Line Listing Report Time run: 30/11/2022 13:18:20

| 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 | Child | Reaction List PT (Duration – Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) | Concomitant/Not Administered Drug (Drug Char - Indic PT - Action taken - [Duration - Dose - Route]) |
|-----------------------|----------------------------------|-------------|------------------------------------|---|------------------------------|-------------------------|--|----------------|-------|--|--|--|
| EU-EC- 10014103815 | 25/11/2022 | Spontaneous | Non Healthcare Professional | European Economic | Not available | 12-17 Years | Not Specified | Female | No | Arthralgia (n/a - Recovering/Resolving -), Fatigue (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMEAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{OF} - Intravenous use]) | Not reported |
| EU-EC- 10014105618 | 25/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | | Contusion (n/a - Recovering/Resolving -), Lymphadenopathy (4d - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014106315 | 25/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | | SARS-CoV-2 test positive (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014107308 | 25/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Extrasystoles (n/a - Recovering/Resolving - Other Medically Important Condition), Tachycardia (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{OF} - Intramuscular use]) | [MEQUITAZINE] ((n/a - n/a - [n/a - n n/a]) |
| EU-EC- 10014108616 | | Spontaneous | Professional | Area | Not available Not available | Years 12-17 | Not Specified | Female | No | Chest pain (n/a - Recovering/Resolving -), Dyspnoea (n/a - Unknown -), Inappropriate schedule of product administration (n/a - Unknown -), Myocarditis (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - Recovering/Resolving -), Pericarditis (n/a - Unknown - Other Medically Important Condition), Tachycardia (n/a - Unknown -) Blood urine present | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id - n/a - n/a]), IBUPROFEN [IBUPROFEN SODIUM] (S - n/a - Unknown - [n/a - 200mg - n/a - More in ICSR]) | Not reported Not reported |
| 10014108617 | 23/11/2022 | Sportaneous | Healthcare Professional | Economic | Not available | Years | Specified | riale | | (n/a - Not Recovered/Not Resolved -) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- | | Spontaneous | Healthcare Professional | | Not available | Years | Not Specified | Male | | Fatigue (2d - Recovered/Resolved -), Feeling abnormal (3d - Recovered/Resolved -), Pain (3d - Recovered/Resolved -), Pain in extremity (3d - Recovered/Resolved -), Paraesthesia (3d - Recovered/Resolved -), Vaccination site pain (3d - Recovered/Resolved -), Authoriaio (2d - Authoriai | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014093828 | 24/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | | Arthralgia (2d - Recovered/Resolved -), Body temperature increased (1d - Recovered/Resolved -), Headache (7d - Recovered/Resolved -), Myalgia (2d - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported |

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|--------|-----------------------|------------|----------------|--------------|------------------------------|---------------|----------------|------------------|--------|-----|--|--|--|
| | | | | | | | | | | | Recovered/Resolved -), | | |
| | | | | | | | | | | | Vertigo (7d - | | |
| | | | | | | | | | | | Recovered/Resolved -), | | |
| | | | | | | | | | | | Visual impairment (2d - Recovered/Resolved -) | | |
| | EU-EC- 10014094347 | 24/11/2022 | Spontaneous | | Non European | Not available | 12-17 Years | Not Specified | Male | No | COVID-19 (n/a - Unknown - Other | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | | | Economic Area | | | | | | Medically Important Condition), | COVID-19 immunisation - Not | |
| | | | | | | | | | | | | applicable - [1d - n/a - Intramuscular use - | |
| | | | | | | | | | | | Unknown - Other Medically Important Condition) | More in ICSR]) | |
| | EU-EC- 10014094510 | 24/11/2022 | Spontaneous | Healthcare | Non European Economic | Not available | 12-17 Years | Not Specified | Male | No | Erythema multiforme (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 | [AMOXICILLIN, AMOXICILLIN TRIHYDRATE] (C - r |
| | | | | Professional | Area | | | | | | Resolved - Other Medically Important Condition), | immunisation - Not | - n/a - [n/a - n/a - n/a]) |
| | | | | | | | | | | | Product use issue (n/a - Unknown -), | [INFLUENZA A VIRUS A/BRISBANE/10/2010 (H1N1) ANTIGEN | |
| | | | | | | | | | | | Rash (n/a - Not Recovered/Not | (MDCK CELL DERIVED, PROPIOLACTONE | |
| | | | | | | | | | | | Resolved - Other Medically Important | INACTIVATED)] (S - Immunisation - Not | |
| | | | | | | | | | | | Condition) | applicable - [1d - n/a - n/a]) | |
| | EU-EC- 10014094728 | 24/11/2022 | Spontaneous | Healthcare | European Economic | Not available | 12-17 Years | Adolescent | Female | No | Anti-GAD antibody positive (n/a - | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | | Professional | Area | | | | | | Unknown - Caused/Prolonged Hospitalisation), | COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) | |
| | | | | | | | | | | | Blood glucose increased (n/a - | | |
| | | | | | | | | | | | Unknown - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | | Glycosylated haemoglobin | | |
| | | | | | | | | | | | increased (n/a - Unknown - | | |
| | | | | | | | | | | | Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | | Headache (n/a - Recovered/Resolved - Caused/Prolonged | | |
| | | | | | | | | | | | Hospitalisation), Polydipsia (n/a - | | |
| | | | | | | | | | | | Recovered/Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | | Type 1 diabetes mellitus (n/a - Not | | |
| | | | | | | | | | | | Recovered/Not Resolved - | | |
| | | | | | | | | | | | Caused/Prolonged Hospitalisation, Disabling) | | |
| | EU-EC- 10014094850 | 24/11/2022 | Spontaneous | | European Economic | Not available | 12-17 Years | Adolescent | Male | No | Arthralgia (1d - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - | [PARACETAMOL, PHENYLEPHRINE |
| | 1001 103 1030 | | | roressional | Area | | rears | | | |), | COVID-19 immunisation - Not | HYDROCHLORIDE, PARACETAMOL] (C |
| | | | | | | | | | | | Body temperature increased (2d - Recovered/Resolved - | applicable - [n/a - 1{DF} - Intramuscular use]) | n/a - n/a - [n/a - n/a Oral use]) |
| | | | | | | | | | | |), Myalgia (1d - Recovered/Resolved - | | |
| | | | | | | | | | | |), Nausea (2d - | | |
| | | | | | | | | | | | Recovered/Resolved -) | | |
| | EU-EC- 10014095653 | 24/11/2022 | Spontaneous | | 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 reported |
| | | | | | | | | | | | Vaccination failure (n/a - Unknown - | and an ascalar ascay | |
| | | | | | | | | | | | Other Medically Important Condition) | | |
| | EU-EC- 10014095790 | 24/11/2022 | Spontaneous | Healthcare | European Economic | Not available | 12-17 Years | Not Specified | Male | No | Epistaxis (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - | [PARACETAMOL] (C n/a - n/a - [n/a - n/a |
| - | EU-EC- | 24/11/2022 | Spontaneous | | Area | Not available | 12-17 | Not | Male | No | Body temperature | n/a - n/a - [n/a - n/a - n/a]) COMIRNATY | n/a]) |
| | 10014097290 | 24/11/2022 | Spontaneous | | European Economic Area | Not available | Years | Not Specified | маје | INO | increased (2d - Recovered/Resolved - | [TOZINAMERAN] (S - COVID-19 | Not reported |
| | | | | | . . | | | | | |), | immunisation - Not applicable - [n/a - n/a | |
| | | | | | | | | | | | Headache (2d - Recovered/Resolved -), | - n/a]) | |
| | | | | | | | | | | | Nausea (2d - | | |
| | | | | | | | | | | | Recovered/Resolved - | | |
| | | | | | | | | | | | Pruritus (2d - Recovered/Resolved -), | | |
| | | | | | | | | | | | Rash (2d - | | |
| h# | tns://dan.e | ma euro | l na eu/ana | lvtice/eav | r qiiseo I | I | I | I | I | I | Recovered/Resolved - | I | 2/71 |

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|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|--------|----|--|--|--|
| | | | | | | | | | |), Renal pain (2d - Recovered/Resolved -), Spinal pain (2d - Recovered/Resolved - | | |
| EU-EC- 10014097302 | 24/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No |) Fatigue (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | n/a]) | |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Pain (n/a - Unknown - | | |
| EU-EC- 10014097332 | 24/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Arthralgia (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Chills (n/a - Not Recovered/Not Resolved -), | 1,,21) | |
| | | | | | | | | | | Dizziness (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Epistaxis (n/a - Recovering/Resolving -), | | |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Lip pain (n/a - Unknown -), | | |
| | | | | | | | | | | Lip swelling (1d - Recovered/Resolved -), | | |
| | | | | | | | | | | Lymph node pain (n/a - Unknown -), | | |
| | | | | | | | | | | Lymphadenopathy (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Myalgia (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Pain (n/a - Unknown -), | | |
| | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving -), | | |
| | | | | | | | | | | Vaccination site pain (n/a - Not Recovered/Not Resolved -) | | |
| EU-EC- 10014097648 | 24/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | | Not Specified | Male | No | Fatigue (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | [CEFALEXIN] (C - n, Not applicable - [n/a n/a - n/a]), |
| | | | | | | | | | | Headache (n/a - Recovering/Resolving -), | immunisation - Not applicable - [n/a - 1{DF} - n/a]) | [PHENPROCOUMON (C - n/a - Not applicable - [n/a - n |
| | | | | | | | | | | Injection site pain (n/a - Not Recovered/Not Resolved -), | | - n/a]) |
| | | | | | | | | | | Malaise (n/a - Recovering/Resolving -) | | |
| EU-EC- 10014097940 | 24/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | | Not Specified | Female | No | Hypoaesthesia (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| | | | | | | | | | | Paraesthesia (n/a - Not Recovered/Not Resolved -) | n/a]) | |
| EU-EC- 10014097979 | | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Abdominal pain (n/a - Unknown - Other Medically Important | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported |
| | | | | | | | | | | Condition), Dyspepsia (n/a - Unknown - Other Medically Important | immunisation - n/a - [n/a - n/a - Intramuscular use]) | |
| | | | | | | | | | | Condition), Infection susceptibility | | |
| | | | | | | • | | | | | | |

