009116 | 15/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | 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 - Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Rot Resolved - Other Mesolved - Caused/Prolonged Hospitalisation), Headache (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a]) | Not |
| | | | | | | | | | | Vomiting (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | |
| 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), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not |
| | | | | | | | | | | Malaise (n/a - Unknown -), Vomiting (n/a - Unknown -) | | |
| EU-EC- 10013009689 | 15/07/2022 | Spontaneous | | Economic | Not available | | Not Specified | Ma l e | No | ' | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not |
| EU-EC- 10013009703 | 15/07/2022 | Spontaneous | | European Economic | 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), 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 -) | - Immunisation - n/a - [n/a - î | Not |
| EU-EC- 10013011089 | 15/07/2022 | Spontaneous | | 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 |

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|-----------------------|------------|-------------|------------|-------------------------------------|---------------|----------------|------------------|--------|----|--|---|-----|
| | | | | | | | | | | Important Condition), | | |
| | | | | | | | | | | Tinnitus (n/a - Not Recovered/Not Resolved - | | |
| | | | | | | | | | | Caused/Prolonged Hospitalisation, Disabling, Other | | |
| EU-EC- | 15/07/2022 | Spontaneous | Non | European | Not available | 12-17 | Not | Male | No | Medically Important Condition) Blood fibrinogen | COMIRNATY [TOZINAMERAN] (S | Not |
| 10013014058 | | , | | Economic | | Years | Specified | | | increased (n/a - | - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | |
| | | | | | | | | | | 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 -) | | |
| EU-EC- 10013014084 | 15/07/2022 | Spontaneous | | Non European Economic Area | Not available | | Not Specified | Female | No | Deep vein thrombosis (n/a - Unknown - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | Fibula fracture (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10013014851 | 15/07/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | | Not Specified | Male | No | Lymph node pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| | | | | | | | | | | Lymphadenopathy (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10013015001 | 15/07/2022 | Spontaneous | | Non European Economic Area | Not available | | Not Specified | Female | No | Swelling (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | Not |
| EU-EC- 10013015047 | 15/07/2022 | Spontaneous | Healthcare | 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 | | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | - Other Medically | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use - More in ICSR]) | Not |
| EU-EC- 10013015567 | 15/07/2022 | Spontaneous | | 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 | | Non European | Not available | | Not Specified | Male | No | Abdominal pain (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |
| | | | | Economic Area | | | | | | Resolved -), Decreased appetite | applicable - [1d - n/a - Intramuscular use]) | |
| | | | | | | | | | | (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 | | |

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|---|-----------------------|------------|--------------|----------------------------|-------------------------------------|---------------|---------|------------------|------------------|----|--|--|--|
| | | 14/07/1005 | Chart | Lig-lib. | | Not available | 1247 | Not | Na. I. | Ne | 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), Vision blurred (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Visual impairment (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Figure 1 | COMPANY | |
| | EU-EC- 10012994753 | 14/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | | Not Specified | Male | No | Fatigue (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | [FLU PRO SALI FLU PRO SALI XIN/ - n/a [MO MON (C n/a |
| | EU-EC- 10012994800 | 14/07/2022 | Spontaneous | Healthcare Professional | | Not available | | 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 | | Not Specified | Female | No | | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| | EU-EC- 10012995830 | 14/07/2022 | Spontaneous | | Non European Economic Area | Not available | | 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), 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 |

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|-----------------------|------------|-------------|----------------------------|------------------------------|---------------|----------------|------------------|------------------|-----|--|--|-------------|
| | | | | | | | | | | 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 | | |
| EU-EC- | 14/07/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Adolescent | Male | No | Hospitalisation) COVID-19 (n/a - | COMIRNATY [TOZINAMERAN] (S | Not |
| 10012996162 | | | | Economic Area | | Years | | | | Unknown - Other Medically Important | - n/a - n/a - [n/a - n/a - Intramuscular use]) | |
| | | | | | | | | | | Condition), | | |
| | | | | | | | | | | Vaccination failure (n/a - Unknown - | | |
| | | | | | | | | | | Other Medically Important Condition) | | |
| EU-EC- 10012996611 | 14/07/2022 | Spontaneous | | European Economic | Not available | 12-17 Years | Not Specified | Not Specified | No | Dizziness (n/a - Unknown -), | - COVID-19 immunisation - Not | Not |
| | | | | Area | | | | | | Headache (n/a - Unknown -) | applicable - [n/a6mL - Intramuscular use]) | |
| EU-EC- 10012996701 | 14/07/2022 | Spontaneous | | European | Not available | 12-17 | Adolescent | Male | No | Thrombophlebitis | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - | Not |
| 10012996/01 | | | Healthcare Professional | Economic Area | | Years | | | | (n/a - Recovered/Resolved -) | 1{DF} - n/a]) | |
| EU-EC- 10012997107 | 14/07/2022 | Spontaneous | Healthcare Professional | European Economic | Not available | 12-17 Years | Not Specified | Not Specified | No | Arthralgia (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |
| 10012997107 | | | riolessional | Area | | Icais | Specified | эрестеи | | Asthenia (n/a - | applicable - [n/a3mL - Intramuscular use]) | |
| | | | | | | | | | | Unknown -), | , | |
| | | | | | | | | | | Decreased appetite (n/a - Unknown -), | | |
| | | | | | | | | | | Myalgia (n/a - | | |
| | | | | | | | | | | Unknown -), Pyrexia (n/a - | | |
| EU-EC- | 14/07/2022 | Cooptonoous | Haaltheara | Europopp | Not available | 12.17 | Not | Not | No | Unknown -) | COMIDNATY [TOZINAMEDAN] (C | Not |
| 10012997847 | 14/0//2022 | Spontaneous | Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Specified | INO | Pyrexia (24h - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - | Not |
| | | | | / ii cu | | | | | | Vomiting (n/a - | Intramuscular use]) | |
| EU-EC- | 14/07/2022 | Spontaneous | Non | Non | Not available | 12-17 | Not | Female | No | Unknown -) COVID-19 (n/a - | TOZINAMERAN [TOZINAMERAN] | cos |
| 10012998115 | ,,,,,, | | Healthcare Professional | European | | | Specified | | | Unknown - Other Medically Important | (S - COVID-19 immunisation - Not applicable - [1d - n/a - | |
| | | | | Area | | | | | | Condition), | Intramuscular use]) | n/a |
| | | | | | | | | | | Fatigue (n/a - Unknown -), | | REM (C - |
| | | | | | | | | | | Throat irritation (n/a - Unknown -), | | n/a |
| | | | | | | | | | | Vaccination failure | | |
| | | | | | | | | | | (n/a - Unknown - Other Medically | | |
| EU-EC- | 14/07/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Not | No | Important Condition) Decreased appetite | COMIRNATY [TOZINAMERAN] (S | Not |
| 10012998737 | ' ' | | | Economic Area | | Years | Specified | Specified | | (n/a - Unknown -), | - COVID-19 immunisation - Not applicable - [n/a3mL - | |
| | | | | | | | | | | Diarrhoea (n/a - Unknown -), | Intramuscular use]) | |
| | | | | | | | | | | Insomnia (n/a - | | |
| | | | | | | | | | | Unknown -), Peripheral swelling | | |
| | | | | | | | | | | (n/a - Recovered/Resolved | | |
| | | | | | | | | | | -), | | |
| | | | | | | | | | | Sleep disorder (n/a - Unknown -) | | |
| EU-EC- 10012999949 | 14/07/2022 | Spontaneous | Healthcare Professional | European Economic | Not available | 12-17 Years | Adolescent | Ma l e | No | COVID-19 (n/a - Unknown - Other | - n/a - n/a - [n/a - n/a - | Not |
| | | | | Area | | | | | | Medically Important Condition), | Intramuscular use]) | |
| | | | | | | | | | | Vaccination failure (n/a - Unknown - | | |
| | | | | | | | | | | Other Medically Important Condition) | | |
| EU-EC- 10013000415 | 14/07/2022 | Spontaneous | | European Economic | Not available | 12-17 Years | Not Specified | Male | No | Diarrhoea (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |
| | | | | Area | | | Specificu | | | Pyrexia (n/a - | applicable - [n/a - n/a - Intramuscular use]) | |
| EU-EC- | 14/07/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Not | No | Unknown -) Chest pain (n/a - | - | Not |
| 10013000759 | . , | | Professional | Economic Area | | Years | Specified | Specified | | Unknown -) | - COVID-19 immunisation - Not applicable - [n/a3mL - | |
| EU-EC- | 14/07/2022 | Spontaneous | | Non | Not available | | Not | Male | No | COVID-19 (n/a - | Intramuscular use]) TOZINAMERAN [TOZINAMERAN] | Not |
| 10013001114 | | | Professional | European Economic | | Years | Specified | | | Unknown - Other Medically Important | (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), | |
| | | | | Area | | | | | | Condition), | [SARS-COV-2, STRAIN HB02, | |
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| | | | | | | | | | | Death (n/a - Fatal - Results in Death), Drug ineffective (n/a - Unknown - Other Medically Important Condition), | BETA-PROPIOLACTONE INACTIVATED] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | 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) | | |
| :U-EC- 0013001169 | 14/07/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | | Not Specified | Male | No | COVID-19 (n/a - Unknown - Other | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Noi applicable - [1d - n/a - n/a]) | |
| 11.50 | 14/07/2022 | Caratana | I I a likk a a | Non | Not available | 12.17 | Note | F | NI- | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S | 1 |
| U-EC- 0013001170 | 14/07/2022 | Spontaneous | Professional | Non European Economic Area | NOT AVAILABLE | 12-17 Years | Not Specified | Female | No | CSF test abnormal (n/a - Unknown - Other Medically Important Condition), | - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | |
| | | | | | | | | | | 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) | | |
| U-EC- 0013001706 | 14/07/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | | Not Specified | Female | No | Cardiac discomfort (n/a - Unknown - Disabling, Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | 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), | | |
| | | | | | | | I | | | I | | |

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|-----|---------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|-----------|----|--|--|--------------------------------------|
| | | | | | | | | | | | 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), | | |
| F | U-EC- | 14/07/2022 | Spontaneous | Healthcare | Non | Not available | 12-17 | Not | Female | No | Tachycardia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition) Feeling abnormal | TOZINAMERAN [TOZINAMERAN] | [CE1 |
| | 0013002406 | 11/07/2022 | Spontaneous | Professional | European Economic Area | Not ordinate | Years | Specified | remake | | (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition), | (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | DIH' Mult [n/a [LOF Rhin |
| | | | | | | | | | | | Vomiting (n/a - Unknown -) | | [n/a [MO FUR - n/a use] |
| | | | | | | | | | | | | | [SEF SER HYD Anxi - [n/ |
| | U-EC- 0013002459 | 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 | - Product used for unknown indication - Unknown - [n/a - 1{DF} - n/a]), | Not |
| | | | | | | | | | | | Recovered/Not Resolved -), Costochondritis (n/a - Not Recovered/Not Resolved -), | SPIKEVAX [COVID-19 MRNA VACCINE MODERNA (CX- 024414)] (S - COVID-19 prophylaxis - Unknown - [n/a - 1{DF} - n/a]) | |
| | | | | | | | | | | | 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 | | |
| | | 14/07/2022 | Spontaneous | | Non | Not available | | Not | Male | No | Resolved - Other Medically Important Condition) Abdominal pain (n/a | COMIRNATY [TOZINAMERAN] (S | Not |
| 1 | 0013003063 | | | Professional | European Economic Area | | Years | Specified | | | - Unknown -), Immune system disorder (52d - Recovered/Resolved With Sequelae -), | - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | | Lymphadenopathy (52d - Recovered/Resolved With Sequelae - Caused/Prolonged | | |
| - | | | | | | | | | | | Hospitalisation) | | \vdash |

| /07/2022 | | | | | | | | | | | |
|----------|--|---|--|---|--|---|--|---|---|--|--|
| | Spontaneous | Non Healthcare Professional | Economic | Not available | 12-17 Years | Not Specified | Male | No | COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | Drug ineffective (n/a | | |
| | | | | | | | | | - Recovering/Resolving | | |
| | | | | | | | | | Important Condition) | | |
| /07/2022 | Spontaneous | | | Not available | 12-17 Years | Not Specified | Female | No | Incorrect route of product administration (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intraarticular use]) | No |
| | | | | | | | | | Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | |
| | | | | | | | | | Neuralgic amyotrophy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | |
| /07/2022 | Constant | Usalkhana | 5 | Nah or 3-blo | 12.17 | Adelegant | Mala | No | Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMPNADY (TOTINAMEDAN) (C | Net |
| 707/2022 | Spontaneous | | | NOL AVAILABLE | Years | Adolescent | Male | INO | Unknown -), Pyrexia (n/a - | - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not |
| /07/2022 | Spontaneous | | Non | Hsu, T Acute Genital Ulceration After Severe | | | Female | No | Genital ulceration | | No |
| | | | Economic Area | Vaccination and Infection. Journal of Pediatrics. 2022;246:271-273. doi:10.1016/j.jpeds.2022.04.005 | | | | | Recovered/Resolved - Other Medically Important Condition) | applicable - [n/a - n/a - n/a]) | |
| /07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | | No | - Unknown -), | - COVID-19 immunisation - Not applicable - [n/a3mL - | No |
| | | | | | | | | | Unknown -), | Intramuscular use]) | |
| | | | | | | | | | Recovered/Resolved | | |
| /07/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Female | No | Unknown -) Chest pain (0d - | COMIRNATY [TOZINAMERAN] (S | Not |
| | | | Economic Area | | Years | Specified | | | Recovered/Resolved -), Palpitations (0d - | - n/a - n/a - [n/a - 1{DF} - Intramuscular use]) | |
| | | | | | | | | | -), Pyrexia (0d - Recovered/Resolved | | |
| /07/2022 | Spontaneous | | | Not available | | | Female | No | Pyrexia (n/a - | COMIRNATY [TOZINAMERAN] (S | Not |
| | | | Area | | | · . | | | -) | [n/a3mL - Intramuscular use]) | |
| /0//2022 | Spontaneous | | | Not available | Years | Specified | | No | decreased (n/a - Recovered/Resolved -), | COMIRNALY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | Not |
| | | | | | | | | | Syncope (n/a - Unknown - Other Medically Important Condition) | | |
| /07/2022 | Spontaneous | Healthcare | | Not available | 12-17 Years | Not Specified | Male | No | - Unknown - Other | - COVID-19 immunisation - Not | Not |
| | | | | | | | | | Asthenia (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | Hallucination (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | Hyperhidrosis (n/a - Unknown - Other Medically Important | | |
| | | | | | | | | | Nausea (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | Night sweats (n/a - Unknown - Other | | |
| | | | | | | | | | Medically Important Condition), | | |
| | 07/2022 07/2022 07/2022 07/2022 | 07/2022 Spontaneous 07/2022 Spontaneous 07/2022 Spontaneous 07/2022 Spontaneous 07/2022 Spontaneous | 707/2022 Spontaneous Healthcare Professional | Professional European Economic Area Professional European Economic Area | Professional European Economic Area Professional European Professional Economic Area Professional Economic Area | Professional European Not available 12-17 Years | Professional European European Professional European Not available 12-17 Adolescent Years Specified Professional Economic Area Professional Economic Area Professional European Not available 12-17 Not Specified Professional European Not available 12-17 Not Specified Professional Economic Not available 12-17 Not Specified Not available 12-17 Not Specified Professional Economic Not available 12-17 Not Specified No | Professional European Concomic Area Specified Section Area Section Area Section Area Section Section Area Section | Professional European Concomic Area European Not available 12-17 Addescent Male No No No No No No No N | Procession Pro | 20-20 Destinance Production of Processing Process |

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|-----------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|------------------|----|--|--|--|
| | | | | | | | | | | Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - Other Medically | | |
| EU-EC- 10012985528 | 13/07/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Important Condition) 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 | | 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 | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | Not |
| | | | | | | | | | | - Caused/Prolonged Hospitalisation), Myalgia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (48h - | | |
| EU-EC- 10012985744 | 13/07/2022 | Spontaneous | Healthcare Professional | European Economic | Not available | 12-17 Years | Not Specified | Female | No | Recovered/Resolved - Caused/Prolonged Hospitalisation) Auditory disorder (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - | Not |
| | | | | Area | | | | | | Recovered/Resolved -), Hypotonic- hyporesponsive episode (n/a - Unknown -), | [n/a3mL - Intramuscular use]) | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown -), Visual impairment (n/a - | | |
| EU-EC- 10012985968 | 13/07/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Recovered/Resolved -) Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not |
| | | | | | | | | | | 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 | | |
| 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]) | [FLU PRO SALI FLU PRO SALI XIN/ - n/a |
| EU-EC- | 13/07/2022 | Spontaneous | | European | Not available | 12-17 | Not | Not | No | Pyrexia (24h - | COMIRNATY [TOZINAMERAN] (S | [MON MON (C - - n/a Not |
| 10012986194 | | | Professional | Economic Area | | Years | Specified | Specified | | Recovered/Resolved -), Vomiting (n/a - Unknown -) | - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | |
| EU-EC- 10012986540 | 13/07/2022 | Spontaneous | 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 | Not |

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| | | | | | | | | | | Vaccination site pain (3d - Recovered/Resolved | applicable - [n/a3mL - Intramuscular use]) | |
| EU-EC- .0012987065 | 13/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | Not |
| | | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | | |
| :U-EC- 0012987203 | 13/07/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Asthenia (n/a - Not Recovered/Not Resolved -), Loss of personal | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | independence in daily activities (n/a - Unknown -) | | |
| EU-EC- 10012987427 | 13/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Decreased appetite (9h - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | CELI [MY: MOF), |
| | | | | | | | | | | Fatigue (1d - Recovered/Resolved -), | | [DR: SUL [n/a |
| | | | | | | | | | | Headache (2d - Recovered/Resolved -), | | (C - - Or |
| | | | | | | | | | | Nausea (1d - Recovered/Resolved -) | | [PAN SES n/a Oral |
| | | | | | | | | | | | | [SUI TRII - n/a |
| | | | | | | | | | | | | TAC MON - n/a |
| EU-EC- 10012987727 | 13/07/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Skin disorder (30min - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | Urticaria (30min - Recovered/Resolved -) | | |
| EU-EC- 10012988016 | 13/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Not Specified | No | Loss of consciousness (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | Not |
| | | | | | | | | | | Syncope (n/a - Unknown - Other Medically Important Condition) | | |
| 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) | - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - | Not |
| EU-EC- 10012988350 | | Spontaneous | 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/a3mL - Intramuscular use]) | Not |
| EU-EC- 10012988644 | 13/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Ma j e | No | Asthenia (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | Not |
| | | | | | | | | | | Pruritus (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Rash morbilliform (n/a - Not Recovered/Not Resolved -) | | |
| 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), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | Not |
| | | | | | | | | | | Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Paraesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10012990115 | 13/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Not Specified | No | Confusional state (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | Not |
| | | | | | | | | | | Hypotonic- hyporesponsive episode (n/a - Unknown - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Presyncope (n/a - Unknown - | | |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|--|---|--|
| | | | | | | | | | | Caused/Prolonged Hospitalisation), Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically | | |
| EU-EC- 10012990398 | 13/07/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | | Not Specified | Female | No | Important Condition) Feeling hot (n/a - Unknown -), Vomiting (n/a - | 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 | Unknown -) Physical deconditioning (n/a - Unknown -), Pyrexia (n/a - Unknown - Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| | 13/07/2022 | Spontaneous | | Non | Not available | | Not | Male | No | Medically Important Condition) Chest discomfort | COMIRNATY [TOZINAMERAN] (S | Not |
| 10012992254 | | | Professional | European Economic Area | Not well-blo | Years | Specified | Esmale | No | -), 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), Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Troponin I increased (n/a - Recovering/Resolving -) | - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | |
| 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]) | [CET t DIH' n/a 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 - | | 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 -), | | Not |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|------------------|------|--|--|------|
| | | | | | | | | | | Vomiting (n/a - Recovering/Resolving -) | | |
| EU-EC- 10012994053 | 13/07/2022 | Spontaneous | Non Healthcare Professional | | Not available | | Not Specified | Male | No | COVID-19 (n/a - Unknown - Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | ١ |
| | | | | | | | | | | Drug ineffective (n/a | | |
| | | | | | | | | | | Recovered/Resolved - Other Medically Important Condition), | | |
| | | | | | | | | | | Headache (4d - Recovered/Resolved -), | | |
| | | | | | | | | | | Pyrexia (4d - Recovered/Resolved -) | | |
| :U-EC- .0012994105 | 13/07/2022 | Spontaneous | | Non European Economic Area | Not available | | Not Specified | Male | No | COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Noi applicable - [1d - n/a - n/a]) | ot N |
| | | | | | | | | | | 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) | | |
| EU-EC- 10012971391 | 12/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | | Not Specified | Not Specified | No | Arthralgia (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | N |
| | | | | | | | | | | Blood pressure decreased (n/a - Recovering/Resolving -), | | |
| | | | | | | | | | | Myalgia (n/a - Recovering/Resolving -), | | |
| | | | | | | | | | | Presyncope (n/a - Recovering/Resolving -) | | |
| EU-EC- 10012972378 | 12/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | | Not Specified | Female | No | Epistaxis (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | N |
| | | | | | | | | | | Hypoaesthesia (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Vaccination site reaction (n/a - Recovered/Resolved -) | | |
| EU-EC- 10012973028 | 12/07/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Not Specified | Not Specified | No | Hypoaesthesia (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - | N |
| | | | | | | | | | | Malaise (n/a - Unknown -), | Intramuscular use]) | |
| | | | | | | | | | | Palpitations (n/a - Unknown -), | | |
| EU-EC- | 12/07/2022 | Spontaneous | Haalthaara | Non | Not available | 12-17 | Not | Male | No | Pyrexia (72h - Recovered/Resolved -) Chest pain (n/a - | COMIRNATY [TOZINAMERAN] (S | N |
| 10012973439 | 12/07/2022 | эропшнеоиз | Professional | | Not available | | Specified | Male | NO . | Recovering/Resolving - Caused/Prolonged Hospitalisation), | - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | 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 | | |
| EU-EC- | 12/07/2022 | Spontaneous | Healthcare Professional | European | Not available | | Not Specified | Not Specified | No | Hospitalisation) Lymph node pain | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | N |
| 10012973604 | | | | | | Years | | | | (n/a - | | |