| | | | | | | | | | | increased (n/a - | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|--|----------------|------------------|--------|----|--|--|---|
| | | | | | | | | | | Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | | Upper respiratory tract infection (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | | Urinary tract infection (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10014098022 | 24/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dizziness (0d - Recovered/Resolved -), | | [PARACETAMOL] (n/a - n/a - [n/a - I Oral use]) |
| | | | | | | | | | | Headache (n/a - Unknown -), Malaise (0d - | | |
| | | | | | | | | | | Recovered/Resolved -), Nausea (0d - | | |
| EU-EC- 0014099236 | 24/11/2022 | Spontaneous | Healthcare | European Economic | Not available | | Not Specified | Male | No | Recovered/Resolved -) General physical health deterioration | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | | Area | | | | | | (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation) | COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | |
| EU-EC- 10014099246 | 24/11/2022 | Spontaneous | Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Complement factor increased (50d - Recovered/Resolved - Disabling, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| | | | | | | | | | | Electrocardiogram ST segment abnormal (n/a - Not Recovered/Not Resolved - Disabling), | | |
| | | | | | | | | | | Electrocardiogram ST segment elevation (n/a - Not Recovered/Not Resolved - Disabling, Other Medically | | |
| | | | | | | | | | | Important Condition), Electrocardiogram abnormal (n/a - Not Recovered/Not | | |
| | | | | | | | | | | Resolved - Disabling), Hypoaesthesia (n/a - Not Recovered/Not Resolved - Disabling), | | |
| | | | | | | | | | | Lymphocyte count decreased (50d - Recovered/Resolved - Disabling, Other Medically Important Condition), | | |
| | | | | | | | | | | Pain (174d - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), | | |
| | | | | | | | | | | Paraesthesia (n/a - Unknown -), | | |
| | | | | | | | | | | Poor quality sleep (n/a - Not Recovered/Not Resolved - Disabling), | | |
| | | | | | | | | | | Sinus bradycardia (n/a - Not Recovered/Not Resolved - Disabling) | | |
| EU-EC- 10014099766 | 24/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Thammathiwat, T Multiple Venous and Pulmonary Artery Thrombosis as the Presenting Features of Spontaneously Reversible Nephrotic Syndrome after Exposure to SARS-CoV-2 Virus (Pfizer/BioNTech BNT162b2) Vaccination, Vaccines, 2022;10 (11):1888, doi:10.3390/vaccines10111888 | | Not Specified | Male | No | Nephrotic syndrome (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), | TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Pulmonary artery thrombosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Pulmonary venous thrombosis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | |
| EU-EC- 10014100598 | 24/11/2022 | Spontaneous | Non Healthcare | European Economic | Not available | 12-17 Years | Not Specified | Female | No | Vaccination site pain (n/a - Not | COMIRNATY [TOZINAMERAN] (S - | Not reported |

| | | | | | | | | | | Recovered/Not Resolved -) | n/a - n/a - [n/a - n/a - n/a]) | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|--|--|---|
| EU-EC- 10014101240 | 24/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Feeding intolerance (n/a - Unknown -), Pyrexia (n/a - Unknown -), Vomiting (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | COVID-19 MRNA VACCINE MODERN/ (CX-024414) [ELASOMERAN] (C COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) |
| EU-EC- 10014082660 | 23/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Loss of consciousness (n/a - Recovering/Resolving - Other Medically Important Condition), Pallor (n/a - Recovering/Resolving -), Seizure (n/a - Recovering/Resolving - Other Medically Important Condition), Shock (n/a - Recovering/Resolving - Recovering/Resolving - Other Medically Important Condition), Shock (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | Not reported |
| | | | | | | | | | | - Other Medically Important Condition) | | |
| EU-EC- 10014083425 | 23/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Headache (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10014084475 | 23/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Fatigue (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| EU-EC- 10014084529 | 23/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Administration site pain (3d - Recovered/Resolved -), Body temperature increased (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), | COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| | | | | | | | | | | Vomiting (1d - Recovered/Resolved - | | |
| EU-EC- 10014086177 | 23/11/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | | Not Specified | Male | No | Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014086439 | 23/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Important Condition) Heavy menstrual bleeding (n/a - Unknown -), Menstrual disorder | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| 10014086727 | | Spontaneous | Healthcare Professional | European Economic Area | Not available | Years | Not Specified | Female | No | (n/a - Unknown -) Fatigue (n/a - Recovering/Resolving -), Insomnia (n/a - Unknown -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Pain (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Pyrexia (n/a - Recovering/Resolving -), Vaccination site swelling (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014086815 | 23/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (30d | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Dyspnoea (30d - Recovered/Resolved -) | | |
| EU-EC- 10014086892 | 23/11/2022 | Spontaneous | | European Economic | Not available | 12-17 Years | Not Specified | Male | No | Flank pain (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - | Not reported |

| | | | Professional | Area | | | | | | Resolved -) | n/a - n/a - [n/a - n/a - n/a]) | |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|--------|----|---|--|--|
| EU-EC- 10014087065 | 23/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Rash (3d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | AERIUS [DESLORATADINE] - - n/a - n/a - [n/a - r - Oral use]) |
| EU-EC- 10014087394 | 23/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Epistaxis (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovering/Resolving -), Malaise (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Myalgia (n/a - Recovering/Resolving -), Pain (n/a - Unknown -), Pyrexia (n/a - Unknown -) | | |
| EU-EC- 10014087848 | 23/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Fatigue (2d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | INTUNIV [GUANFACINE] (C - n/a - n/a - n/a - n/a - n/a - n/a - n/b - n/a |
| | | | | | | | | | | Vaccination site pain (2d - Recovered/Resolved -) | | use]) |
| EU-EC- 10014087969 | 23/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Parosmia (n/a - Not Recovered/Not Resolved -), Taste disorder (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014088475 | 23/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Resolved -) Arthralgia (1d - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Malaise (1d - Recovered/Resolved -), Pain in extremity (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3m.L - Intramuscular use]) | Not reported |
| EU-EC- 10014088608 | 23/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Immunisation reaction (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular | Not reported |
| EU-EC- 10014088730 | 23/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Haematemesis (1a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Haemoptysis (1a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Menstruation irregular (1a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Muscle spasms (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Rectal haemorrhage (n/a - Not Resolved - Caused/Prolonged Hospitalisation), Rectal haemorrhage (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | use]) COMIRNATY [TOZINAMERAN] (5 - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10014088846 | 23/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Dehydration (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | [ANHYDROUS AZITHROMYCIN] (C Large intestine infection - Unknown [6d - n/a - Intramuscular use]) |

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|-----------------------|------------|-------------|----------------------------|-------------------------------------|--|----------------|------------------|----------|----|--|--|---|
| | | | | | | | | | | Hospitalisation), Kidney enlargement (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10014089100 | 23/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Sensory disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014089104 | 23/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use]) | Not reported |
| | | | | | | | | | | Diplopia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | | |
| | | | | | | | | | | Pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | | |
| | | | | | | | | | | Paralysis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | | |
| | | | | | | | | | | Strabismus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | | |
| | | | | | | | | | | Wheelchair user (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | | |
| EU-EC- 10014089118 | 23/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014089560 | 23/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Lee, J A Suspected Case of Multisystem Inflammatory Disease in Children Following COVID-19 Vaccination: A Case Report and Systematic Literature Review. Pediatric Infectious Disease Journal. 2022;41 (11):E456-E460. doi:10.1097/INF.000000000003674 | 12-17 Years | Not Specified | Female | No | Multisystem inflammatory syndrome in children (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| EU-EC- 10014089576 | 23/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Giray, D Acute myocarditis following COVID-19 mRNA vaccination: a paediatric case. Cardiology in the Young. 2022;1-3 doi:10.1017/S1047951121004698 Giray, D Acute myocarditis following COVID-19 mRNA vaccination: a paediatric case. Cardiology in the Young. 2022;32(7):1178-1180. doi:10.1017/S1047951121004698 | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014089577 | 23/11/2022 | Spontaneous | | Non European Economic Area | Morita, Y Acute Perimyocarditis in an Adolescent Japanese Male after a Booster Dose of the BNT162b2 COVID-19 Vaccine. The Tohoku journal of experimental medicine. 2022;258(3):177-182. doi:10.1620/tjem.2022.J068 | 12-17 Years | Not Specified | Male | No | Myopericarditis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014090173 | 23/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chills (n/a - Unknown -), Lymphadenopathy (n/a - Unknown -), Pyrexia (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | [ALDER POLLEN, CORYLUS AVELLAN/ POLLEN, ALLERGEN ALNUS, ARTEMISIA VULGARIS, POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMER, POLLEN, ARTEMISI/ VULGARIS POLLEN, POLLEN, FOLLEN, POLLEN, FOLLEN, POLLEN, FOLLEN, POLLEN, FOLLEN, POLLEN, FOLLEN, POLLEN, FESTUCA PRATENSIS POLLEN, POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS |

| | | | | | | | | | | | FARINAE] (C - Immunisation - [1d1mL - Subcutaneous u |
|------------------|------------|-------------|-------------------------|---------------|----------------|------------------|------|----|-------------------------|--|---|
| EC- 114090182 | 23/11/2022 | Spontaneous | Healthcare Professional | Not available | 12-17 Years | Not Specified | Male | No | Injection site swelling | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id - n/a - Intramuscular use]), [ALDER POLLEN, CORYLUS AVELLANA POLLEN, ALLERGENS, ALNUS, ARTEMISIA VULGARIS, ARTEMISIA VULGARIS, ARTEMISIA VULGARIS, ARTEMISIA VULGARIS POLLEN, PHLEUM PRATENSE POLLEN, FESTUCA PRATENSIS POLLEN, POA PRATENSIS POLLEN, LOLIUM PERENNE POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMERATA POLLEN, ARTEMISIA VULGARIS POLLEN, POLLEN, FESTUCA PRATENSIS POLLEN, FESTUCA PRATENSIS POLLEN, POLLEN, DACTYLIS GLOMERATA POLLEN, POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, SECALE CEREALE POLLEN, HOLCUS LANATUS POLLEN, DACTYLIS GLOMERATA POLLEN, HOLCUS LANATUS POLLEN, POLLEN, HOLCUS LANATUS POLLEN, POLLEN, HORDEUM VULGARE POLLEN, BETULA, BETULA POLLEN, HORDEUM VULGARE POLLEN, POAP PRATENSIS POLLEN, LOLIUM PRATENSIS POLLEN, POAP PRATENSIS POLLEN, HOLCUS LANATUS POLLEN, POAP PRATENSIS POLLEN, HOLCUS LANATUS POLLEN, POLLEN, BETULA POLLEN, POAP PRATENSIS POLLEN, POAL PRATENSIS POLLEN, POAL PRATENSIS POLLEN, POLLEN, POLLEN, BETULA POLLEN, BETULA POLLEN, BETULA POLLEN, POAL PRATENSIS POLLEN, POAL PRATENSIS POLLEN, POAL PRATENSIS POLLEN, POLLEN, POAL PRATENSIS POLLEN, POLLEN, BETULA POLLEN, | Not reported |