| | | | | | | | | | Lymphadenopathy (n/a - Recovered/Resolved | |
|---------------------|------------|-------------|-------------------------------------|---------------|----------------|------------------|---------------|----|--|--|
| U-EC- 0012974194 | 12/07/2022 | Spontaneous | Non European Economic | Not available | 12-17 Years | Not Specified | Ma l e | No | Headache (3d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| | | | Area | | | | | | 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 -) | |
| J-EC- 0012974294 | 12/07/2022 | Spontaneous | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain upper (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| | | | | | | | | | 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) | |
| U-EC- 0012974613 | 12/07/2022 | Spontaneous | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) |
| | | | | | | | | | 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) | |
| U-EC- 0012974659 | 12/07/2022 | Spontaneous | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Seizure (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) |
| | | | | | | | | | Vomiting (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|------------------|----|---|---|-----|
| EU-EC- 10012975717 | 12/07/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Adolescent | Male | No | Body temperature increased (1d - Recovered/Resolved -), Lymphadenitis (3d - Recovered/Resolved -), Lymphadenopathy | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not |
| | | | | | | | | | | (3d - Recovered/Resolved | | |
| 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 - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not |
| | | | | | | | | | | Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), | | |
| | | | | | | | | | | Somnolence (n/a - Recovering/Resolving | | |
| 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not |
| EU-EC- | 12/07/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Not | No | Pyrexia (n/a - Unknown -) Headache (30min - | COMIRNATY [TOZINAMERAN] (S | Not |
| 10012976248 | | | Professional | Economic Area | | Years | Specified | Specified | | Recovered/Resolved -), Hypoaesthesia (30min - Recovered/Resolved | - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | |
| 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 | - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - | Not |
| EU-EC- 10012976741 | 12/07/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Resolved -) Immunisation reaction (n/a - Recovered/Resolved | - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - | 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 -) | Intramuscular use]) 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 | | Not |
| | | | | | | | | | | Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -) | | |
| 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 - | 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 | Unknown -) Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| | | | | | | | | | | 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) | | |
| 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), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | Not |
| | | | | | | | | | | Dyspnoea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (n/a - | | |
| | | | | | | | | | | Recovered/Resolved - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10012978088 | 12/07/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - n/a]) | Not |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------------------------|----------------|------------------|--------|----|---|---|---|
| | | | | | | | | | | Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Presyncope (1d - Recovered/Resolved -) | | |
| EU-EC- 10012978426 | 12/07/2022 | Spontaneous | | European Economic Area | Not available | | Not Specified | Male | No | Expired product administered (n/a - Unknown -), Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | [F PF S/ FL PF S/ XI - I |
| EU-EC- 10012978812 | 12/07/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | | Not Specified | Female | No | - Caused/Prolonged Hospitalisation), Headache (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | No |
| | | | | | | | | | | - Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - | | |
| EU-EC- | 12/07/2022 | Spontaneous | Non | Non | Not available | 12-17 | Not | Female | No | Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) Loss of | | Ne |
| 10012979843 | | | Healthcare Professional | European | | | Specified | | | consciousness (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Tunnel vision (10d - Recovered/Resolved - Caused/Prolonged | - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | |
| | | | | | | | | | | Hospitalisation, Other Medically Important Condition) | | |
| EU-EC- 10012979945 | 12/07/2022 | Spontaneous | Non Healthcare Professional | Economic | Not available | N | Not Specified | Male | No | Ageusia (2d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | N |
| EU-EC- 10012980077 | 12/07/2022 | Spontaneous | Non Healthcare Professional | Economic | Not available | | Not Specified | Female | No | -) Menstruation delayed (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | N |
| EU-EC- 10012980582 | 12/07/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Resolved -) Abdominal pain (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | N |
| | | | | | | | | | | Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10012981348 | 12/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Abdominal pain lower (n/a - Unknown -), Vaginal haemorrhage | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | No |
| EU-EC- | 11/07/2022 | Spontaneous | Healthcare | Non | Ridolfi, A Lipshutz's acute vulvar | 12-17 | Not | Female | No | (n/a - Unknown -) Vulval ulceration (n/a | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not | No |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|--|----------------|------------------|------------------|-----|---|--|---------------------------|
| 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 | 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 | (n/a - Unknown -) Heavy menstrual bleeding (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 |
| | | | | | | | | | | Polymenorrhoea (n/a - Not Recovered/Not Resolved -) | | |
| 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 - | | Not |
| | | | | | | | | | | Recovering/Resolving -) | | |
| EU-EC- 10012961853 | 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;10.1161/CIRCULATTONAHA.121.056. doi:10.1161/CIRCULATTONAHA.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(5):345-356. doi:10.1161/CIRCULATTONAHA.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]) | |
| 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 - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | Disabling), Peripheral swelling (n/a - Not Recovered/Not | | |
| EU-EC- 10012962738 | 11/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Resolved - Disabling) 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | Not |
| FIL FC | 11/07/2022 | Ct | 1111 | F | Not a cillable | 12.17 | Net | NI-E | NI- | Vomiting (n/a - Unknown -) | COMIDNATY STOZINAMEDANI (C | Note |
| EU-EC- 10012963090 | 11/0//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/a3mL - 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 | 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 | Hospitalisation) Dyspnoea (n/a - Recovering/Resolving -), Immunisation reaction (n/a - | 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 | Fema l e | No | - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intercept of the control of | Not |
| | | | | | | | | | | -), Heavy menstrual bleeding (1wk - Recovered/Resolved -), | Intramuscular use]) | |
| | | | | | | | | | | Vomiting (1wk - Recovered/Resolved -) | | |
| 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 |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|------------------|----|---|---|-----|
| EU-EC- 10012963625 | 11/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Pigmentation disorder (10d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | Not |
| | | | | | | | | | | Urticaria (1d - Recovered/Resolved -) | | |
| 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 |
| 10012963685 | 11/07/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Pain (n/a - Recovered/Resolved With Sequelae -) | - 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 |
| 10012963690 | | Spontaneous | 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 |
| 10012963691 | | Spontaneous | 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), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a5mL - Intramuscular use]) | Not |
| | | | | | | | | | | Lymphadenopathy (n/a - Unknown - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10012964292 | 11/07/2022 | Spontaneous | Healthcare | 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 | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Back pain (n/a - Not Recovered/Not Resolved -), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| | | | | | | | | | | Feeling hot (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important | | |
| EU-EC- 10012964414 | 11/07/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Condition) Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not |
| | | | | | | | | | | 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) | | |
| 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | Not |
| | | | | | | | | | | Feeling hot (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), | | |
| | | | | | | | | | | Nausea (n/a - Recovered/Resolved | | |

| 30.11.2022 | 15.34 | | | | Run | Line L | isting Re | eport | | | | |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|------------------------------|-----------------------------|------------------|--------|----|--|--|-----|
| EU-EC- 10012965193 | 11/07/2022 | Spontaneous | | Non European Economic Area | Not available | | Not Specified | Female | No | - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | Not |
| | | | | | | | | | | - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10012965303 | 11/07/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12 - 17 Years | Adolescent | Male | No | -), Vomiting (1d - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | Recovering/Resolving -) | | |
| EU-EC- 10012965310 | 11/07/2022 | Spontaneous | | 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), Tremor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tremor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Tremor (n/a - Not Recovered/Not Resolved - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not |
| EU-EC- | | Spontaneous | Healthcare Professional | European | Not available Not available | 12-17 | Adolescent | | No | Hospitalisation) 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), Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pallor (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), Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Diarrhoea (1d - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not |
| 10012965331 | , , | | | Economic | | Years | | | | | - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | |

| | | | | | | | | | | Fatigue (2d - Recovering/Resolving -), Vomiting (1d - Recovering/Resolving | | |
|----------------------|------------|-------------|-----------------------------------|-------------------------------------|---|----------------|------------------|--------|-----|--|--|-----|
| EU-EC- 1001296533 | | 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 - | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) | Not |
| | | | | | | | | | | Unknown -), Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Hypoaesthesia (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), | | |
| EU-EC- | 11/07/2022 | Spontaneous | Non | European | Not available | 12-17 | Not | Female | No | Tremor (n/a - Not Recovered/Not Resolved -) Dyspnoea (n/a - Not | COMIRNATY [TOZINAMERAN] (S | Not |
| 1001296544 | | Sportaneous | Healthcare Professional | Economic | not available | Years | Specified | Temale | INO | Recovered/Not Resolved - Disabling), | - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | 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) | | |
| EU-EC- 1001296546 | | 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 | 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]) | |
| | | | | | 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 | | | | | Oedema due to cardiac disease (n/a - Unknown -) | | |
| EU-EC- 1001296652 | | 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 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. 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]) | |

| | | | | | | | | | | | Condition), Pruritus (n/a - | | |
|---|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------|--------|----|--|--|---|
| | EU-EC- 10012968364 | 11/07/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Unknown -) Abdominal pain upper (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | | 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) | | |
| | 10012969502 | | | Healthcare Professional | European Economic Area | | Years | Adolescent | | No | Vaccination site lymphadenopathy (n/a - Not Recovered/Not Resolved -) | - 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 -), | - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), | GAR PAP 31 L |
| | | | | | | | | | | | Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a]). | ADS FOR PAR' YEA' (SAC CER |
| | | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved -), Infection | infection - Not applicable - [10d - 500mg - Oral use]) | 5 (S RDN PAPI 33 L |
| | | | | | | | | | | | susceptibility increased (n/a - Not Recovered/Not Resolved -), | | ADS FOR PAR YEA (SAC |
| | | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not | | CER 5 (S RDN PAPI 45 L |
| | | | | | | | | | | | Recovered/Not Resolved -) | | 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) |
| 1 | | ı l | | | | I | l | I | | | I | l | 1 |

| 0 | 7.11.2022 | 10.04 | | | | Run | LIIIC L | isting it | port | | | | |
|---|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|------------------|-----|---|---|--|
| | | | | | | | | | | | | | 18 L ADS FOR YEA: (SAC CER S CDN PAP! L1 P VIRL PRO CER 5 (S RDN VIRL PRO CER 5 (S RDN ALU PAPI SULI SULI SULI SULI SULI SULI SULI SUL |
| | 10012970189 | | Spontaneous | Professional | Area | Not available | Years | Not Specified | | 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 | | 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/a3mL - Intramuscular use]) | Not |
| | EU-EC- 10012949510 | 08/07/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | | 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 |
| | 10012949565 | | Spontaneous | Professional | European Economic Area | Not available | Years | Not Specified | Not Specified | No | Diarrhoea (n/a - Unknown -), Vomiting (n/a - Unknown -) | - COVID-19 immunisation - Not applicable - [n/a3mL - 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/a3mL - Intramuscular use]) | Not |
| | 10012949607 | | Spontaneous | Healthcare Professional | | Not available | Years | Not Specified | | 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) | - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) | Not |
| | EU-EC- 10012950205 | υ8/υ//2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | | 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 -) | | |
|---------------------|------------|-------------|-----------------------------------|--------------------------------------|---------------|----------------|------------------|------------------|----|--|---|------------------|
| U-EC- 0012950210 | 08/07/2022 | Spontaneous | Healthcare Professional | European Economic | Not available | 12-17 Years | Not Specified | Male | No | Urticaria (n/a - Recovering/Resolving | - COVID-19 immunisation - Not | Not |
| U-EC- 0012950234 | 08/07/2022 | Spontaneous | Healthcare Professional | Area European Economic Area | Not available | 12-17 Years | Not Specified | Not Specified | No | Body temperature abnormal (n/a - Unknown -), | applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - | Not |
| | | | | 7.00 | | | | | | Decreased appetite (n/a - Unknown -), | Intramuscular use]) | |
| | | | | | | | | | | Dizziness (n/a - Unknown -), | | |
| | | | | | | | | | | Eructation (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 -) | | |
| U-EC- 0012951493 | 08/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Parotid gland enlargement (n/a - Recovering/Resolving - Other Medically Important Condition), | - n/a - n/a - [n/a - n/a - | Not |
| | | | | | | | | | | Rash (n/a - Recovering/Resolving - Other Medically Important Condition) | | |
| U-EC- 0012951574 | 08/07/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Decreased activity (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | [PC AM CAI |
| | | | Troressional | Aica | | | | | | Dizziness exertional (n/a - Recovering/Resolving -), | 174) | PO - n/a |
| | | | | | | | | | | Educational problem (n/a - Unknown -), | | |
| | | | | | | | | | | Fatigue (n/a - Recovering/Resolving -), | | |
| | | | | | | | | | | General physical health deterioration (n/a - Unknown -), | | |
| | | | | | | | | | | Headache (n/a - Recovering/Resolving -) | | |
| U-EC- 0012951820 | 08/07/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Pain in extremity (n/a - Unknown - Disabling), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | Vomiting (n/a - Not Recovered/Not Resolved - Disabling) | | |
| U-EC- 0012951982 | 08/07/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chills (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| | | | | | | | | | | 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) | | |
| U-EC- 0012952149 | 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), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | No |
| | | | | | | | | | | Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving | | |

| | | | | | | | | | | - 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 | | 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 | Healthcare | 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), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Troponin T increased (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Troponin T increased (n/a - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) | KAF ELE IVA n/a KAL (C n/ |
| EU-EC- 10012953225 | 08/07/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | | Not Specified | Male | No | Hospitalisation) Vaccination site lymphadenopathy (6d - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not |
| EU-EC- 10012953237 | 08/07/2022 | Spontaneous | | European Economic | Not available | 12-17 Years | Not Specified | Fema l e | No | Recovered/Resolved -) Syncope (0d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |
| EU-EC- 10012953673 | 08/07/2022 | Spontaneous | Healthcare | Area European Economic | Not available | 12-17 Years | Not Specified | Male | No | Skin reaction (n/a - Not Recovered/Not | applicable - [n/a3mL - Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |
| | 08/07/2022 | Spontaneous | Healthcare | Area European Economic | Not available | 12-17 Years | Not Specified | Male | No | Resolved -) Vaccination site erythema (n/a - | applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |
| EU-EC- 10012953911 | 08/07/2022 | Spontaneous | | Area European Economic | Not available | 12-17 Years | Not Specified | Female | No | Unknown -) Fibrin D dimer increased (n/a - | applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |
| EU-EC- 10012937920 | 07/07/2022 | Spontaneous | Non Healthcare Professional | Area European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Unknown -) Lip swelling (n/a - Recovered/Resolved -), | applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| | | | | | | | | | | 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 - Not Resolved -), | | |