| EU-EC- | 23/11/2022 | Spontaneous | Non | European | Not available | 12-17 | Not | Female | No | Medically Important Condition) Fatigue (2d - | COMIRNATY | Not reported |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|---|----------------|------------------|--------|----|---|--|--------------|
| 10014090377 | | Spontaneous | Healthcare Professional | Economic | Not available | Years | Specified | Male | No | ratigue (20 -), Headache (1d - Recovered/Resolved -), Pain in extremity (n/a - Unknown -), Pyrexia (1d - Recovered/Resolved -), Urticaria (n/a - Unknown -), Vaccination site pain (2d - Recovered/Resolved -) Cough (n/a -) | TOZINAMERAN | Not reported |
| 10014090660 | | | Healthcare Professional | European Economic Area | | Years | Specified | | | Unknown -), Illness (n/a - Unknown -), Immunisation (n/a - Unknown - Other Medically Important Condition), Off label use (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown - Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | |
| 10014091156 | | Spontaneous | Professional | European Economic Area | from the Pharamacovigilance Risk Assessment Committee (PRAC) 30 August - 2 september 2021 COVID-19 vaccines: EMA reviewing cases of multisystem inflammatory syndrome. European Medicines Agency. 2022;29:620-623. doi:10.1016/j.arcped.2022.08.018 | Years | Not Specified | Male | No | Multisystem inflammatory syndrome in children (n/a - Recovered/Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014091788 | 23/11/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014070391 | 22/11/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |
| 10014070680 | | Spontaneous | Professional | Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Not Recovered/Not Resolved -), Dyspnoea exertional (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Hypokalaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Palpitations (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| 10014073009 | | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Not Specified | Male | No | Listless (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| 10014073346 | | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain (n/a - Not Recovered/Not Resolved -), Dysmenorrhoea (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014073375 | 22/11/2022 | Spontaneous | | Economic | Not available | 12-17 Years | Not Specified | Male | No | Body temperature increased (3d - Recovered/Resolved -), Fatigue (n/a - Unknown -), Pain in extremity (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|-----|---|--|--------------|
| EU-EC- 10014073760 | 22/11/2022 | Spontaneous | Non Healthcare Professional | Economic | Not available | 12-17 Years | Not Specified | Female | No | Diarrhoea (n/a - Unknown -), Eye paraesthesia (n/a - Unknown -), Fatigue (n/a - Unknown -), Hypoaesthesia (n/a - Unknown -), Hypoaesthesia eye (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | (n/a - Unknown -), Paraesthesia (n/a - Unknown -), | | |
| | | | | | | | | | | Paraesthesia oral (n/a - Unknown -) | | |
| EU-EC- 10014074007 | 22/11/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest pain (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014074059 | 22/11/2022 | Spontaneous | Non Healthcare | European Economic | Not available | 12-17 Years | Not Specified | Female | No | Lymph node pain (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | Professional | Area | | | | | | Lymphadenopathy (4d - Recovered/Resolved - | n/a - n/a - [n/a - n/a - n/a]) | |
| EU-EC- 10014076089 | 22/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Blood potassium decreased (n/a - Unknown - Other Medically Important Condition), Diarrhoea (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |
| | | | | | | | | | | Recovering/Resolving - Other Medically | | |
| EU-EC- 10014076674 | 22/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Important Condition) Angina pectoris (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Arrhythmia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Dizziness (346d - Recovered/Resolved | | |
| | | | | | | | | | | With Sequelae - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Lymphadenopathy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Neuralgia (336d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Palpitations (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10014076773 | 22/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | remale | No | Diarrhoea (14h - Recovered/Resolved -), Vomiting (14h - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - | Not reported |
| | | | | | | | | | | Recovered/Resolved -) | 1{DF} - Intramuscular use]) | |
| EU-EC- 10014077726 | 22/11/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest pain (n/a - Unknown - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported |
| | | | | | | | | | | Heart rate increased (n/a - Unknown - Other Medically Important Condition), | 30ug - n/a]) | |
| | | | | | | | | | | Hypertension (n/a - Unknown - Other Medically Important Condition), | | |
| EH EC | 22/44/2027 | Coorte | IIIaabb - | Nor | Note variable | 12.15 | Net | Mal- | Nic | Pericarditis (n/a - Unknown - Other Medically Important Condition) | COMPNATY | Not no set s |
| EU-EC- 10014078022 | 22/11/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported |

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| | | | | | | | | | | Chills (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (1d - | applicable - [1d - n/a - Intramuscular use]) | |
| | | | | | | | | | | Recovered/Resolved - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10014078370 | 22/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported |
| | | | | | | | | | | Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | applicable - [1d - n/a - Intramuscular use]) | |
| | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10014080000 | 22/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Petruzzi, M Oral erythema multiforme after Pfizer-BioNTech COVID-19 vaccination: a report of four cases, BMC Oral Health. 2022;22(1):90, doi:doi- /10.1186/s12903-022-02124-2 | 12-17 Years | Not Specified | Male | No | Erythema multiforme (n/a - Recovering/Resolving - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014080750 | 22/11/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | Not reported |
| | | | | | | | | | | Dyspepsia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | - n/a]) | |
| | | | | | | | | | | Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10014060810 | 21/11/2022 | Spontaneous | | European Economic Area | Collignon, C Two pediatric cases of multisystem inflammatory-like syndrome following COVID-19 vaccination. Archives de pediatrie. 2022;29:620-623. doi:10.1016/j.arcped.2022.08.018 | 12-17 Years | Not Specified | Male | No | Multisystem inflammatory syndrome (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| EU-EC- 10014060826 | 21/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Pareek, M., Myopericarditis after Covid-19 Vaccination - a Case Series, Social Science Research Network, 2021 Pareek, M., Short- Term Outcomes After Myopericarditis Related to COVID-19 Vaccination, JACC: Cardiovascular Imaging, 2022;15 (11):2002-2005, doi:10.1016/j.jcmg.2022.03.026 | 12-17 Years | Not Specified | Male | No | Myopericarditis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014060854 | 21/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Pareek, M Myopericarditis after Covid-19 Vaccination - A Case Series, Social Science Research Network. 2021 Pareek, M Short- Term Outcomes After Myopericarditis Related to COVID-19 Vaccination. JACC: Cardiovascular Imaging. 2022;15(11):2002- 2005. doi:10.1016/j.jcmg.2022.03.026 | 12-17 Years | Not Specified | Male | No | Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014060937 | 21/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | [FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE] (C - Asthma - n/a - [n/a n/a - n/a]) |
| EU-EC- 10014060962 | 21/11/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Not Specified | Male | No | Arthralgia (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | | Area | | | | | | Resolved -), Cardiac failure (n/a - Unknown - Other Medically Important Condition), | COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | Depressed mood (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Dizziness (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Dyspnoea (n/a - Not Recovered/Not Resolved -), Exercise tolerance | | |
| | | | | | | | | | | increased (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not | | |
| 4 11.1 | | | 1.42 | | | | | | | Recovered/Not Resolved -), | | |
| tos://dap.e | ema euro | na eu/ana | alvtics/sav | v dll?Go | | | | | | | | 13/71 |

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|----|-----------------------|------------|-------------|----------------------------|------------------------------|---------------|----------------|------------------|-----------|----|--|---|--|
| | | | | | | | | | | | Muscular weakness (n/a - Unknown -), | | |
| | | | | | | | | | | | Myalgia (n/a - Not Recovered/Not | | |
| | | | | | | | | | | | Resolved -), Nausea (n/a - | | |
| | | | | | | | | | | | Unknown -), Pain in extremity (n/a | | |
| | | | | | | | | | | | - Unknown -), Pyrexia (n/a - | | |
| | | | | | | | | | | | Unknown -), Somatic symptom | | |
| | EU-EC- | 21/11/2022 | Spontaneous | | European | Not available | 12-17 | | Female | No | disorder (n/a - Unknown -) Muscle twitching (0d - | COMIRNATY | Not reported |
| | 10014061959 | | | Professional | Economic Area | | Years | Specified | | | Recovered/Resolved -) | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | |
| | EU-EC- 10014062149 | 21/11/2022 | Spontaneous | Healthcare Professional | Non European Economic | Not available | | Not Specified | Female | | Headache (n/a - Unknown - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported |
| | | | | | Area | | | | | | Hospitalisation), Malaise (n/a - | immunisation - Not applicable - [1d - n/a - Intramuscular use]) | |
| | | | | | | | | | | | Unknown - Caused/Prolonged Hospitalisation), | - | |
| | | | | | | | | | | | Pruritus (n/a - Unknown - | | |
| | EU-EC- | 21/11/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Female | | Caused/Prolonged Hospitalisation) Asthenia (n/a - | COMIRNATY | Not reported |
| | 10014062895 | 21,11,2022 | эропшисоцэ | Professional | Economic Area | Not dvallable | | Specified | remaie | | Unknown -), Headache (n/a - | [TOZINAMERAN] (S - COVID-19 immunisation - n/a - | Not reported |
| | | | | | | | | | | | Unknown -), | [n/a - n/a - [ntramuscular use]) | |
| | | | | | | | | | | | Injected limb mobility decreased (n/a - Unknown -), | | |
| | | | | | | | | | | | Nausea (n/a - Unknown -), | | |
| | | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | | Vaccination site pain (n/a - Unknown -) | | |
| | EU-EC- 10014062975 | 21/11/2022 | Spontaneous | | European Economic Area | Not available | | Not Specified | Male | | Arthralgia (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| | | | | | | | | | | | Chills (1d - Recovered/Resolved - | n/a]) | |
| | | | | | | | | | | |), Dizziness (1d - | | |
| | | | | | | | | | | | Recovered/Resolved -), | | |
| | | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | | Headache (1d - Recovered/Resolved - | | |
| | | | | | | | | | | |), Increased tendency to bruise (1d - | | |
| | | | | | | | | | | | Recovered/Resolved -), | | |
| | | | | | | | | | | | Malaise (n/a - Recovering/Resolving -), | | |
| | | | | | | | | | | | Myalgia (n/a - Recovering/Resolving | | |
| | | | | | | | | | | | -), Pyrexia (1d - | | |
| | | | | | | | | | | | Recovered/Resolved -), | | |
| | | | | | | | | | | | Rash (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | | Vaccination site pain (n/a - Recovering/Resolving | | |
| | EU-EC- 10014063047 | 21/11/2022 | Spontaneous | | European Economic | Not available | | Adolescent | Female | | -) Gait disturbance (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | 1001700304/ | | | Professional | | | Years | | | | Resolved - Caused/Prolonged Hospitalisation) | COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | |
| | EU-EC- 10014063252 | 21/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Heavy menstrual bleeding (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - | [PARACETAMOL] (C Headache - n/a - [n - n/a - n/a]) |
| | | | | , roressional | a ca | | | | | | Intermenstrual bleeding (n/a - | Immunisation - n/a - [n/a - n/a - n/a]) | iya - iyajj |
| | | | | | | | | | | | Unknown -), Menstrual disorder | | |
| | | | | | | | | | | | (6mo - Recovered/Resolved - | | |
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| EU-EC- 10014063580 | 21/11/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Adrenal insufficiency (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014063794 | 21/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Resolved -) Herpes zoster (n/a - Not Recovered/Not Resolved -), Oral mucosal blistering (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| 511.50 | 24 /44 /2022 | | | | | 10.17 | | | | Unknown -) | TOTTUMED 111 | |
| EU-EC- 10014064745 | 21/11/2022 | Spontaneous | | Non European Economic Area | Pareek, M., Short-Term Outcomes After Myopericarditis Related to COVID-19 Vaccination. JACC: Cardiovascular Imaging. 2022;15 (11):2002-2005. doi:10.1016/j.jcmg.2022.03.026 | 12-17 Years | Not Specified | Male | No | Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014064762 | 21/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Abdominal pain (2d - Recovered/Resolved -), Administration site erythema (5d - Recovered/Resolved -), Fatigue (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved - | COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| | | | | | | | | | | Vertigo (1d - Recovered/Resolved - | | |
| EU-EC- 10014064930 | 21/11/2022 | Spontaneous | Healthcare Professional | Economic | Not available | 12-17 Years | Not Specified | Female | No | Atrioventricular block first degree (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported |
| | | | | Area | | | | | | Electroencephalogram abnormal (n/a - Unknown -), | immunisation - Not applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | Epilepsy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Pyrexia (1040min - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Seizure (1040min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | |
| EU-EC- 10014065181 | 21/11/2022 | Spontaneous | | Economic | Not available | 12-17 Years | Adolescent | Female | No | Headache (2d - Recovered/Resolved -), Influenza like illness (2d - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular use]) | Not reported |
| | | | | | | | | | |), Pain (2d - Recovered/Resolved -), | | |
| | | | | | | | | | | Pyrexia (2d - Recovered/Resolved - | | |
| EU-EC- 10014065199 | 21/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Vaccination site erythema (n/a - Not Recovered/Not Resolved -), Vaccination site | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | pruritus (n/a - Not Recovered/Not Resolved -) | | |
| EU-EC- 10014065246 | 21/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Pain (n/a - Unknown -), Rash pruritic (n/a - Recovering/Resolving | | |
| EU-EC- 10014066048 | 21/11/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | -) Hyperthermia (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Not Recovered/Not Resolved - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | [LOMERIZINE HYDROCHLORIDE] - Migraine - n/a - [- n/a - Oral use]) |

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| | | | | | | | | | | Caused/Prolonged Hospitalisation), Sjogren's syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other | | |
| EU-EC- 10014066427 | 21/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Medically Important Condition) Menstruation irregular (n/a - Not Recovered/Not | [TOZINAMERAN] (S - Immunisation - n/a - | Not reported |
| EU-EC- 10014066684 | 21/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important | [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular use]) | Not reported |
| EU-EC- 10014066729 | 21/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use - More in ICSR]) | Not reported |
| EU-EC- 10014066740 | 21/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use - More in ICSR]) | Not reported |
| EU-EC- 10014067026 | 21/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Menstrual disorder (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10014067649 | 21/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | [HEPARIN, HEPARI SODIUM] (C - Card disorder - n/a - [n/. n/a - n/a]), [PHENPROCOUMOI (C - Cardiac disorder n/a - [n/a - n/a - n/a]), [PHENPROCOUMOI (C - Heart disease congenital - n/a - [- n/a - 0 - 1]), [RAMIPRIL] (C - He disease congenital n/a - [n/a - n/a - 0 - 0]) |

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| | | | | | | | | | | Performance status decreased (n/a - Not Recovered/Not Resolved -), Peroneal nerve injury | | |
| | | | | | | | | | | (n/a - Recovering/Resolving - Other Medically Important Condition), | | |
| | | | | | | | | | | Somnolence (n/a - Unknown -), | | |
| | | | | | | | | | | Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10014067655 | 21/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Collignon, C Two pediatric cases of multisystem inflammatory-like syndrome following COVID-19 vaccination. Archives de pediatrie. 2022;29:620-623. doi:10.1016/j.arcped.2022.08.018 | 12-17 Years | Not Specified | Male | No | Multisystem inflammatory syndrome (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| EU-EC- L0014067670 | 21/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Ahmed, H A Case Series of Myocarditis Related to the COVID-19 Vaccine. Cureus. 2022;14(10):10.7759/cureus.29892. doi:10.7759/cureus.29892 | | Not Specified | Male | No | Myocarditis (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a] - n/a] | Not reported |
| EU-EC- 10014068485 | 21/11/2022 | Spontaneous | | European Economic Area | Not available | | Not Specified | Male | No | Blood creatine phosphokinase increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | [FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE] (C - Asthma - n/a - [n/a n/a - Inhalation use |
| | | | | | | | | | | Chronic fatigue syndrome (n/a - Not Recovered/Not Resolved -), | | [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asth - n/a - [n/a - n/a - Inhalation use]) |
| | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | Muscle discomfort (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | |
| | | | | | | | | | | Myositis (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | | Performance status decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | |
| | | | | | | | | | | Post viral fatigue syndrome (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | White blood cell count decreased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | |
| EU-EC- 10014068751 21/1 | 21/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Tanaka, A A case of coronary spastic angina as post-COVID-19 vaccination myocarditis. The 516th Fukuoka Regional Meeting of the Japan Pediatric Society, 2022;516th:21 Tanaka, A A case of coronary spastic angina-associated myocarditis occurred after COVID-19 vaccination. The 58th Annual Meeting of | | Not Specified | Male | No | Atrioventricular block complete (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d2mL - Intramuscular use]) | Not reported |
| | | | | | Japanese Society of Pediatric Cardiology and Cardiac. 2022;58th Tanaka, A A case of coronary spastic angina-associated myocarditis occurred after COVID-19 vaccination. The 54th Annual Meeting of | | | | | Electrocardiogram ST segment elevation (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | Japanese Society of Pediatric Infectious disease, 2022;54th:184 | | | | | Ischaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Prinzmetal angina (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important | | |
| tps://dap.e | ma ouro | na ou/ana | lytics/say | | | | | | | Condition), | | 17/7 |

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| | | | | | | | | | | Pyrexia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Wall motion score index abnormal (n/a - | | |
| EU-EC- 10014068842 | 21/11/2022 | Spontaneous | | | Reshef, E Orbital Inflammation Following COVID-19 Vaccination, Ophthalmic plastic and reconstructive surgery. | 12-17 Years | Not Specified | Male | No | Unknown -) Disease recurrence (n/a - Recovered/Resolved - | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 | Not reported |
| | | | | Area | 2022;38(3):e67-e70. doi:10.1097/IOP.000000000000161 | | | | |), Erythema (n/a - Recovered/Resolved - | immunisation - Not applicable - [n/a - n/a - n/a]) | |
| | | | | | | | | | |), Erythema of eyelid (n/a - Recovered/Resolved - | | |
| | | | | | | | | | |), Exophthalmos (n/a - Recovered/Resolved - Other Medically Important Condition), | | |
| | | | | | | | | | | Eye movement disorder (n/a - Recovered/Resolved - | | |
| | | | | | | | | | | Eyelid oedema (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Lacrimal gland enlargement (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Parophthalmia (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Periorbital fat herniation (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Periorbital oedema (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Periorbital pain (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Periorbital swelling (n/a - Recovered/Resolved -) | | |
| EU-EC- 10014068906 | 21/11/2022 | Spontaneous | | | Vorster, L., COVID-19 vaccine (mRNA BNT162b2) and COVID-19 infection-induced thrombotic thrombocytopenic purpura in adolescents. Pediatric Blood and Cancer. 2022;69(6):e29681. doi:10.1002/pbc.29681 | 12-17 Years | Not Specified | Female | No | Thrombotic thrombocytopenic purpura (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - n/a - n/a]) | Not reported |
| EU-EC- 10014069683 | 21/11/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Adolescent | Male | No | Abdominal pain (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not reported |
| EU-EC- 10014039774 | 18/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Appendicitis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014040044 | 18/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Unknown -), Nausea (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014041557 | 18/11/2022 | Spontaneous | Healthcare | Economic | Not available | 12-17 Years | Not Specified | Male | No | Pyrexia (n/a - Unknown -) Hypokinesia (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | Professional | AIEd | | | | | | Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), | COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Paraesthesia (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Pruritus (n/a - Not Recovered/Not Resolved -), Vaccination site | | |
| | | | | | | | | | | erythema (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Vaccination site pain (n/a - Not Recovered/Not | | |

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| | | | | | | | | | | Resolved -), Vaccination site rash (n/a - Not Recovered/Not Resolved -) | | |
| EU-EC- 10014042096 | 18/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Administration site pain (2d - Recovered/Resolved -), Chills (2d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| | | | | | | | | | | Headache (n/a - Unknown -), Pyrexia (2d - Recovered/Resolved - | | |
| EU-EC- 10014042339 | 18/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest discomfort (20d - Recovered/Resolved -), Chest pain (19d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspepsia (20d - Recovered/Resolved -), Myocarditis (20d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |
| | | | | | | | | | | Medically Important Condition), Pyrexia (20d - Recovered/Resolved - | | |
| EU-EC- 10014043061 | 18/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Arthralgia (5d - Recovered/Resolved -), Body temperature increased (1d - Recovered/Resolved -), Myalgia (5d - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10014043166 | 18/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No |) Arthralgia (5d - Recovered/Resolved -), Body temperature increased (1d - Recovered/Resolved -), Myalgia (5d - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10014043777 | 18/11/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Recovered/Resolved -) Oligomenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014043936 | | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014044065 | 18/11/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Herpes zoster (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014044229 | 18/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Balance disorder (n/a - Recovering/Resolving -), Feeling abnormal (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Photosensitivity reaction (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), | (COMIRNATY (TOZINAMERAN) (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |

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|--|-------------|------------|-------------|----------------------------|----------|---------------|-----------|------------|--------|-----|--|--|---|
| Ex-Section Ex- | | | | | | | | | | | Recovering/Resolving | | |
| March Marc | | 18/11/2022 | Spontaneous | | Economic | Not available | | | Female | No | COVID-19 immunisation (n/a - Not Recovered/Not | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| March Marc | EU EO | 10/11/2022 | Constant | Mari | - | N | 12.17 | Net | FI- | Nie | Recovered/Not Resolved -) | COMPNATA | Not assessed |
| Math | | 18/11/2022 | Spontaneous | Healthcare | Economic | Not available | | | remaie | INO | Recovered/Not Resolved -), Headache (n/a - Not | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| Modern M | ELLEC | 10/11/2022 | Chontangous | Non | Europoan | Not available | 12 17 | Not | Fomalo | No | Resolved -) | COMIDNATY | Not reported |
| Modern M | 10014046734 | | | Healthcare Professional | Economic | | Years | | | | (n/a - Not Recovered/Not Resolved -) | [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | · |
| Build Part | | 18/11/2022 | Spontaneous | Healthcare | Economic | Not available | | | Male | No | | [TOZINAMERAN] (S - | [BUDESONIDE] (C - n/a - n/a - [n/a - n/a Oral use]) |
| 101-101-101-101-101-101-101-101-101-101 | | | | | | | | | | | | | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, |
| EU-EC 18/11/2022 Sportaneous Productional Security Productional Secu | | | | | | | | | | | | | |
| Professional Research Professional Research Resea | | | | | | | | | | | test decreased (n/a - Recovering/Resolving -) | | |
| ### Support | | 18/11/2022 | Spontaneous | | Economic | Not available | | | Female | No | erythema (n/a - Recovering/Resolving | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| ELFC- 18/11/2022 Sportseneous Non Healthcase European Not available 12-17 Not Not Not reported Not available Not avail | | | | | | | | | | | induration (n/a - | | |
| EL-EC- 101/1/2022 Sportaneous Non Healthcase European Not available | | | | | | | | | | | | | |
| EU-EC- 1001-1049538 Sportaneous Non- Healthcare European Professional Ferrale Non- Healthcare European Professional Ferrale Non- Healthcare Professional EU-EC- 1001-1049538 Sportaneous Non- Healthcare European Professional Ferrale Non- Healthcare Professional EU-EC- 1001-1049535 Sportaneous Non- Healthcare European Professional EU-EC- 1001-1049535 Sportaneous Non- Healthcare Professional EU-EC- 1001-1049535 Sportaneous Non- Healthcare European Not available Sportaneous Non- Healthcare European Not available Sportaneous Non- Professional EU-EC- 1001-1049535 Sportaneous Non- Healthcare European Not available Sportaneous Not available Sp | | | | | | | | | | | swelling (n/a - Recovering/Resolving | | |
| Healthurse Economic Professional Area Professional Economic Professional E | | | | | | | | | | | Vaccination site warmth (n/a - | | |
| EU-EC- 18/11/2022 Spontaneous Non Healthcare European Not available 12-17 Not Pemale No Not reported Not Not reported Not Not Not reported Not Not Not reported Not No | | 18/11/2022 | Spontaneous | Healthcare | Economic | Not available | | | Female | No | Unknown -), | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| EU-EC- 10014049945 Spontaneous Non Healthcare European Not available 12-17 Not Years Specified Female No Disy sin (n/a - n/a n/a n/a - n/a n | | | | | | | | | | | bleeding (n/a - Not Recovered/Not | [n/a]) | |
| Helathcare Professional Area Professional | 511.50 | 10/11/2022 | | | | N | 42.47 | | | | Unknown -) | COMPNIATI | |
| ELFEC- 10014049582 18/11/2022 Spontaneous Non Healthcare European Healthcare | | 18/11/2022 | Spontaneous | Healthcare | Economic | Not available | | | remale | NO | Recovering/Resolving -), | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| EU-EC- 10014049582 18/11/2022 Spontaneous Non Healthcare Conomic Professional Not available 12-17 Not Years Specified Female No Recovered/Nessolved - Caused/Prolonged Hospitalisation), Demyelmation (Na Recovered/Resolved - Caused/Prolonged Hospitalisation), Demyelmation (Na Recovered/Resolved - Caused/Prolonged Hospitalisation), Demyelmation (Na Recovered/Resolved - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Recovering/Resolving | | | | | | | | | | | Recovering/Resolving | | |
| EU-EC- 10014049582 Recovering/Resolving - Frofessional Recovering/Resolving - Recovering/ | | | | | | | | | | | Recovering/Resolving -), | | |
| Healthcare Professional Profe | | | | | | | | | | | sensation (n/a - | | |
| EU-EC- 10014050855 18/11/2022 Spontaneous Non Healthcare Professional European (n/a - Not available 12-17 Adolescent Female No Burning sensation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Demyelination (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Recovereng/Resolving - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Recovereng/Resolving - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) Sensory disturbance (n/a - Rec | | 18/11/2022 | Spontaneous | Healthcare | Economic | Not available | | | Female | No | Unknown -), | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| EU-EC- 10014050855 18/11/2022 Spontaneous Spontaneous Professional Spontaneous Spontaneo | | | | | | | | | | | Recovering/Resolving | n/a]) | |
| Healthcare Professional Real Healthcare Professional Recoverd Resolved - Caused/Prolonged Hospitalisation), Demyelination (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) Recovering/Resolving - Caused/Prolonged Hospitalisation Recover | | | | | | | | | | | Recovered/Not | | |
| Hospitalisation), applicable - [n/a - 1{DF} - n/a]) Demyelination (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) Sensory disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) Caused/Prolonged Hospitalisation Committee | | 18/11/2022 | Spontaneous | Healthcare | Economic | Not available | | Adolescent | Female | No | (n/a - Recovered/Resolved - | [TOZINAMERAN] (S - COVID-19 | Not reported |
| Recovered/Resolved - Caused/Prolonged Hospitalisation), Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) Recovering/Resolving - Caused/Prolonged Hospitalisation Recovering/Resolving - Caused/Prolonged Hospitalis | | | | | | | | | | | Hospitalisation), | applicable - [n/a - | |
| Recovering/Resolving - Caused/Prolonged Hospitalisation), Sensory disturbance (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | | | | | | | | | | | Recovered/Resolved - Caused/Prolonged | | |
| EU-EC- 10014050909 18/11/2022 Spontaneous Healthcare Professional Economic Eco | | | | | | | | | | | Recovering/Resolving - Caused/Prolonged | | |
| EU-EC- 18/11/2022 Spontaneous Healthcare Professional Economic Professional Economic Years 10014050909 | | | | | | | | | | | Sensory disturbance (n/a - | | |
| 10014050909 | | | | | | | | | | | Recovering/Resolving - Caused/Prolonged Hospitalisation) | | |
| Caused/Prolonged immunisation - Not Hospitalisation), applicable - [n/a - | | 18/11/2022 | Spontaneous | | | Not available | | Adolescent | Male | No | (305d - Recovered/Resolved - Caused/Prolonged | [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported |

| Line Listing Report | port | ing it | | 1 | | | | IUILL | 10.11.2022 |
|---|--------|-----------|------------------|---------------|-------------------------------------|-----------------------------------|-------------|------------|-----------------------|
| Infectious mononucleosis (283d - Recovered/Resolved With Sequelae - | | | | | | | | | |
| Caused/Prolonged Hospitalisation), | | | | | | | | | |
| Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | | | | | | | |
| Urticaria (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | | | | | | | |
| 17 Adolescent Male No Blindness unilateral COMIRNATY Not reported | No | cent Male | -17 <i>F</i> ars | Not available | | Healthcare Professional | Spontaneous | 18/11/2022 | EU-EC- 10014051084 |
| Keratoconus (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | | | | | | | |
| urs Unknown -), [TOZINAMERAN] (S - COVID-19 | No | cent Male | -17 / ars | Not available | | Healthcare Professional | Spontaneous | 18/11/2022 | EU-EC- 10014051086 |
| Headache (n/a - immunisation - Not Unknown -), | | | | | | | | | |
| inflammation (n/a - [TOZINAMERAN] (S - Unknown -), COVID-19 immunisation - Not Vaccination site pain applicable - [1d - | No | cent Male | -17 A | Not available | | | Spontaneous | 18/11/2022 | EU-EC- 10014051120 |
| rs Specified | ale No | | | Not available | European | Healthcare Professional | Spontaneous | 17/11/2022 | EU-EC- 10014029426 |
| Unknown - Other Medically Important Condition), immunisation - Not applicable - [n/a - n/a - n/a]) Seizure (n/a - | | | | | Economic Area | | | | |
| Unknown - Other Medically Important Condition) | | | | | | | | | |
| | No | | | Not available | Non European Economic Area | Non Healthcare Professional | Spontaneous | 17/11/2022 | EU-EC- 10014029500 |
| Myocardial fibrosis (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | | | | | | | |
| | ale No | | | Not available | Economic | | Spontaneous | 17/11/2022 | EU-EC- 10014029742 |
| Not Recovered/Not CHLORIDE, Resolved -), AMMONIUM CHLORIDE, CALCIU Concomitant disease GULCONATE, aggravated (n/a - POTASSIUM CITRAT | | | | | | | | | |
| Unknown -), (C - n/a - n/a -), Eye pruritus (n/a - [THIAMINE Not Recovered/Not HYDROCHLORIDE, | | | | | | | | | |
| Resolved -), RETINOL] (C - n/a -) Fatigue (n/a - Not Recovered/Not Resolved -), RESOlved -), RETINOL] (C - n/a -) | | | | | | | | | |
| Hypersensitivity (n/a - Not Recovered/Not Resolved -), | | | | | | | | | |
| Lacrimation increased (n/a - Not Recovered/Not Resolved -), | | | | | | | | | |
| Menstruation irregular (n/a - Unknown -), | | | | | | | | | |
| Nasal congestion (n/a - Unknown -), | | | | | | | | | |
| Nasal pruritus (n/a - Not Recovered/Not Resolved -), | | | | | | | | | |
| Pruritus (n/a - Unknown -), | | | | | | | | | |
| Rash (n/a - Not Recovered/Not Resolved -), | | | | | | | | | |
| Rhinorrhoea (n/a - Not Recovered/Not Resolved -), | | | | | | | | | |
| Seasonal allergy (n/a - Unknown -) | No | Male | -17 N | Not available | Non | Non | Spontaneous | 17/11/2022 | EU-EC- |
| | | | | | European | Healthcare Professional | , | , :=, 3322 | 10014030276 |

| | | | | | | | | | | | applicable - [1d - n/a - n/a]) | METFORMIN HYDROCHLORIDE, METFORMIN HYDROCHLORIDE (C - Diabetes mellit n/a - [n/a - n/a - n |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|--------|----|---|---|--|
| EU-EC- 10014030324 | 17/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10014030497 | 17/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Important Condition) Vaccination site nodule (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014030621 | 17/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10014030622 | 17/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Important Condition) 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 reported |
| EU-EC- 10014031133 | 17/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Important Condition) Malaise (2d - Recovered/Resolved -), Pyrexia (2d - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014031412 | 17/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Burning sensation (n/a - Unknown -), Erythema (n/a - Unknown -), Eye pruritus (n/a - Unknown -), Rash (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014031460 | 17/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Resolved -) Vaccination site erythema (n/a - Not Recovered/Not Resolved -), Vaccination site warmth (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014031519 | 17/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Unknown -) Vaccination site erythema (n/a - Not Recovered/Not Resolved -), Vaccination site swelling (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014031521 | 17/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Unknown -) Malaise (n/a - Unknown -), Pain in extremity (n/a - Unknown -), Pyrexia (1d - Recovered/Resolved -), Rash (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | [FLUOXETINE] (C - n/a - [n/a - n/a - use]) |
| EU-EC- 10014031529 | 17/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Resolved -) Abdominal pain (n/a - Unknown -), Asthma (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Vaccination site pain (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014031566 | 17/11/2022 | Spontaneous | | European Economic | Not available | 12-17 Years | Not Specified | Female | No | Menstrual disorder (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - | Not reported |

| EU-EC- | 17/11/2022 | Spontaneous | Non | European | Not available | 12-17 | Adolescent | Female | No | Resolved -) Adverse reaction (n/a | COMIRNATY | Not reported |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|--------|-----|--|---|--------------|
| 10014031618 | 1//11/2022 | эрогианеоus | | Economic | no. evellene | Years | Auvjescent | тепаје | INU | Adverse reaction (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | COMINNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 3{DF} - n/a]) | тчос теропей |
| | | | | | | | | | | Autoantibody test (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Dizziness (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Hypoaesthesia oral (0d - Recovered/Resolved -), | | |
| | | | | | | | | | | Myoclonus (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), | | |
| | | | | | | | | | | Palpitations (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Post vaccination syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), | | |
| | | | | | | | | | | Postural orthostatic tachycardia syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Tremor (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | | |
| | | | | | | | | | | Visual impairment (0d - Recovered/Resolved - Other Medically Important Condition), | | |
| | | | | | | | | | | Wheelchair user (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10014031697 | 17/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Swelling (n/a - Unknown -), Vaccination site erythema (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014031706 | 17/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Vaccination site erythema (2d - Recovered/Resolved -), Vaccination site rash | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | (n/a - Unknown -), Vaccination site swelling (n/a - | | |
| | | | | | | | | | | Unknown -), Vaccination site warmth (n/a - Unknown -) | | |
| EU-EC- 10014031813 | 17/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Dizziness (6d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Headache (7d - Recovered/Resolved -), | .,,,,, | |
| | | | | | | | | | | Lymphadenopathy (8d - Recovered/Resolved -), | | |
| | | | | | | | | | | Malaise (8d - Recovered/Resolved -), | | |
| | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved -), | | |