| ELL EC | 07/07/222 | Cassta | Nee | Nex | Not available | 40.15 | Net | Farit | Nic | Recovering/Resolving -) | | 1. |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|------------------|-----|---|--|----|
| EU-EC- 10012937983 | 07/07/2022 | Spontaneous | | Non European Economic Area | Not available | | Not Specified | Female | No | Epiglottic oedema (n/a - Unknown - Other Medically Important Condition), Laryngeal oedema (n/a - Unknown - | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Other Medically Important Condition) | | |
| EU-EC- 10012938300 | 07/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | | Not Specified | Male | No | Hypersensitivity (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash rubelliform (n/a | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | No |
| | | | | | | | | | | Recovered/Resolved - Caused/Prolonged Hospitalisation), Urticaria (n/a - Recovered/Resolved - Caused/Prolonged | | |
| EU-EC- | 07/07/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Female | No | Hospitalisation) Vaccination site | COMIRNATY [TOZINAMERAN] (S | No |
| 10012938341 | | · | Professional | Economic Area | | Years | Specified | | | reaction (n/a - Recovered/Resolved -) | - Immunisation - n/a - [n/a - n/a - n/a]) | |
| 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 - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | No |
| | | | | | | | | | | Unknown -), Vaccination site reaction (n/a - | | |
| EU-EC- 10012938627 | 07/07/2022 | Spontaneous | Healthcare Professional | | Not avaijable | 12-17 Years | Not Specified | Not Specified | No | Unknown -) Chest pain (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - | No |
| | | | | | | | | | | Troponin abnormal (n/a - Recovered/Resolved | Intramuscular use]) | |
| EU-EC- 10012939054 | 07/07/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Not Specified | Not Specified | No | Dizziness (n/a - Unknown -), Vaccination site pain | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use - More in | No |
| | 07/07/2022 | Spontaneous | | European | Not available | | Adolescent | Male | No | (n/a - Unknown -) Headache (7d - | ICSR]) COMIRNATY [TOZINAMERAN] (S | No |
| 10012939301 | | | Healthcare Professional | Economic Area | | Years | | | | Recovered/Resolved -), Oropharyngeal pain (7d - Recovered/Resolved -), | - n/a - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Pyrexia (7d - Recovered/Resolved -) | | |
| EU-EC- 10012940094 | 07/07/2022 | Spontaneous | | 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]) | No |
| 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/a3mL - Intramuscular use]) | No |
| 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/a5mL - Intramuscular use]) | No |
| EU-EC- 10012940731 | 07/07/2022 | Spontaneous | | 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), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | No |
| | | | | | | | | | | 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 | | |

| 0 | 0.11.2022 | 10.0 | | | | rtun | LIIIC L | isting it | port | | | | |
|---|-----------------------|------------|-------------|-----------------------------------|----------------------|--|----------------|------------------|--------|----|--|--|-----|
| | | | | | | | | | | | Important Condition), | | |
| | | | | | | | | | | | Tachycardia (n/a - Recovered/Resolved | | |
| | | | | | | | | | | | - Caused/Prolonged Hospitalisation, | | |
| | | | - | | | | | | | | Other Medically Important Condition) | | |
| | EU-EC- 10012941203 | 07/07/2022 | Spontaneous | | Economic | Not available | | Not Specified | Female | No | Arthralgia (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not |
| | | | | Troressiona | / | | | | | | 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 -) | | |
| | EU-EC- 10012941279 | 07/07/2022 | Spontaneous | Healthcare | European Economic | Not available | 12-17 Years | Adolescent | Female | No | Cold sweat (275d - Not Recovered/Not | - COVID-19 immunisation - n/a - | Not |
| | | | | Professional | Area | | | | | | Resolved - Caused/Prolonged Hospitalisation), | [n/a - n/a - n/a]) | |
| | | | | | | | | | | | 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) | | |
| | EU-EC- 10012941338 | 07/07/2022 | Spontaneous | Non Healthcare Professional | European Economic | Not available | 12-17 Years | Adolescent | Female | No | Dizziness (n/a - Not Recovered/Not Resolved - | - Immunisation - n/a - [n/a - | Not |
| | | | | i i oressional | /AI Cd | | | | | | Caused/Prolonged Hospitalisation), | 1{DF} - n/a]) | |
| | | | | | | | | | | | Nausea (n/a - Not | | |
| | | | | 1 | ı | l Control of the Cont | 1 | | | | I . | I | |

| Spontaneou Spontaneou | Spontaneous H | Healthcare Economics Area Healthcare Euro Professional Economics E | nomic | lot available | | Not | | | Hospitalisation) | | 1 |
|------------------------|-------------------|--|--------------------------------|---|-------------------------------------|---|---|---|---|--|---|
| D22 Spontaneou | | rofessional Eco | | | Years | 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 |
| | | Area | nomic | ot available | 12 - 17 Years | Adolescent | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | No |
| | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | | |
|)22 Spontaneou | Spontaneous H.P. | | nomic | lot available | 12-17 Years | Adolescent | Fema l e | No | Carpal tunnel syndrome (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular use]) | No |
| | | | nomic | ot available | 12-17 Years | Adolescent | Male | No | | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | No |
| O22 Spontaneou | Spontaneous H | | nomic | ot 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 |
| 022 Spontaneou | | | nomic | lot available | 12-17 Years | Adolescent | Male | No | Urticaria (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - | Not |
| 022 Spontaneou | | | nomic | lot available | 12 - 17 Years | Adolescent | Female | No | Menstrual disorder (n/a - Not Recovered/Not Resolved -) | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | Not |
| O22 Spontaneou | | | nomic | ot 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 |
| 022 Spontaneou | | | nomic | lot 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 |
| 022 Spontaneou | | | nomic | lot 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 |
| 022 Spontaneou | | | nomic | lot 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 |
| 022 Spontaneou | | | nomic | lot 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 |
| O22 Spontaneou | | lon Euro lealthcare Eco Professional Area | nomic | lot 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 |
| Spontaneou | | | nomic | lot 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 |
| O22 Spontaneou | | | nomic | lot 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 |
| 022 Spontaneou | | | nomic | lot available | 12-17 Years | Adolescent | Fema l e | No | Immunisation reaction (4d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not |
| 022 Spontaneou | | | nomic | lot 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 |
| O22 Spontaneou | | | nomic | lot 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 |
| O22 Spontaneou | Spontaneous H. Pr | | nomic | lot available | 12-17 Years | Adolescent | Male | No | Fatigue (n/a - Recovered/Resolved -), Incorrect dose administered (1d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 4{DF} - Intramuscular use]) | Not |
| | | | | | | | | | -), Vaccination site oedema (n/a - Recovered/Resolved | | |
| 322 Spontaneou | | Professional Euro Eco | opean nomic | iot available | | | Male | No | -) Abnormal behaviour (n/a - Unknown -), Encephalitis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Encephalopathy (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | No |
| 022 | | | Professional Eur Eco Are | Professional European Economic Area | Professional European Economic Area | Professional European Economic Area Years | Professional European Economic Area Specified | Professional European Economic Area Specified | Professional European Economic Area Specified | Spontaneous Healthcare Professional European Economic Area Not available Not available 12-17 Years Specified Not 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 With Sequelae - Caused/Prolonged Resolved With Sequelae - Caused/Prolonged Resolved With Sequelae - Caused/Prolonged Resolved Resolv | Spontaneous Healthcare Professional European Economic Area Not available Not available 12-17 Years Specified Not available Not available 12-17 Years Specified Not available Not available Not available Covered/Resolved (n/a - Unknown -), |

| Description | 0.11.2022 | 10.04 | | | | run | LIIIC L | isting it | port | | | | |
|--|-------------|------------|-------------|--------------|----------------------|---------------|---------|------------|--------|----|---|--|---------------------------|
| Button Part | | | | | | | | | | | Other Medically Important | | |
| Part | | | | | | | | | | | Nausea (n/a - Recovered/Resolved | | |
| E.E.C. 1007/2022 Sextences Part Exercised Part | | | | | | | | | | | Recovered/Resolved | | |
| B-EC 17(07)232 Sportness Recovery | | | | | | | | | | | (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important | | |
| | | | | | | | | | | | Unknown - Caused/Prolonged Hospitalisation, Other Medically | | |
| | | 07/07/2022 | Spontaneous | Healthcare | Economic | Not available | | Adolescent | Female | No | | - COVID-19 immunisation - n/a - | Not |
| EMEC. 10012943791 10707/2022 Sportaneous Months: European Not available 12-17 Not Not available 12-17 | | 07/07/2022 | Spontaneous | Healthcare | Economic | Not available | | Adolescent | Female | No | Recovered/Resolved -), | - COVID-19 immunisation - n/a - | Not |
| COVID-19 immunistation No. | | | | | | | | | | | Recovered/Resolved -) | | |
| EU-EC- 1017/20122 Sportaneous Healthcare European Pot available Professional European Pot available Professional European Pot available Professional European Professional | | 07/07/2022 | Spontaneous | Healthcare | Economic | Not available | | | | | Unknown -), | - COVID-19 immunisation - Not | Not |
| EU-EC 07/07/2022 Sportaneous Healthcare European Not available 12-17 Not Not available 12-17 Not Specified No Administration also Swelling (V/o) Uniform Not available 12-17 Not Not available 12-17 Not availab | | | | | | | | | | | product administration (n/a - | | |
| EU-EC- 10/12/943079 10/17/2022 Sportaneous Healthcare European Professional Not available 12-17 Not Professional Not Available 12-17 | | | | | | | | | | | | | |
| 10012943979 | | | | | | | | | | | swelling (n/a - | | |
| 10012943999 Professional Economic Professional Economic Professional European Not available 12-17 Not avai | 10012943077 | | | Professional | Economic Area | | Years | Specified | | | reaction (n/a - Unknown -) | - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) | Not |
| Healthcare European Professional Eur | 10012943094 | 07/07/2022 | Spontaneous | | Economic | Not available | | | Female | No | reaction (n/a - | - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) | Not |
| EU-EC- 1012943300 70/77/2022 Spontaneous Healthcare European Not available European Not available 12-17 Not years Specified No Administration (n/a - Unknown -) COVID-19 (manusation - n/a - 10/12943588 70/77/2022 Spontaneous Healthcare European Not available European Not available 12-17 Not years Specified No Ear pain (n/a - Unknown -) COVID-19 (manusation - n/a - 10/12943589 COVID-19 (manusation - Not available Covid-19 (manusation - Not ava | | 07/07/2022 | Spontaneous | Healthcare | European Economic | Not available | | | Male | No | Not Recovered/Not Resolved - Other Medically Important | - COVID-19 immunisation - Not | Not |
| EU-EC- 07/07/2022 Spontaneous Frofessional Economic Area Not available Not ava | | | | | | | | | | | schedule of product administration (n/a - | | |
| EU-EC- 10012943589 07/07/2022 Spontaneous Non Healthcare European Not available 12-17 Not Specified | | 07/07/2022 | Spontaneous | | Economic | Not available | | | Male | No | reaction (n/a - | - COVID-19 immunisation - n/a - | Not |
| Healthcare Driversional Healthcare European Not available 12-17 Not Specified Female Not available 12-17 Not Specified Female Not available 12-17 Not Specified Specif | | 07/07/2022 | Spontaneous | Healthcare | European Economic | Not available | | | Male | No | Ear pain (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |
| EU-EC- 10012944108 EU-EC- 10012944108 FUND The professional Area | | 07/07/2022 | Spontaneous | | Economic | Not available | | | Female | No | Injection site erythema (n/a - Not Recovered/Not | - COVID-19 immunisation - Not | Not |
| EU-EC- 10012943613 EU-EC- 10012944168 EU-EC- 10012944202 O7/07/2022 Spontaneous Particles Professional Read Professio | | | | | | | | | | | Lymphadenopathy (n/a - Not Recovered/Not | | |
| EU-EC- 10012943613 O7/07/2022 Spontaneous Professional Economic Area EU-EC- 10012944168 O7/07/2022 Spontaneous Professional Spontaneous Professio | | | | | | | | | | | Vaccination site pain (n/a - Not Recovered/Not | | |
| EU-EC- 10012944168 O7/07/2022 Spontaneous Non Healthcare Professional Non Non Healthcare Professional Non Healthcare Professional Non Non Non Healthcare Professional Non | | 07/07/2022 | Spontaneous | | Economic | Not available | | | | No | Amenorrhoea (n/a - | - COVID-19 immunisation - Not | Not |
| EU-EC- 10012944202 Spontaneous Non Healthcare Professional Healthcare Professional Not available European Healthcare Professional European Healthcare Professional Not available European Healthcare Professional Not available European Healthcare Professional European Healthcare Professional Not available European Healthcare Professional European | | 07/07/2022 | Spontaneous | Healthcare | European Economic | Not available | | | Male | No | Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |
| Professional Area | | 07/07/2022 | Spontaneous | | | Not available | | | Female | No | Unknown -) Body temperature | | [EXT |
| Headache (n/a - Unknown -), Pain in extremity | 10012944202 | | | | | | leais | Specified | | | Unknown -), Fatigue (n/a - | | VER COM CUT, RUB |
| Pain in extremity | | | | | | | | | | | Headache (n/a - | | FLO' CUT |
| | | | | | | | | | | | Pain in extremity | | ETH GEN ROC |
| | | | | | | | | | | | (i/a - Ulikiluwiii -) | | COM PRIM |
| | | | | | | | | | | | | | CAL' FLO' GEN |
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|-----------------------|------------|-------------|--|-------------------------------------|---|----------------|------------------|------------------|-----|--|--|--|
| | | | | | | | | | | | | VER FLO: PRII' GAR VER SAM ROC COI' PRII' [n/a ACH L. H HAR POW HER HOR POW II/a n/a |
| EU-EC- 10012944226 | 07/07/2022 | Spontaneous | Healthcare | European Economic | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |
| EU-EC- 10012944714 | 07/07/2022 | Spontaneous | Professional Healthcare Professional | Area 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 Hospitalisation, Other Medically Important Condition), Pyrexia (30d - Recovered/Resolved -) | applicable - [n/a - n/a] 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 Chee |
| EU-EC- 10012926814 | 06/07/2022 | Spontaneous | Healthcare Professional | | 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 -), Somnolence (24h - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | n/a Not |
| EU-EC- 10012927497 | 06/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | | 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 | Not available | | Not Specified | Male | No | Skin discolouration (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |
| EU-EC- 10012927533 | 06/07/2022 | Spontaneous | Healthcare Professional | Area 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 | applicable - [1d - n/a - n/a] TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not |

| 1.11.2022 | 15.34 | | | | Run | Line L | isting Re | eport | | | | |
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| | | | | | | | | | | 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 | Healthcare | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Colitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) | Not |
| | | | | | | | | | | Crohn's disease (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | | |
| 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), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Subcutaneous use]) | Not |
| | | | | | | | | | | Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), | | |
| | | | | | | | | | | Urinary incontinence (n/a - Recovered/Resolved -) | | |
| 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 - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use]) | Not |
| | | | | | | | | | | Unknown -), Vaccination site pain (n/a - Not Recovered/Not Resolved -) | | |
| EU-EC- 10012931651 | 06/07/2022 | Spontaneous | | 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: |
| 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | Not |
| | | | | | | | | | | Menstrual disorder (n/a - Not Recovered/Not Resolved -) | | |
| EU-EC- 10012931876 | | Spontaneous | 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 - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1(DF) - Intramuscular use]) | Not |
| | | | | | | | | | | Recovered/Resolved | | |
| EU-EC- 10012931885 | 06/07/2022 | Spontaneous | Healthcare | 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} - | 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 | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - | 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 -), | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 3{DF} - n/a]) | Not |
| | | | | | | | | | | Paraesthesia (n/a - Not Recovered/Not Resolved -) | | |
| 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 | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| | | | | | | | | | 1 | Condition) | | |

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| | | | | | | | | | | (n/a - Recovering/Resolving | | |
| | | | | | | | | | | -), Swelling (n/a - Recovering/Resolving | | |
| U-EC- 0012933293 | 06/07/2022 | Spontaneous | Non Healthcare | European Economic | Not available | 12-17 Years | Not Specified | Male | No | Fatigue (2d - Recovered/Resolved | - COVID-19 immunisation - Not | Not |
| | | | Professional | Area | | | · | | | -), Headache (3d - Recovered/Resolved | applicable - [1d - n/a - n/a]) | |
| :U-EC- .0012915706 | 05/07/2022 | Spontaneous | Healthcare Professional | Non European Economic | Not available | 12-17 Years | Not Specified | Male | No | Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged | - COVID-19 immunisation - Not applicable - [1d - n/a - | Not |
| U-EC- 0012916096 | 05/07/2022 | Spontaneous | Healthcare Professional | Non European Economic | Not available | 12-17 Years | Not Specified | Male | No | Hospitalisation) Syncope (15min - Recovered/Resolved - Other Medically | - COVID-19 immunisation - Not applicable - [n/a - n/a - | Not |
| U-EC- 0012916114 | 05/07/2022 | Spontaneous | Healthcare Professional | Area European Economic | Not available | 12-17 Years | Not Specified | Not Specified | No | Important Condition) Petechiae (n/a - Unknown -), | - COVID-19 immunisation - Not | Not |
| | | | | Area | | | | | | Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | applicable - [n/a3mL - Intramuscular use]) | |
| :U-EC- 0012916803 | 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 - | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | 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) | | |
| 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not |
| | | | | | | | | | | Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | | |
| U-EC- 0012917015 | 05/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | -), Urticaria (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a3mL - Intramuscular use]) | Not |
| U-EC- 0012917459 | 05/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Unknown -) Cough (2d - Unknown -), Oropharyngeal pain | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a3mL - Intramuscular use]) | Not |
| | | | | | | | | | | (n/a - Unknown -), Pyrexia (n/a - | | |
| | | | | | | | | | | Unknown -), Rhinorrhoea (n/a - Unknown -), | | |
| | | | | | | | | | | Vaccination site reaction (n/a - Unknown -) | | |
| :U-EC- 0012917516 | 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 - | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a3mL - Intramuscular use]) | Not |
| EU-EC- 10012917538 | 05/07/2022 | Spontaneous | Healthcare Professional | European Economic | Not available | 12-17 Years | Not Specified | Female | No | Unknown -) Pyrexia (n/a - Unknown -) | - COVID-19 prophylaxis - n/a - | Not |
| U-EC- 0012917598 | 05/07/2022 | Spontaneous | Healthcare Professional | Non European Economic | Not available | 12-17 Years | Adolescent | Female | No | Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important | [n/a3mL - Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - n/a]), | Not |
| | | | | Area | | | | | | Condition), Erythema (n/a - Not Recovered/Not | IBUPROFEN [IBUPROFEN, IBUPROFEN SODIUM] (S - Premenstrual syndrome - Unknown - [n/a - n/a - n/a]), | |
| | | | | | | | | | | Resolved - Other Medically Important Condition), | [IBUPROFEN, IBUPROFEN LYSINE, IBUPROFEN PH. EUR., IBUPROFEN SODIUM, | |
| | | | | | | | | | | Inappropriate schedule of product administration (n/a - Unknown -), | IBUPROFEN SODIUM DIHYDRATE] (S - Product used for unknown indication - Unknown - [3d - n/a - n/a]), | |
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| | | | | | | | | | | | 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 | | 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/a3mL - Intramuscular use]) | Not |
| | EU-EC- 10012917851 | 05/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Myocarditis (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Subcutaneous use]) | Not |
| | 10012917984 | | Spontaneous | Healthcare Professional | 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), 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), | - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| | 10012918199 | | Spontaneous | Healthcare Professional | Economic | Not available | Years | Not Specified | Female | No | Headache (n/a - Not Recovered/Not Resolved -), Nausea (0d - Recovered/Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -) | - 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), Disabling), Dizziness (n/a - Not Recovered/Not Resolved - Disabling), Eye pain (n/a - Not Recovered/Not Resolved - Disabling), Eye pain (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Fatigue (n/a - Not Recovered/Not Resolved - Disabling), Headache (n/a - Not Redovered/Not Resolved - Disabling), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |

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| | | | | | | | | | | 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 | Healthcare | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Asthenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | Not |
| | | | | | | | | | | Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10012918688 | 05/07/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Dyspnoea (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | Fatigue (n/a - Recovered/Resolved -) | | |
| 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | Not |
| | | | | | | | | | | Swelling (n/a - Unknown -), | | |
| | | | | | | | | | | Vaccination site reaction (n/a - Unknown -) | | |
| 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | Influenza (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Insomnia (n/a - Not Recovered/Not Resolved -) | | |
| 10012919790 | | Spontaneous | Healthcare Professional | European Economic Area | Not available | Years | Not Specified | | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -) | - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not |
| EU-EC- 10012920255 | 05/07/2022 | Spontaneous | Healthcare Professional | | Not available | | Not Specified | Male | No | Anxiety (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular use]) | Not |
| | | | | | | | | | | Dizziness (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Headache (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Vaccination site reaction (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Vomiting (n/a - Recovered/Resolved -) | | |
| 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 | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intraocular use]) | Not |
| EU-EC- 10012920713 | 05/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | (n/a - Unknown -) Malaise (n/a - Recovering/Resolving - Other Medically | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - | Not |
| | | | | | | | | | | Important Condition), | Intramuscular use]) | |
| | | | | | | | | | | Tonic clonic movements (n/a - Recovering/Resolving - Other Medically Important Condition) | | |
| EU-EC- 10012920722 | 05/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Fatigue (48d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | Not |
| | | | | | | | | | | Hypersomnia (48d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10012920975 | 05/07/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | | 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 -) | | Not |
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|---------------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|--------|----|--|---|------|
| 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/Resolving -), Tremor (n/a - Recovering/Resolving | 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 | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - | Not |
| EU-EC- 10012921174 | 05/07/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Resolved -) Amenorrhoea (n/a - Not Recovered/Not Resolved -), | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use]) | No |
| | | | | | | | | | | Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -) | Industrial design | |
| 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 | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use]) | No |
| | 05/07/2022 | Spontaneous | | European | Not available | 12-17 | Adolescent | Female | No | - Not Recovered/Not Resolved -) Urticaria (2d - | COMIRNATY [TOZINAMERAN] (S | No |
| 10012921266 EU-EC- | 05/07/2022 | Spontaneous | Professional | Economic Area European | Not available | Years | Not | Female | No | Recovered/Resolved -) Bell's palsy (n/a - | - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use]) COMIRNATY [TOZINAMERAN] (S | |
| 10012921802 | 03/07/2022 | эропшпсоиз | Professional | Economic Area | not available | Years | Specified | remale | No | Not Recovered/Not Resolved - Other Medically Important Condition), | - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | |
| | | | | | | | | | | 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 -), | | |
| EU-EC- | 05/07/2022 | Spontaneous | Non | European | Not available | 12-17 | Not | Male | No | Product use issue (n/a - Unknown -) Chest pain (2d - | COMIRNATY [TOZINAMERAN] (S | No |
| 10012921822 | ,, | | Healthcare | Economic Area | | Years | Specified | | | Recovered/Resolved -), | - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | |
| | | | | | | | | | | 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 | | |
| EU-EC- 10012921862 | 05/07/2022 | Spontaneous | Non Healthcare Professional | European Economic | Not available | 12-17 Years | Not Specified | Male | No | Illness (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | No |
| | | | riolessional | Alea | | | | | | Pyrexia (n/a - Unknown -), | applicable - [1u - II/a - II/a]) | |
| EU-EC- | 05/07/2022 | Spontaneous | Non | European | Not available | 12-17 | Not | Female | No | Somnolence (n/a - Unknown -) Vaccination site | COMIRNATY [TOZINAMERAN] (S | No |
| 10012922403 EU-EC- | | Spontaneous | Healthcare Professional | Economic Area European | Not available | Years | Specified | Female | No | urticaria (n/a - Unknown -) Cardiovascular | - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S | |
| 10012922417 | 33,37,2022 | Sportaneous | Healthcare | Economic | тес ачания. | Years | Specified | Cindle | | disorder (n/a - Unknown -), | - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | 1401 |
| | | | | | | | | | | Dizziness (n/a - Unknown -), | | |