| 00 | | 10.22 | | | | • | tuii Lii | ic Listing | , repoi | | | |
|----|-----------------------|------------|-------------|----------------------------|----------------------------------|------------------------------|----------------|------------------|---------|---|---|--------------|
| | | | | | | | | | | Rash (n/a - Recovering/Resolving -), Vaccination site pain (5d - Recovered/Resolved -) | | |
| | EU-EC- 10014031929 | 17/11/2022 | Spontaneous | | European Economic Area | Not available | | Not Specified | Male | Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Nausea (n/a - Not Recovered/Not Resolved -); | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved -), Rash (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Recovered/Resolved - | | |
| | EU-EC- 10014031951 | 17/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female |) Headache (n/a - Recovered/Resolved -), Pruritus (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | EU-EC- 10014031964 | 17/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | Dizziness (n/a - Unknown -), Malaise (n/a - Unknown -), Nausea (n/a - Unknown -), Photopsia (n/a - Unknown -), Vaccination site pain (n/a - Unknown -), Vomiting (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | EU-EC- 10014031985 | 17/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | | Not Specified | Male | Eye swelling (n/a - Unknown -), Pyrexia (n/a - Recovering/Resolving -), Swelling face (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | 10014032101 | | Spontaneous | Professional | European Economic Area European | Not available Not available | Years | Not Specified | Female | Unknown -), Rash erythematous (n/a - Recovering/Resolving -), Rash macular (n/a - Recovering/Resolving -), Rash pruritic (n/a - Unknown -), Swelling face (n/a - Recovering/Resolving -), Swelling of eyelid (n/a - Recovering/Resolving -), | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | 10014032216 | | | Healthcare Professional | Economic Area | | Years | Specified | | Recovered/Not Resolved -), Nausea (n/a - Recovered/Resolved With Sequelae -) | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | |
| | 10014032441 | | Spontaneous | Professional | European Economic Area | Not available | 12-17 Years | Adolescent | | Erythema (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Oedema (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| | EU-EC- 10014032659 | 17/11/2022 | Spontaneous | | European Economic Area | Not available | | Not Specified | Male | Chest pain (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovering/Resolving -), Myalgia (n/a - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |

|).11.2022 | 13.22 | | | | ı | Kun Lii | ne Listing | g Repo | | 1. | 1 | ı |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|--------|----|---|--|---|
| | | | | | | | | | |), Pyrexia (n/a - Recovered/Resolved - | | |
| EU-EC- 10014032860 | 17/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Abdominal pain (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Nausea (n/a - Percovering/Resolving | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014033449 | 17/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Recovering/Resolving -) Burning sensation (n/a - Unknown -), Chest discomfort (n/a - Unknown -), Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Pruritus (n/a - Unknown -), Rash (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (5 - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014033453 | 17/11/2022 | Spontaneous | Healthcare | European Economic | Not available | 12-17 Years | Not Specified | Male | No | Urticaria (n/a - Recovering/Resolving -) Chills (3d - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | Professional | Area | | | | | |), Fatigue (5d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Oropharyngeal pain (n/a - Unknown -), Pyrexia (4d - Recovered/Resolved -), Vaccination site pain (2d - Recovered/Resolved -) | n/a - n/a - [n/a - n/a - n/a]) | |
| EU-EC- 10014033469 | 17/11/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| EU-EC- 10014033601 | 17/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain (n/a - Unknown -), Headache (n/a - Unknown -), Myalgia (n/a - Unknown -), Pyrexia (n/a - Unknown -) | n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | NOT AVAILABLE (C n/a - n/a - [n/a - n/ Oral use]), [LACTULOSE] (C - n - n/a - [n/a - n/a - 0 use]) |
| EU-EC- 10014033603 | 17/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Neck pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Unknown -), Supraclavicular fossa pain (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014033629 | 17/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Resolved -) Burning sensation (n/a - Unknown -), Dizziness (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Unknown -), Pyrexia (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014034212 | 17/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Arthralgia (1d - Recovered/Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |

| Company Comp | 11.2022 1 | L | |
|--|-----------|--|--------|
| 1711-1712-2022 Spectamental Professional Services Marie State Ma | | Tenderness (n/a - | |
| 17-11-17-17-17-17-17-17-17-17-17-17-17-1 | | | |
| Page | | No Rash pruritic (n/a - COMIRNATY Not reported |] |
| Pack-Processory Pack-Proce | 014034581 | n/a - n/a - [n/a - n/a - Urticaria (n/a - n/a]) | |
| Processor Proc | | | ı |
| ## 1711/2022 Spontamental Healthcare Preferenciarial (Company No. 1711/2022 Spontamental Healthcare (Company No. 1711/ | | Malaise (n/a - | |
| EL-EC- 1101/11/2022 Sportamensa Roma Roman Rot available Roman Roman Roman Rot available Roman Roman Roman Roman Roman Rot available Roman Rom | | (n/a - | |
| EL-ECT 1711/2022 Sportaneous Peatlineous Peatlin | | (n/a - | |
| | J-EC- |) | |
| EUROPE 17/11/2002 Spontaneous Non Recommon Recommon Non Recommon Non Recommon Non Recommon Recommon Non Recommon Recommon Recommon Recommon Non Recommon Recommon Recommon Recommon Recommon Non Recommon Recommo | | Unknown -), [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a - n/a]) | |
| ELEC- 17/11/2022 Sportlamous Non Perfessional Professional Response Non Perfessional Response Non Perfessional Response Non Perfessional Response Non Perfessional Response Non Response No | | | |
| EU-EC 17/11/2022 Sportaneous Neathcurre Next processional Next available 12-17 Not. Permile Not available 17/11/2022 Sportaneous Next processional Next proces | | No Arthralgia (2d - Recovered/Resolved -), COMIRNATY [TOZINAMERAN] (S - n/a - n/a - n/a - n/a - n/a - | ı |
| Packed P | | Back pain (n/a - Unknown -), | |
| EU-EC- 17/11/2022 Spontaneous Healthcare Commissional Economic Area More Eu-EC- 10/11/2022 Spontaneous Healthcare Economic Area Healthcare Economic Healthcare Econo | | Recovered/Resolved -), | |
| Recovered Resolved - J., Meck pain (n/a - Unknown - J.) Pain (n/a - Unknown - J.) Pain in externity (n/a - Unknown - J.) Pain (n/a - Unknown - J.) Phyrexia (1d - Recovered Resolved - J.) Phyrexia (1d - Recovered Resolved - J.) Phyrexia (1d - Recovered Resolved - J.) Vaccinations take pain (n/a - Unknown - J.) Vaccinations take | | Recovered/Resolved -), | |
| Recovered/Resolved - Next pain (r/a - Unknown -) Pain in extremity (r/a - Unknown -) Pain (r/a - Unknown -) Pain in extremity (r/a - Unknown -) Pain (r/a - Valuation -) | | Recovered/Resolved -), | |
| EU-EC- 10014034814 17/11/2022 Spontaneous Healthcare Professional European Round Professional European Recombination Professional Fernal European Round Professional European Round Recombine Recom | | Recovered/Resolved -), | |
| EU-EC- 10014034514 17/11/2022 Spontaneous Healthcare Roomeric Area Non Professional European Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Recovered Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Professional Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available 17/11/2022 Spontaneous Non Healthcare Roomeric Resolved - Not available Roomeric Recovered Resolved - Not available Roomeric Roomeric Roomeric Recovered Resolved - Not available Roomeric Roomeric Roomeric Roomeric Ro | | Unknown -), | |
| EU-EC- 10014034814 17/11/2022 Spontaneous Healthcare Roomerd/Resolved - Non Professional European Economic Area Non Professional Fernale Resolved - Non Professional European Economic Area Non Professional Fernale Resolved - Non Professional European Economic Resolved - Non Professional Area Non Professional Fernale Resolved - Non Professional European Resolved - Non Professional Area Non Resolved - Non | |), Pain in extremity (n/a | |
| EU-EC- 10014034814 IT/11/2022 Spontaneous Healthcare conomic Area Non Professional 1 European Economic Area Non Professional 1 European Healthcare Professional Area 17/11/2022 Spontaneous Non Healthcare Professional Professional Reconomic Area 17/11/2022 Spontaneous Healthcare Professional Professional Reconomic Area 17/11/2022 Spontaneous Healthcare Healthcare Healthcare Professional Reconomic Area 17/11/2022 Spontaneous Non Healthcare Healthcare Healthcare Healthcare Professional Area 17/11/2022 Spontaneous Healthcare Healthcare Healthcare Healthcare Healthcare Professional Area 17/11/2022 Spontaneous Non Healthcare Healthcare Professional Area Not available 12-17 Adolescent Female No Gough (n/a - Not Recovered/Not Resolved -) n/a) COUID-19 (n/a - n/a) Invalvation Not available Not availabl | | Pyrexia (1d - | |
| Professional European Prof | 150 | (n/a - Unknown -) | |
| EU-EC- 10014035599 T/11/2022 Spontaneous Non Healthcare Professional Healthcare Professional Healthcare Professional Healthcare Professional Not available T/2-17 Not Specified | | Unknown - Other Medically Important CovID-19 immunisation - Not | |
| EU-EC- 10014035559 17/11/2022 Spontaneous Spontane | | Drug ineffective (n/a n/a]) Unknown - Other Medically Important | |
| EU-EC- 10014035600 T/11/2022 Spontaneous Professional Economic Area T/11/2022 Spontaneous Professional Economic Professional Economic Area T/2-17 Years T/2-17 Years T/2-17 Adolescent Professional Premale No Bone marrow failure (n/a - Recovering/Resolving - Other Medically Important Condition) T/11/2022 Spontaneous Professional Professional Professional Professional Economic Professional Professional Economic Professional Economic Professional Professional Economic Professional Profe | | No Cough (n/a - Not Recovered/Not Resolved -) COMIRNATY Not reported [TOZINAMERAN] (S - n/a - n/a - n/a - n/a - | |
| EU-EC- 10014035795 17/11/2022 Spontaneous Non Healthcare Frofessional Non Healthcare Frofessional Non Healthcare Healthcare Professional Non Healthcare No | | No Bone marrow failure (n/a - COMIRNATY (n/a - Recovering/Resolving - Other Medically Important Condition) (P) - Intramuscular | |
| Vertigo (n/a - Intramuscular use] Recovered/Resolved -), Visual field tests abnormal (n/a - Recovered/Resolved - Other Medically Important Condition) | | No Immunisation COMIRNATY [TOZINAMERAN] (S - Recovered/Resolved - COVID-19 | l |
| abnormal (n/a - Recovered/Resolved - Other Medically Important Condition) | | [1d - 30ug - Vertigo (n/a - Intramuscular use]) | |
| | | abnormal (n/a - Recovered/Resolved - Other Medically | |
| | | No Chills (n/a - Unknown COMIRNATY Not reported | |
| | | n/a - n/a - [n/a - n/a - Pyrexia (6d - n/a]) | |
| EU-EC- 17/11/2022 Spontaneous Healthcare European 10014036830 For Specified | | No Anosmia (6d - COMIRNATY INTUNIV Recovered/Resolved - [TOZINAMERAN] (5 - [GUANFACIN | IE] (C |