| | | | | | | | | | | Pyrexia (n/a - Unknown -) | |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|----------------|----------------|------------------|-----------------|-----|---|---|
| U-EC- 0012922419 | 05/07/2022 | Spontaneous | | 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]) |
| J-EC- 0012922446 | 05/07/2022 | Spontaneous | Non Healthcare Professional | Economic | 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]) |
| -EC- 012922491 | 05/07/2022 | Spontaneous | | Non | Not available | 12-17 Years | Not Specified | Male | No | Abdominal pain (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) |
| | | | | | | | | | | 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 -) | |
| U-EC- 0012922972 | 05/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chills (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| | | | | | | | | | | Fatigue (n/a - Recovered/Resolved -), | |
| | | | | | | | | | | Myalgia (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not | |
| U-EC- | 05/07/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Fema l e | No | Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S |
| 0012922984 | 03/07/2022 | Sportaneous | Professional | | NOL available | Years | Specified | remaje | INO | - | COMINIANT I (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| U-EC- | 05/07/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Ma l e | No | Recovered/Resolved -) Diarrhoea (n/a - | COMIRNATY [TOZINAMERAN] (S |
| 0012922993 | 03/07/2022 | Spontaneous | Professional | | Not available | Years | Specified | male. | No | Unknown -), Headache (n/a - Unknown -), Pain in extremity | - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) |
| | | | | | | | | | | (n/a - Unknown -), Vomiting (n/a - | |
| U-EC- 0012923005 | 05/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Unknown -) Rash pruritic (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| | | | | | | | | | | Urticaria (n/a - Recovered/Resolved -) | |
| U-EC- (0012923027 | 05/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | Yes | Epistaxis (n/a - Recovered/Resolved -), Headache (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) |
| U-EC- | 05/07/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Fema l e | No | Recovered/Resolved -) Alopecia (n/a - Not | COMIRNATY [TOZINAMERAN] (S |
| 0012923220 | 03/07/2022 | эропапева | Professional | | The distribute | Years | Specified | remaie | | Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | - n/a - n/a - [n/a - n/a - n/a]) |
| | | | | | | | | | | 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), | |
| | | | I | I | | | I | | | | |

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| | | | | | | | | | | 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 | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Fatigue (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Myalgia (n/a - Recovering/Resolving -) | | |
| EU-EC- 10012902547 | 04/07/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Abdominal pain upper (n/a - Not Recovered/Not Resolved -), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | 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 -) | | |
| 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 | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dizziness (n/a - Unknown -), Dyspnoea (n/a - Not Recovered/Not Resolved - Disabling), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | Educational problem (n/a - Unknown -), Fatigue (n/a - | | |
| | | | | | | | | | | Recovering/Resolving - Disabling), Headache (n/a - Not Recovered/Not | | |
| | | | | | | | | | | Resolved - Disabling), Impaired quality of | | |
| EU-EC- | 04/07/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Not | No | life (n/a - Unknown -) Headache (n/a - | COMIRNATY [TOZINAMERAN] (S | Not |
| 10012903921 | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | 9,000 | | Economic Area | | Years | Specified | Specified | | Unknown -), Myalgia (n/a - Unknown -), | - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | |
| | | | | | | | | | | Pyrexia (72h - Recovered/Resolved -) | | |
| 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/a3mL - 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) | | 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3{DF} - n/a]) | Not |
| | | | | | | | | | | Pain in extremity (1d - Recovered/Resolved -) | | |
| EU-EC- 10012906041 | 04/07/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not |
| | | | | | | | | | | Arthralgia (n/a - Fatal - Results in Death, Caused/Prolonged | | |
| | | | | | | | | | | Hospitalisation), Myalgia (n/a - Fatal - | | |
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| | | | | | | | | | | 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 -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | Not |
| | | | | | | | | | | Goitre (n/a - Not Recovered/Not Resolved -) | | |
| EU-EC- 10012908232 | 04/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Ma l e | 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), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | Not |
| | | | | | | 10.17 | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10012908745 | 04/0//2022 | Spontaneous | 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), | [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | 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) | | |
| 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 -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | | |
| EU-EC- 10012909781 | 04/0//2022 | Spontaneous | Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | Not |
| | | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10012909858 | 04/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Dyspnoea (5d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular use]) | Not |
| | | | | Aicu | | | | | | Headache (5d - Recovered/Resolved -), | [iya isine maanasedal ase]) | |
| | | | | | | | | | | Pain in extremity (5d - Recovered/Resolved | | |
| EU-EC- | 04/07/2022 | Spontaneous | | European | Not available | 12-17 | Adolescent | Male | No | Syncope (n/a - | COMIRNATY [TOZINAMERAN] (S | Not |
| 10012910210 | | | Professional | Economic Area | | Years | | | | Unknown - Other Medically Important Condition) | - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use]) | |
| EU-EC- 10012910544 | 04/07/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Dysmenorrhoea (3d - Recovered/Resolved -), Heavy menstrual | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use]) | Not |
| | | | | | | | | | | bleeding (3d - Recovered/Resolved -) | | |
| EU-EC- 10012910610 | | Spontaneous | 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 | European Economic | Not available | 12-17 Years | Adolescent | Male | No | Herpes zoster (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S | Not |
| | | | | | | | | | | | | |

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| | | | Professional | Area | | | | | | -) | applicable - [1d - 1{DF} - Intramuscular use]) | |
| EU-EC- 10012910730 | 04/07/2022 | Spontaneous | | 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 | | Not |
| EU-EC- 10012910913 | 04/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Resolved -) Angioedema (n/a - Recovering/Resolving -) | | Not |
| EU-EC- 10012911041 | 04/07/2022 | Spontaneous | | 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 - | | Not |
| EU-EC- 10012911535 | 04/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Unknown -) COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | Not |
| EU-EC- 10012912169 | 04/07/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Important Condition) 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 | | 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 -), Erzthema (2wk - Recovered/Resolved -), Erythema (1d - Recovered/Resolved -), Erythema (2wk - Recovered/Resolved -), Hypersensitivity (2wk - Recovered/Resolved -), Peripheral swelling (2wk - Recovered/Resolved -), Peripheral swelling (2wk - Recovered/Resolved -), Pyrexia (5d - Recovered/Resolved -), Swelling face (2wk - Recovered/Resolved -), Urticaria (2wk - Recovered/Resolved -) | | 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 |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|---------------|-----|---|--|-----------------------|
| | | | | | | | | | | Palpitations (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition) | | |
| :U-EC- 0012913204 | 04/07/2022 | Spontaneous | Non Healthcare Professional | Economic | Not available | 12-17 Years | Adult | Female | No | Asthenia (n/a - Unknown -), Disturbance in | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | attention (n/a - Unknown -), Fatigue (n/a - Unknown -), | | |
| | | | | | | | | | | Headache (n/a - Unknown -) | | |
| :U-EC- 0012913296 | 04/07/2022 | Spontaneous | Non Healthcare Professional | | 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 |
| :U-EC- 0012913528 | 04/07/2022 | Spontaneous | Non Healthcare Professional | Economic | Not available | 12-17 Years | Not Specified | Ma l e | No | Drug ineffective (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition) | | |
| :U-EC- .0012913929 | 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), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | [EPI n/a [NO n/a n/a] |
| | | | | | | | | | | Asthenia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | Ches n/a |
| | | | | | | | | | | 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), | | |

| 30.11.2022 15.34 | Run | Line Listing Re | port | | | |
|---|---------------|-----------------|---------|--|---|------------|
| | | | | Multi-organ disorder (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | Multiple organ dysfunction syndrome (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | Myocardial ischaemia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | Myocarditis (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | Pulseless electrical activity (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | Renal failure (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | Rhinovirus infection (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| EU-EC- 04/07/2022 Spontaneous Non Non | Not available | 12-17 Not | Male No | Ventricular tachycardia (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition) Chest discomfort | COMIRNATY [TOZINAMERAN] (S | [СНІ |
| 10012914351 Healthcare Professional Economic Area | | Years Specified | | (n/a - Not | - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | MAL [3d |
| | | | | Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | |
| | | | | Dizziness (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | |
| | | | | Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | |
| | | | | Fatigue (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | |
| https://dap.ema.europa.eu/analytics/saw.dll?Go | | | | Inappropriate | | 5/62 |

| 30.11.2022 | 10.01 | | | | T Carr | | isting it | port | | | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|------------------|----|--|--|---------------------------|
| | | | | | | | | | | 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 | | | Not available | 12-17 Years | Adolescent | Ma l e | No | Vaccination site inflammation (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |
| EU-EC- 10012914632 | 04/07/2022 | Spontaneous | Non Healthcare Professional | Area Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Unknown -) Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), | applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 30ug - n/a]) | Not |
| | | | | | | | | | | Overdose (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | | Product preparation error (n/a - Unknown - Other Medically Important Condition) | | |
| 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 | Healthcare | European Economic Area | Not available | | Not Specified | Male | No | Asthenia (n/a - | [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) | [BEODIP - n/ |
| | | | | | | | | | | Fatigue (n/a - Recovering/Resolving - Other Medically Important | | PRO Hyp [n/a |
| | | | | | | | | | | Condition), Rash (n/a - Not Recovered/Not Resolved - Other | | Hyp [n/a [PH PHL |
| | | | | | | | | | | Medically Important Condition) | | PRA PHL POL TIM |
| | | | | | | | | | | | | EXT Hyp [n/a |
| EU-EC- 10012892863 | 01/07/2022 | Spontaneous | Healthcare | 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]) | - n/ Not |
| EU-EC- 10012893261 | 01/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Not Specified | No | Vaccination site erythema (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use]) | Not |
| | | | | | | | | | | 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 -), | | |
| ELLEC | 01/07/2022 | Coortes | Uoolikka | Europe | Net voilable | 12.47 | Not | Eoma': | Ne | Vaccination site warmth (n/a - Not Recovered/Not Resolved -) | COMIDNATY FTOTTMANERALS (2) | Nici |
| EU-EC- 10012893742 | 01/0//2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Lymphadenopathy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | Not |
| nttos://dap.e | | | | | | | | | | Vaccination site joint movement impairment (n/a - | | |

| | | | | | | | | | | Recovered/Resolved - Caused/Prolonged | | |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|--|--|-----|
| EU-EC- 10012893854 | 01/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Hospitalisation) Blood pressure decreased (n/a - Unknown - Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use]) | No |
| | | | | | | | | | | 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) | | |
| EU-EC- 10012893952 | 01/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Headache (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | No |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | |
| EU-EC- 10012894026 | 01/07/2022 | Spontaneous | Healthcare | 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]) | No |
| EU-EC- 10012894425 | 01/07/2022 | Spontaneous | | 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]) | No |
| EU-EC- 10012894982 | 01/07/2022 | Spontaneous | | European Economic Area | Not available | | Not Specified | Male | No | Pyrexia (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | No |
| EU-EC- 10012895273 | 01/07/2022 | Spontaneous | | 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]) | No |
| EU-EC- 10012895284 | 01/0//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 | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | No |
| EU-EC- | 01/07/2022 | Spontaneous | Hoaltheare | Non | Not available | 12-17 | Not | Male | No | Nausea (4h - Recovered/Resolved -), Vomiting (4h - Recovered/Resolved -) Blood pressure | COMIRNATY [TOZINAMERAN] (S | No |
| 10012895743 | 01/07/2022 | | | European Economic Area | NOC available | | Specified | Male | NO | decreased (0d - Recovered/Resolved -), Heart rate decreased (n/a - Recovered/Resolved -), Pallor (n/a - | COMINIATI (Incidentification - Not applicable - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | Recovered/Resolved -), Syncope (0d - Recovered/Resolved - Other Medically Important Condition) | | |
| EU-EC- 10012896349 | υ1/υ7/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | ıMale | 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]) | No |
| EU-EC- 10012896394 | 01/07/2022 | Spontaneous | | European Economic Area | Not available | | Not Specified | Female | No | Gastritis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3{DF} - n/a]) | No |
| ļ | | | | | | | | | | Migraine (n/a - Not Recovered/Not Resolved - | | |
| | | | | | | | | | | Caused/Prolonged Hospitalisation) | | |

| .11.2022 | 15.54 | | | | Run | Line L | isting Re | port | | | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|--|----------------|------------------|---------------|-----|---|--|-----|
| EU-EC- 10012897972 | 01/07/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | Yes | COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| | | | | | | | | | | Drug ineffective (n/a - Unknown - Other Medically Important Condition) | | |
| U-EC- 0012897982 | 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | No |
| | | | | | | | | | | Headache (n/a - Unknown -), | | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown -), Pruritus (n/a - | | |
| | | | | | | | | | | Unknown - Other Medically Important Condition), | | |
| | | | | _ | | | | | | Somnolence (n/a - Unknown -) | | 1 |
| :U-EC- 0012898065 | 01/07/2022 | Spontaneous | | 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] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | |
| EU-EC- 10012898453 | 01/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | Yes | Polyarthritis (7d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a3mL - Intramuscular use]) | Not |
| EU-EC- 10012898696 | 01/07/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | 1 | |
| | | | | | | | | | | Pain in extremity (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10012904359 | 01/07/2022 | Spontaneous | | 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), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Myocarditis (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Pneumonia mycoplasmal (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | |
| EU-EC- 10012905875 | 01/07/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Ma l e | No | Dermatitis atopic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use]) | Not |
| | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition) | | |
| 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 | | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Labyrinthitis (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use]) | Not |
| EU-EC- 10012906771 | 01/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Haemophagocytic lymphohistiocytosis (30d - Not Recovered/Not Resolved - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | Not |
| EU-EC- 10012906999 | 01/07/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Hospitalisation) 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 | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Syncope (31min - Recovered/Resolved - Other Medically | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not |
| EU-EC- 10012907440 | 01/07/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dizziness (64min - Recovered/Resolved -), Syncope (64min - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not |

| | | | | | | | | | | - Other Medically Important Condition) | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---|----------------|------------------|--------|----|--|--|-----|
| EU-EC- 10012881486 | 30/06/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | No |
| EU-EC- 10012881845 | 30/06/2022 | Spontaneous | Healthcare Professional | European Economic | Not available | 12-17 Years | Adolescent | Male | No | Vaccination failure (n/a - Unknown - Other Medically Important Condition) COVID-19 (n/a - Unknown - Other | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | No |
| | | | | Area | | | | | | Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically | Intramuscular use]) | |
| EU-EC- 10012882458 | 30/06/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Important Condition) Application site pain (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | No |
| | | | | | | | | | | Application site warmth (n/a - Not Recovered/Not Resolved -) | | |
| 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]) | No |
| 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), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | Parapsoriasis (n/a - Recovered/Resolved - Other Medically | | |
| EU-EC- 10012886123 | 30/06/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Important Condition) Immune thrombocytopenia (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id - 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 | Important Condition) Chest pain (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (4d - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | No |
| | | | | | | | | | | Recovered/Resolved - Caused/Prolonged Hospitalisation) | | |
| 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]) | No |
| 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 | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not |
| | | | | | | | | | | decreased (10h - Recovered/Resolved -), Pyrexia (10h - Recovered/Resolved | | |
| 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | No |
| | | | | | | | | | | 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 -), | | |

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| | | | | | | | | | | 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 | | 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| EU-EC- | 30/06/2022 | Spontaneous | Healthcare | Non | Not available | 12-17 | Not | Female | No | Cough (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S | Not |
| 10012887542 | 30/00/2022 | Spontaneous | Professional | | NOT available | Years | Specified | remale | NO | thrombosis (n/a - Unknown - Other Medically Important Condition) | - 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), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| | | | | | | | | | | Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition), | | |
| | | | | | | | | | | Vaccine breakthrough infection (n/a - Recovered/Resolved - Other Medically Important Condition) | | |
| EU-EC- 10012887848 | 30/06/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | | Not Specified | Female | No | Rash (90min - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | Rash erythematous (90min - Recovered/Resolved - Other Medically Important Condition), | | |
| | | | | | | | | | | Rash pruritic (90min - Recovered/Resolved - Other Medically Important Condition), | | |
| EU-EC- | 20/06/2022 | Spontaneous | Non | European | Not available | 12-17 | Not | Ma l e | No | Urticaria (n/a - Unknown -) Malaise (n/a - | COMIRNATY [TOZINAMERAN] (S | Not |
| 10012887968 | 30/00/2022 | Spontaneous | Healthcare Professional | Economic Area | NUL available | | Specified | Male | NO | Unknown -), Product quality issue (n/a - Unknown -) | - 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 | | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | |
| | | | | | | | | | | Lymphadenopathy (n/a - Recovering/Resolving - Other Medically Important Condition) | | |
| 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), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [36d - 2{DF} - n/a]) | Not |
| | | | | | | | | | | Ecchymosis (n/a - Unknown - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Headache (n/a - Unknown - | | |

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| | | | | | | | | | | Caused/Prolonged Hospitalisation), Paresis (n/a - | | |
| | | | | | | | | | | Unknown - Caused/Prolonged | | |
| EU-EC- 10012888988 | 30/06/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Hospitalisation) Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use]) | |
| | | | | | | | | | | 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) | | |
| 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]) | No |
| EU-EC- 10012889234 | 30/06/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Adolescent | Ma l e | No | Lymphadenopathy (5d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not |
| EU-EC- | 20/06/2022 | Spontaneous | Non | European | Not available | 12-17 | Child | Female | No | Vaccination site pain (7d - Recovered/Resolved -) Vaccination site pain | COMIRNATY [TOZINAMERAN] (S | No |
| 10012889235 | 30/06/2022 | Sportaneous | Healthcare Professional | European Economic Area | Not available | Years | Cilia | remale | INO | (2d - Recovered/Resolved -) | - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | INO |
| EU-EC- 10012889236 | 30/06/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Child | Ma l e | No | Pain (2d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | No |
| | | | | | | | | | | Vaccination site pain (2d - Recovered/Resolved -) | | |
| 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]) | No |
| EU-EC- 10012889239 | 30/06/2022 | Spontaneous | Non Healthcare Professional | Economic | Not available | 12-17 Years | Adolescent | Female | No | Myalgia (1d - Recovered/Resolved -), Pain (1d - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | No |
| | | | | | | | | | | Recovered/Resolved -), Vaccination site pain | | |
| | | | | | | | | | | (1d - Recovered/Resolved -) | | |
| 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not |
| | | | | | | | | | | Vaccination site swelling (1d - Recovered/Resolved -) | | |
| 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | No |
| | | | | | | | | | | Vaccination site pain (2d - Recovered/Resolved -) | | |
| 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | No |
| | | | | | | | | | | Pain (1d - Recovered/Resolved -), | | |
| | | | | | | | | | | Skin reaction (1d - Recovered/Resolved -) | | |
| 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 | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not |
| | | | | | | | | | | (1d - Recovered/Resolved -) | | |
| EU-EC- 10012889249 | 30/06/2022 | Spontaneous | Non Healthcare | European Economic | Not available | 12-17 Years | Adolescent | Female | No | Myalgia (1d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | No |

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|---------------------|---------|-------------|-----------------------------------|-------------------------------------|---|----------------|------------------|--------|----|--|---|------------------------------|
| | | | | | | | | | | Pain (1d - Recovered/Resolved | | |
| | | | | | | | | | | Vaccination site pain | | |
| | | | | | | | | | | (1d - Recovered/Resolved -) | | |
| EU-EC- 100128892 | | Spontaneous | | 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- 100128892 | | Spontaneous | Non Healthcare Professional | European Economic | Not available | 12-17 Years | Adolescent | Female | No | Adnexa uteri pain (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not |
| | | | | | | | | | | // Menstruation delayed (n/a - Recovering/Resolving -) | | |
| EU-EC- 100128892 | | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Anaemia (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not |
| | | | | | | | | | | Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -) | | |
| EU-EC- 100128893 | | 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- 100128893 | | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Dysmenorrhoea (n/a - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not |
| | | | | | | | | | | Headache (n/a - Recovered/Resolved | | |
| | | | | | | | | | | Pain in extremity (n/a - Recovered/Resolved | | |
| EU-EC- | | Spontaneous | | Non | Dawoud, N The first case report of Pityriasis | | Not | Male | No | Parapsoriasis (n/a - | TOZINAMERAN [TOZINAMERAN] | Not |
| 100128894 | 23 | | Professional | European Economic Area | lichenoides chronica following COVID-19 mRNA vaccination. Dermatologic Therapy. 2022;35(6):10.1111/dth.15445. doi:10.1111/dth.15445 | Years | Specified | | | Recovered/Resolved - Other Medically Important Condition) | (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | |
| EU-EC- 100128898 | | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | | Not Specified | Male | No | COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not |
| | | | | | | | | | | Vaccination failure (n/a - Recovered/Resolved - Other Medically Important Condition) | | |
| EU-EC- 100128916 | | 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 | | Not Specified | Female | No | Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | [CET DIH' Rhin Oral |
| | | | | | | | | | | 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) | | |

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|-----------------------|-------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|-----------------|----|---|--|-----|
| | | | | | | | | | | Pyrexia (n/a - Unknown -), | | |
| | | | | | | | | | | Seizure (0d - Recovered/Resolved - Other Medically Important Condition) | | |
| EU-EC- 10012870159 | 29/06/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Back pain (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not |
| | | | | | | | | | | Body temperature increased (1d - Recovered/Resolved -), | | |
| | | | | | | | | | | Fatigue (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Headache (2d - Recovered/Resolved -) | | |
| EU-EC- 10012870780 | 29/06/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | | 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 | | Not Specified | Female | No | Antinuclear antibody positive (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]) | |
| | | | | | | | | | | Antisynthetase syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), | | |
| | | | | | | | | | | Juvenile polymyositis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling) | | |
| 10012871505 | | | Professional | Non European Economic Area | Not available | 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]) | |
| EU-EC- 10012871851 | 29/06/2022 | | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Fema l e | No | Arthralgia (n/a - Unknown -), Chills (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not |
| | | | | | | | | | | 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 -), | | |
| EU-EC- | 29/06/2022 | Spontaneous | Non | European | Not available | 12-17 | Not | Male | No | Skin disorder (n/a - Unknown -) Chest discomfort | COMIRNATY [TOZINAMERAN] (S | Not |
| 10012871914 | 23,030,2022 | | | Economic | | | Specified | | | (n/a - Recovered/Resolved -), Chest pain (n/a - | - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | Recovered/Resolved -), Sleep disorder due to general medical condition, insomnia type (n/a - Recovered/Resolved | | |
| EU-EC- 10012871933 | 29/06/2022 | Spontaneous | | Non European Economic | Not available | 12-17 Years | Not Specified | Female | No | -) Back pain (n/a - Recovering/Resolving - Other Medically | 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 | Years | Adolescent | | No | Syncope (0d - 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 | | European Economic | Not available | | Not Specified | Female | No | Swelling of eyelid (n/a - Not Recovered/Not Resolved -) | | 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not |
| | | | | | | | | | | | 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 | | |
| | EU-EC- 10012872745 | 29/06/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | | Not Specified | Ma l e | No | Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular]) | Not |
| | | | | | | | | | | | 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 -) | | |
| | EU-EC- 10012872917 | 29/06/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | | Not Specified | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -) | - Immunisation - n/a - [n/a - n/a - Intramuscular]) | [LEV LEV(SOD Hyp [n/a |
| | EU-EC- 10012873191 | 29/06/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | | Not Specified | Male | No | - Caused/Prolonged | | Not |
| | | | | | | | | | | | Hospitalisation), Pyrexia (n/a - Recovering/Resolving | - | |
| | | 29/06/2022 | Spontaneous | | Non | Not available | | Not | Ma l e | No | - Caused/Prolonged Hospitalisation) COVID-19 (n/a - | TOZINAMERAN [TOZINAMERAN] | Not |
| 1 | 10012874857 | | | Healthcare Professional | European Economic Area | | Years | Specified | | | | (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | |

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| | | | | | | | | | | Drug ineffective (n/a | | |
| | | | | | | | | | | Recovering/Resolving Other Medically | | |
| EU-EC- 10012875345 | 29/06/2022 | Spontaneous | Non Healthcare | European Economic | Not available | | Not Specified | Female | No | Important Condition) Insomnia (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |
| EU-EC- | 29/06/2022 | Spontaneous | Professional Non | Area European | Not available | 12-17 | Not | Female | No | Resolved -) Drug ineffective (n/a | applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S | Not |
| 10012875347 | | | Healthcare Professional | Economic Area | | Years | Specified | | | Condition), | - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR]) | |
| | | | | | | | | | | Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10012875358 | 29/06/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | | Not Specified | Male | No | Abdominal pain (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-/ n/a n/a |
| | | | | | | | | | | 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) | | |
| 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 | | Not Specified | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Drug ineffective (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10012876791 | 29/06/2022 | Spontaneous | | European Economic Area | Not available | | Not Specified | Fema l e | No | Arthralgia (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not |
| | | | | | | | | | | Recovered/Not Resolved -), Nausea (n/a - Not | | |
| | | | | | | | | | | Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not | | |
| EU-EC- 10012877021 | 29/06/2022 | Spontaneous | Non Healthcare Professional | European Economic | Not available | 12-17 Years | Adolescent | Female | No | Resolved -) Headache (1d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - | Not |
| | | | Trolessional | 71100 | | | | | | Loss of consciousness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | Intramuscular]) | |
| | | | | | | | | | | Tonic convulsion (1d Recovered/Resolved | | |
| | | | | | | | | | | - Caused/Prolonged Hospitalisation), Tremor (1d - Recovered/Resolved | | |
| EU-EC- 10012877297 | 29/06/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) | Not |
| | | | | | | | | | | Polymenorrhoea (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Vomiting (5d - Recovered/Resolved -) | | |
| 10012877314 | | Spontaneous | Professional | European Economic Area | Not available | 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- | 29/06/2022 | Spontaneous | Non | European | Not available | 12-17 | Adolescent | Male | No | Back pain (n/a - Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not |

|).11.2022 | 15.34 | | | | Kui | | isting Re | eport | | 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 | Healthcare | 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 -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not |
| | | | | | | | | | | Skin reaction (3d - Recovered/Resolved -), Somnolence (3d - Recovered/Resolved | | |
| EU-EC- 10012877331 | 29/06/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Chi l d | 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 | Healthcare | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Immunisation reaction (5d - Recovered/Resolved -) | | 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 | | European Economic Area | Not available | 12-17 Years | Child | Ma l e | No | -) Pain (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id - 1{DF} - Intramuscular]) | Not |
| EU-EC- 10012877337 | 29/06/2022 | Spontaneous | | 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 - [Id - 1{DF} - Intramuscular]) | Not |
| EU-EC- 10012877338 | 29/06/2022 | Spontaneous | Healthcare | 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 | Healthcare | 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 | Ma l e | 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 - | 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 | Recovered/Resolved -) COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Recovered/Resolved | 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 | - Other Medically Important Condition) Facial paralysis (n/a - | COMIRNATY [TOZINAMERAN] (S | Not |

| 0.11.2022 | 10.0 | | | | i tan | | isting Re | Sport | | | | |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|--------|----|---|--|----|
| 10012877947 | | | Professional | European Economic Area | | Years | Specified | | | Recovered/Resolved - Other Medically Important Condition), Pericarditis (n/a - | - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | Recovered/Resolved - Other Medically Important Condition) | | |
| EU-EC- 10012878312 | 29/06/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | | Not Specified | Male | No | Myalgia (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | No |
| | | | | | | | | | | Vaccination site lymphadenopathy (n/a - Not Recovered/Not Resolved -) | | |
| 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), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) | No |
| | | | | | | | | | | 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) | | |
| 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), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | No |
| | | | | | | | | | | 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 | | |
| EU-EC- 10012879320 | 29/06/2022 | Spontaneous | | Non European | Not available | | Not | Female | No | Hospitalisation) Acute disseminated encephalomyelitis | COMIRNATY [TOZINAMERAN] (S | No |
| 100120/3320 | | | Professional | Economic Area | | Years | Specified | | | (34d - Recovered/Resolved - Caused/Prolonged Hospitalisation, | - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | |

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|----|-----------------------|------------|-------------|-----------------------------------|------|---------------|--------|------------------|--------|----|--|--|-----|
| | | | | | | | | | | | 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 | | Not available | | Not Specified | Female | No | Ageusia (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), | Not |
| | | | | | Area | | | | | | Anosmia (n/a - Not Recovered/Not Resolved -) | IDIPHTHERIA TOXOID, TETANUS TOXOID, HAEMOPHILUS TYPE B CONJUGATE), PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, ALGELDRATE, DIPHTHERIA TOXOID, TETANUS TOXOID, HAEMOPHILUS TYPE B CONJUGATE (TETANUS TOXOID CONJUGATE), PERTUSSIS TOXOID, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ, PERTUSSIS PERTACTIN, POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN), POLIOVIRUS (INACTIVATED) TYPE 2 (MEF-1 STRAIN), POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN), DIPHTHERIA TOXOID, TETANUS TOXOID, HAEMOPHILUS TYPE B CONJUGATE), PERTUSSIS TOXOID, PERTUSSIS PERTACTIN, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 1 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 1 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 1 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 1 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATED) TYPE 1 (MEF-1 STRAIN) PRODUCED ON VERO CELLS, POLIOVIRUS (INACTIVATE | |

| EU-EC- 10012857295 | 28/06/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | Not Specified | Not Specified | No | Abdominal pain (n/a - Unknown -), Diarrhoea (n/a - Unknown -), Dysarthria (n/a - Unknown -), Foaming at mouth (n/a - Unknown -), Hyperhidrosis (n/a - Unknown -), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Respiratory rate increased (n/a - Unknown - Other Medically Important Condition), Seizure (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Unknown -) | ADSORBED ON ALUMINIUM HYDROXIDE, PERTUSSIS FILAMENTOUS HAEMAGGLUTININ ADSORBED ON ALUMINIUM HYDROXIDE, TETANUS 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), POLIOVIRUS (INACTIVATED) TYPE 3 (SAUKETT STRAIN), PRODUCED ON VERO CELLS, ALUMINIUM HYDROXIDE, HAEMAGGLUTININ ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, PETTUSSIS FILAMENTOUS HAEMAGGLUTININ ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN), PERTUSSIS PERTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, POLIOVIRUS (INACTIVATED) TYPE 1 (MAHONEY STRAIN), PERTUSSIS PETTACTIN ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, DIPHTHERIA TOXOID ADSORBED ON ALUMINIUM HYDROXIDE, HYDRATED, DIPHTHERIA TOXOID 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 PROPHYJRAS - Unknown - [n/a - n/a - n/a]), [INFLUENZA VIRUS] (S - PROPHYJRAS - Unknown - [n/a - n/a - n/a]) [INFLUENZA VIRUS] (S - PROPHYJRAS - Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/ | Not |
|-----------------------|------------|-------------|----------------------------|------------------------------|---------------|------------------|------------------|----|--|--|-----|
| EU-EC- 10012857900 | 28/06/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | Not Specified | Not Specified | No | Abdominal pain upper (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Somnolence (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Tachycardia (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular]) | Not |
| EU-EC- 10012857957 | 28/06/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | Not Specified | Male | No | - Caused/Protonged Hospitalisation) Chest pain (n/a - Unknown - Other Medically Important Condition), Chills (n/a - Unknown -), Myocarditis (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 prophylaxis - n/a - [n/a3mL - Intramuscular]) | Not |

| Professional Economic Area Professional Economic Area Years (5d - COVID-19 immunisation - Drug [FLL Recovered/Resolved Caused/Prolonged Hospitalisation) Intramuscular]) Intramuscular] I | J.11.2022 | 15.34 | | | | Rur | ı Line L | isting Re | eport | | | | |
|--|-------------|------------|-------------|-------------------------|------------------------------|----------------|----------|------------|--------|----|---|---|---|
| 1945 1945 | | 28/06/2022 | Spontaneous | | Economic | Not available | | | Male | No | Tachycardia (n/a - Unknown - Other Medically Important Condition), Troponin I increased (n/a - Unknown - Other Medically Important Condition) Chest pain (n/a - Unknown - Other Medically Important | - COVID-19 prophylaxis - n/a - | Not |
| EACC 20/06/2022 Southernoon Healthurn European Not evolvible Southernoon | | 28/06/2022 | Spontaneous | Healthcare | Economic | Not available | | | Male | No | (n/a - Unknown -) Dizziness (n/a - Unknown -), Pallor (n/a - | - Immunisation - n/a - [n/a - n/a | Not |
| Professional Contents Prof | | | | | | | | | | | Syncope (2d - Unknown - Other Medically Important Condition) | | |
| ED-SC 28/06/2002 Sperterroxus Healthure European Not available 12-17 Not available 1 | | 28/06/2022 | Spontaneous | | Economic | Not available | | | Female | No | Recovered/Resolved - Caused/Prolonged Hospitalisation), | - COVID-19 prophylaxis - n/a - | Not |
| EU-CC 28/04/2022 Spontaneous Positionary Positio | | | | | | | | | | | Recovered/Resolved - Caused/Prolonged Hospitalisation), | | |
| EMEC 28/00/2022 Sportaneous Healthcare Sergean Not evolutile 22.17 Not Protestical Confidency Confid | | | | | | | | | | | - Caused/Prolonged Hospitalisation), | | |
| Professional Encomme | FILEC- | 28/06/2022 | Spontaneous | Healthcare | Furonean | Not available | 12-17 | Not | Female | No | Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S | Not |
| Healthcase Common Professional Common Professional Common Professional Common | | 20,00,2022 | эропшисоиз | | Economic | THOSE GYGHADIC | | | remate | | | - COVID-19 prophylaxis - n/a - | |
| Area Adolescent Area No Adolescent Area Adolescent Adolescent Area Adolescent Adolescent Area Adolesce | 10012858778 | | | Healthcare Professional | European Economic Area | | Years | Specified | | | (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), Sleep disorder (n/a - Unknown - Disabling, Other Medically Important Condition), Collagen disorder | - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S | |
| Professional Economic Area Years Years (5d - COVID-19 immunisation - Drug (FLL VIL/ Recovered/Resolved - Caused/Prolonged Hospitalisation) [SAL SALI (C - n/z) - n/z) [SAL SALI (C - n/z) [SAL SALI (C - n/z) [SALI (C - n | | 20/06/2022 | | | Area | | | | Mala | Na | 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), | [n/a - n/a - n/a]) | |
| -n/i | | 28/06/2022 | Spontaneous | | Economic | Not available | | Adolescent | Male | No | (5d - Recovered/Resolved - Caused/Prolonged | - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - | [FLL VIL ⁴ n/a [SAL SALI |
| | EU-EC- | 28/06/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Adolescent | Female | No | Amenorrhoea (n/a - | | - n/a |

| 1.11.2022 | 15.34 | | | | Run | Line L | isting Re | eport | | | | |
|-----------------------|------------|--------------|-----------------------------------|-------------------------------------|---|----------------|------------------|---------------|-----|--|--|------|
| 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]) | No |
| 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]) | No |
| 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]) | No |
| 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]) | No |
| EU-EC- 10012859697 | 28/06/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Ma l e | No | Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) | No |
| 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 - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | No |
| EU-EC- 10012859937 | 28/06/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Other Medically Important Condition) COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | No |
| EII EC | 20/06/2022 | Spontaneous | Non | European | Not available | 12-17 | Not | Male | No | Recovered/Resolved - Other Medically Important Condition) Arthralgia (n/a - | COMIRNATY [TOZINAMERAN] (S | ſυ |
| EU-EC- 10012861032 | 28/00/2022 | Sportarieous | Healthcare Professional | Economic | Not available | Years | Specified | Мане | INO | | - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | n/a |
| | | | | | | | | | | 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 | | |
| EU-EC- 10012861113 | 28/06/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Ma l e | No | Dengue fever (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | No |
| EU-EC- 10012861230 | 28/06/2022 | Spontaneous | Non Healthcare Professional | European Economic | Not available | 12-17 Years | Adolescent | Male | No | Seborrhoeic dermatitis (21d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | No |
| | | | | | | | | | | Type 1 diabetes mellitus (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Vaccination site reaction (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | |
| 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. 202;37 (SUPPL 3):130-131. | 12-17 Years | Not Specified | Female | No | Haemolytic uraemic syndrome (n/a - Recovered/Resolved - Life Threatening, | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | t No |

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|----|-----------------------|------------|-------------|----------------------------|------------------------------|---------------|----------------|------------|---------------|----|---|---|-----|
| | | | | | | | | | | | 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 | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular]) | Not |
| | EU-EC- 10012862838 | 28/06/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | Years | Adolescent | Ma l e | | (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]) | Not |



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