| U.11.2022 | | l | I | Area | I | | ne Listin | у керо | |) | n/a - n/a - [n/a - n/a - | n/a - n/a - [n/a - n/a |
|-----------------------|------------|-------------|----------------------------|------------------|---------------|----------------|------------------|------------|----|---|--|---|
| | | | | | | | | | | , | n/a]) | Oral use]), [COLECALCIFEROL] |
| | | | | | | | | | | | | - n/a - n/a - [n/a - r - Oral use]), |
| | | | | | | | | | | | | [LISDEXAMFETAMIN DIMESYLATE] (C - n |
| | | | | | | | | | | | | - n/a - [n/a - n/a - 0 use]), |
| | | | | | | | | | | | | [RISPERIDONE] (C n/a - n/a - [n/a - n/ |
| EU-EC- | 17/11/2022 | Spontaneous | | European | Not available | 12-17 | | Female | No | COVID-19 (n/a - | COMIRNATY | Oral use]) Not reported |
| 10014037483 | | | Professional | Economic Area | | Years | Specified | | | Recovered/Resolved - Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not | |
| | | | | | | | | | | Vaccination failure | applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | (n/a - Recovered/Resolved - Other Medically | | |
| EU-EC- 10014037564 | 17/11/2022 | Spontaneous | Healthcare Professional | European | Not available | 12-17 Years | Not Specified | Female | No | Important Condition) Arrhythmia (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| 10011037301 | | | rioressional | Area | | rears | Specifica | | | Resolved - Life Threatening, | COVID-19 immunisation - Not | |
| | | | | | | | | | | Caused/Prolonged Hospitalisation, Other Medically Important | applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | Condition), Brain injury (n/a - Not | | |
| | | | | | | | | | | Recovered/Not Resolved - | | |
| | | | | | | | | | | Caused/Prolonged Hospitalisation, Other Medically Important | | |
| | | | | | | | | | | Condition), Cardiac arrest (n/a - | | |
| | | | | | | | | | | Not Recovered/Not Resolved - Life Threatening, | | |
| | | | | | | | | | | Caused/Prolonged Hospitalisation, | | |
| | | | | | | | | | | Disabling, Other Medically Important Condition), | | |
| | | | | | | | | | | Cerebral atrophy (n/a - Not Recovered/Not | | |
| | | | | | | | | | | Resolved - Caused/Prolonged | | |
| | | | | | | | | | | Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Coma (n/a - Not Recovered/Not | | |
| | | | | | | | | | | Resolved - Caused/Prolonged Hospitalisation, Other | | |
| | | | | | | | | | | Medically Important Condition), | | |
| | | | | | | | | | | Communication disorder (n/a - | | |
| | | | | | | | | | | Unknown -), Dysphagia (n/a - | | |
| | | | | | | | | | | Unknown - Other Medically Important | | |
| | | | | | | | | | | Condition), Hyperglycaemia (n/a - Unknown -), | | |
| | | | | | | | | | | Loss of consciousness (n/a - Unknown - Life | | |
| | | | | | | | | | | Threatening, Caused/Prolonged | | |
| | | | | | | | | | | Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Myoclonic dystonia (n/a - Unknown -), | | |
| | | | | | | | | | | Quadriparesis (n/a - Unknown - Other | | |
| | | | | | | | | | | Medically Important Condition), | | |
| | | | | | | | | | | Rales (n/a - Unknown -), | | |
| | | | | | | | | | | Resuscitation (n/a - Unknown - Life | | |
| | | | | | | | | | | Threatening, Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Seizure (n/a - | | |
| | | | | | | | | | | Unknown - Caused/Prolonged Hospitalisation, Other | | |
| | | | | | | | | | | Medically Important Condition), | | |
| | | | | | | | | | | Sinus rhythm (n/a - Unknown -), | | |
| | | | | | | | | | | Staphylococcus test positive (n/a - | | |
| | | | | | | | | | | Unknown -), Tachycardia (n/a - | | |
| ⊥ ttns://dan.e | ma euro | na eu/ana | · alvtice/eav | v dli2Go | 1 | 1 | | 1 | | , | 1 | 27/71 |

| | | | | | | | | | | Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Ventricular fibrillation (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|--|----------------|------------------|--------|----|--|---|--|
| | | | | | | | | | | Medically Important Condition), | | |
| EU-EC- | 17/11/2022 | Spontaneous | | European | Not available | 12-17 | Adolescent | Male | No | (n/a - Unknown -) Leukopenia (n/a - | COMIRNATY | Not reported |
| 10014038522 | | | Professional | Economic Area | | Years | | | | Recovered/Resolved - Other Medically Important Condition), Myopericarditis (3d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | Neutropenia (n/a - Recovered/Resolved - Other Medically Important Condition) | | |
| EU-EC- 10014038938 | 17/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Erythema (0d - Recovered/Resolved -), Swelling (0d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10014039050 | 17/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Vaccination site inflammation (n/a - Unknown -), Vaccination site pain | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported |
| EU-EC- 10014039072 | 17/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | (n/a - Unknown -) Pyrexia (n/a - Unknown -) | 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not reported |
| EU-EC- 10014015215 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014017190 | 16/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Chills (n/a – Recovered/Resolved – Other Medically Important Condition), Pain in extremity (n/a – Recovered/Resolved – Other Medically Important Condition), Vulval ulceration (8d – Recovered/Resolved With Sequelae – Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY 30 MICROGRAMS/DOSE [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intravenous use]) | Not reported |
| EU-EC- 10014017499 | | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Cardiac arrest (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition), Cardiomegaly (n/a - Fatal - Results in Death, Life Threatening), Myocarditis (n/a - Fatal - Results in Death, Life Threatening), Myocarditis (n/a - Fatal - Results in Death, Life Threatening, Other Medically Important Condition) | TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10014017506 | 16/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Pillar, S., Posterior ocular manifestations following BNT162b2 mRNA COVID-19 vaccine: a case series. International Ophthalmology. 2022;10.1007/s10792-022- 02565-2. doi:10.1007/s10792-022-02565-2 | 12-17 Years | Not Specified | Female | No | Scleritis (n/a - Recovered/Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014017941 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chills (1d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Injected limb mobility decreased (n/a - Unknown -), Malaise (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | [DROSPIRENONE, ETHINYLESTRADIO LACTOSE ANHYDROUS] (C - r - n/a - [n/a - n/a - (use]) |

| 0.11.2022 | 13.22 | | | | ſ | Tuii Li | ne Listing | y Kepo | 11 | | | |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|--------|----|--|---|--------------|
| | | | | | | | | | | Recovering/Resolving -), | | |
| | | | | | | | | | | Nausea (0d - Recovered/Resolved -), | | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown -), | | |
| | | | | | | | | | | Vaccination site pain (n/a - Not Recovered/Not Resolved -) | | |
| EU-EC- 10014017950 | 16/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Fatigue (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014017961 | 16/11/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Epistaxis (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014018251 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dyspnoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014018451 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Headache (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - | Not reported |
| | | | | | | | | | | Mastication disorder (n/a - Unknown -), | [n/a - n/a - n/a]) | |
| | | | | | | | | | | Muscle twitching (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Myalgia (3d - Recovered/Resolved -), | | |
| | | | | | | | | | | Pain in jaw (n/a - Unknown -) | | |
| EU-EC- 10014018530 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Fatigue (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | اارا | |
| | | | | | | | | | | Menstrual disorder (n/a - Not Recovered/Not Resolved -) | | |
| 10014018681 | 16/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain (6d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| 10014019116 | | Spontaneous | Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Herpes zoster (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014019211 | 16/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Headache (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014019456 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic | Not available | 12-17 Years | Adolescent | Female | No | Disturbance in attention (406d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported |
| | | | rocssona | Aicu | | | | | | With Sequelae - Caused/Prolonged Hospitalisation), | immunisation - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Lymphadenopathy (406d - Recovered/Resolved | | |
| | | | | | | | | | | With Sequelae - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Muscle twitching (401d - Recovered/Resolved | | |
| | | | | | | | | | | With Sequelae - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Sleep disorder (n/a - Unknown - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10014019760 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014019799 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Muscle spasms (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Pain (n/a - Unknown - | | |
| EU-EC- 10014019803 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Nausea (1d - Recovered/Resolved -), Vomiting (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | 16/11/2022 | Spontaneous | | European | Not available | 12-17 | Not | Female | No | Unknown -) Cough (n/a - Not | COMIRNATY | Not reported |
| 10014019829 | | | Healthcare Professional | Economic Area | | Years | Specified | | | Recovered/Not Resolved -), | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | |

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|--|--|--------------|--|---|------------------------------|----------------------------------|--------------------------------------|-------------|----------|---|--|--------------|
| | | | | | | | | | | Eye pain (n/a - Unknown -), | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not | | |
| U-EC- | 16/11/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Adolescent | Male | No | Resolved -) Behaviour disorder | COMIRNATY | Not reported |
| 0014021973 | 10/11/2022 | Sportarieous | Professional | Economic | Not available | Years | Adolescent | inale | INO | (n/a - Not | [TOZINAMERAN] (S - | Not reported |
| | | | | Area | | | | | | Recovered/Not Resolved -), | COVID-19 immunisation - n/a - | |
| | | | | | | | | | | Encephalitis (n/a - | [n/a - n/a - Intramuscular use]) | |
| | | | | | | | | | | Not Recovered/Not | initiamusculai usej) | |
| | | | | | | | | | | Resolved - Caused/Prolonged | | |
| | | | | | | | | | | Hospitalisation), | | |
| | | | | | | | | | | Loss of personal | | |
| | | | | | | | | | | independence in daily activities (n/a - Not | | |
| | | | | | | | | | | Recovered/Not | | |
| :U-EC- | 16/11/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Male | No | Resolved -) Diarrhoea (n/a - | COMIRNATY | Not reported |
| .0014022017 | , , | ' | Professional | | | Years | Specified | | | Recovered/Resolved - | [TOZINAMERAN] (S - | , |
| | | | | Alea | | | | | | , | n/a - n/a - [n/a - n/a - n/a]) | |
| U-EC- 0014022070 | 16/11/2022 | Spontaneous | | European Economic | Not available | 12-17 Years | Not Specified | Male | No | Arthralgia (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| 10014022070 | | | Professional | | | Tears | Specified | | | Resolved -), | n/a - n/a - [n/a - n/a - | |
| | | | | | | | | | | Fatigue (n/a - Not | n/a]) | |
| | | | | | | | | | | Recovered/Not | | |
| | | | | | | | | | | Resolved -), | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not | | |
| | | | | | | | | | | Resolved -), | | |
| | | | | | | | | | | Influenza like illness | | |
| | | | | | | | | | | (n/a - Unknown -), | | |
| | | | | | | | | | | Malaise (n/a - Not | | |
| | | | | | | | | | | Recovered/Not Resolved -), | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | Myalgia (n/a - Not Recovered/Not | | |
| | | | | | | | | | | Resolved -), | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not | | |
| | | | | | | | | | | Resolved -) | | |
| U-EC- 0014022179 | 16/11/2022 | Spontaneous | | European Economic | Not available | 12-17 Years | Not Specified | Female | No | Arthralgia (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| 0014022179 | | | Professional | | | lears | Specified | | | Resolved -), | COVID-19 | |
| | | | | | | | | | | Headache (n/a - | immunisation - Not applicable - [n/a - | |
| | | | | | | | | | | Recovering/Resolving | 1{DF} - n/a]) | |
| | | | | | | | | | | | | |
| | | | | | | | | | | Myalgia (n/a - Not Recovered/Not | | |
| | | | | | | | | | | Resolved -), | | |
| | | | | | | | | | | Nausea (1d - | | |
| | | | | | | | | | | Recovered/Resolved -), | | |
| | | | | | | | | | | Pyrexia (n/a - | | |
| | | | | | | | | | | Recovering/Resolving | | |
| | | | | | | | | | | -), | | |
| | | | | | | | | | | Vaccination site lymphadenopathy | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | (n/a - Not | | |
| | | | | | | | | | | | | |
| | 16/11/2022 | Spontaneous | | European | Not available | 12-17 | Adult | Male | No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre | COMIRNATY | Not reported |
| | 16/11/2022 | Spontaneous | | Economic | Not available | 12-17 Years | Adult | Male | No | (n/a - Not Recovered/Not Resolved -) | [TOZINAMERAN] (S - COVID-19 | Not reported |
| | 16/11/2022 | Spontaneous | Healthcare | Economic | Not available | | Adult | Male | No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - | [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported |
| | 16/11/2022 | Spontaneous | Healthcare | Economic | Not available | | Adult | Male | No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving | [TOZINAMERAN] (S - COVID-19 | Not reported |
| | 16/11/2022 | Spontaneous | Healthcare | Economic | Not available | | Adult | Male | No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported |
| | 16/11/2022 | Spontaneous | Healthcare | Economic | Not available | | Adult | Male | No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS | Not reported |
| | 16/11/2022 | Spontaneous | Healthcare | Economic | Not available | | Adult | Male | No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S | Not reported |
| | 16/11/2022 | Spontaneous | Healthcare | Economic | Not available | | Adult | Male | No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [r/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not | Not reported |
| EU-EC- 10014022262 | | | Healthcare Professional | Economic Area | | Years | | | | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [n/a - 1{DF} - n/a]) | |
| | | Spontaneous | Healthcare Professional | Economic Area | Not available | Years | Adult Not Specified | Male Female | No No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{0F} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [n/a - 1{0F} - n/a]) COMIRNATY [TOZINAMERAN] (S - | Not reported |
| :U-EC- | | | Healthcare Professional | Economic Area | | Years | Not | | | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not Recovered/Not | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - Immunisation - Immunisation - Immunisation - Immun | |
| :U-EC- | | | Healthcare Professional | European Economic | | Years | Not | | | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{0F} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [n/a - 1{0F} - n/a]) COMIRNATY [TOZINAMERAN] (S - | |
| :U-EC- 0014022279 | 16/11/2022 | Spontaneous | Healthcare Professional Healthcare Professional | European Economic Area | Not available | Years 12-17 Years | Not Specified | Female | No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - n/a - n/a - n/a]) | Not reported |
| 0014022262 EU-EC- 0014022279 | 16/11/2022 | | Healthcare Professional Healthcare Professional Non Healthcare | European Economic Area European Economic Area | | Years 12-17 Years | Not | | | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Rash (n/a - Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{Pr} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [n/a - 1{Pr} - n/a]) [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | |
| 0014022262 EU-EC- 0014022279 | 16/11/2022 | Spontaneous | Healthcare Professional Healthcare Professional | European Economic Area European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Rash (n/a - Not | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [r/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [r/a - 1{DF} - n/a]) (COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a - n/a]) | Not reported |
| U-EC- 0014022279 | 16/11/2022 | Spontaneous | Healthcare Professional Healthcare Professional Non Healthcare Professional Healthcare | European Economic Area European Economic Area European Economic Area European Economic | Not available | 12-17 Years 12-17 Years | Not Specified Not Specified | Female | No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Rash (n/a - Not Recovered/Not Resolved -) Disturbance in | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- .0014022279 | 16/11/2022 | Spontaneous | Healthcare Professional Healthcare Professional Non Healthcare Professional | European Economic Area European Economic Area European Economic Area European Economic | Not available Not available | 12-17 Years | Not Specified Not Specified | Female | No No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Rash (n/a - Not Recovered/Not Resolved -) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [r/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [r/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - In/a - n/a - n | Not reported |
| EU-EC- .0014022279 | 16/11/2022 | Spontaneous | Healthcare Professional Healthcare Professional Non Healthcare Professional Healthcare | European Economic Area European Economic Area European Economic Area European Economic | Not available Not available | 12-17 Years 12-17 Years | Not Specified Not Specified | Female | No No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Rash (n/a - Not Recovered/Not Resolved -) Disturbance in attention (n/a - Unknown -), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [n/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014022279 | 16/11/2022 | Spontaneous | Healthcare Professional Healthcare Professional Non Healthcare Professional Healthcare | European Economic Area European Economic Area European Economic Area European Economic | Not available Not available | 12-17 Years 12-17 Years | Not Specified Not Specified | Female | No No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Rash (n/a - Not Recovered/Not Resolved -) Disturbance in attention (n/a - and attention | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [r/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [r/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - In/a - n/a - n | Not reported |
| EU-EC- 10014022279 | 16/11/2022 | Spontaneous | Healthcare Professional Healthcare Professional Non Healthcare Professional Healthcare | European Economic Area European Economic Area European Economic Area European Economic | Not available Not available | 12-17 Years 12-17 Years | Not Specified Not Specified | Female | No No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Rash (n/a - Not Recovered/Not Resolved -) Disturbance in attention (n/a - Unknown -), Fatigue (n/a - Unknown -), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [r/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [r/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - In/a - n/a - n | Not reported |
| EU-EC- 10014022279 | 16/11/2022 | Spontaneous | Healthcare Professional Healthcare Professional Non Healthcare Professional Healthcare | European Economic Area European Economic Area European Economic Area European Economic | Not available Not available | 12-17 Years 12-17 Years | Not Specified Not Specified | Female | No No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Rash (n/a - Not Recovered/Not Resolved -) Disturbance in attention (n/a - Unknown -), Fatigue (n/a - | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [r/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [r/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - In/a - n/a - n | Not reported |
| EU-EC- 10014022279 | 16/11/2022 | Spontaneous | Healthcare Professional Healthcare Professional Non Healthcare Professional Healthcare | European Economic Area European Economic Area European Economic Area European Economic | Not available Not available | 12-17 Years 12-17 Years | Not Specified Not Specified | Female | No No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Rash (n/a - Not Recovered/Not Resolved -) Disturbance in attention (n/a - Unknown -), Fatigue (n/a - Unknown -), Nasal congestion (n/a - Unknown -), Nasopharyngitis (n/a | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [r/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [r/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - In/a - n/a - n | Not reported |
| EU-EC- .0014022279 | 16/11/2022 | Spontaneous | Healthcare Professional Healthcare Professional Non Healthcare Professional Healthcare | European Economic Area European Economic Area European Economic Area European Economic | Not available Not available | 12-17 Years 12-17 Years | Not Specified Not Specified | Female | No No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Rash (n/a - Not Recovered/Not Resolved -) Disturbance in attention (n/a - Unknown -), Fatigue (n/a - Unknown -), Nasal congestion (n/a - Unknown -), Nasopharyngitis (n/a - Not Recovered/Not Resolved -) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [r/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [r/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - In/a - n/a - n | Not reported |
| EU-EC- 0014022279 EU-EC- 0014022278 EU-EC- 0014022298 | 16/11/2022 16/11/2022 16/11/2022 | Spontaneous | Healthcare Professional Healthcare Professional Non Healthcare Professional Healthcare Professional | European Economic Area European Economic Area European Economic Area European Economic | Not available Not available | Years 12-17 Years 12-17 Years | Not Specified Not Specified | Female | No No | (n/a - Not Recovered/Not Resolved -) Guillain-Barre syndrome (n/a - Recovering/Resolving -) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) Rash (n/a - Not Recovered/Not Resolved -) Disturbance in attention (n/a - Unknown -), Fatigue (n/a - Unknown -), Nasal congestion (n/a - Unknown -), Nasopharyngitis (n/a | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [r/a - 1{DF} - n/a]), [RABIES VACCINE, RABIES VIRUS (INACTIVATED) STRAIN FLURY LEP] (S - Prophylaxis - Not applicable - [r/a - 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - In/a - n/a - n | Not reported |

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| INSULIN ASPART SANOFI [INSULIN ASPART] (C - n/a [n/a - n/a - Subcutaneous use] [FLUOXETINE, FLUOXETINE HYDROCHLORIDE] |
| - n/a - n/a - [n/a - 1 - Oral use]) [IBUPROFEN] (C - r - n/a - [n/a - n/a - 0 |
| use]), [PARACETAMOL, CAFFEINE] (C - n/a |
| n/a - [n/a - n/a - O use]) |
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| Not reported |
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Run Line Listing Report Cold sweat (n/a -Unknown -), Caused/Prolonged Hospitalisation), Decreased appetite (n/a - Unknown -), Dizziness (n/a -Unknown -), Epistaxis (n/a -Unknown -), Gamma-glutamyltransferase decreased (n/a -Unknown -), Gastritis (n/a -Unknown -), Granulocytes abnormal (n/a -Unknown -), Haematoma (n/a -Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Headache (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Impaired gastric emptying (n/a -Unknown - Other Medically Important Condition), Inappropriate schedule of product administration (n/a -Unknown -), (n/a - Unknown -Other Medically Important Condition), Low density lipoprotein increased (n/a - Unknown -), Lymphocyte count decreased (n/a -Unknown -), Memory impairment (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Migraine with aura (n/a - Not Recovered/Not Resolved -), Muscular weakness (n/a - Unknown -), Nausea (n/a - Not Recovered/Not Resolved -Caused/Prolonged Hospitalisation), Orthostatic intolerance (n/a -Unknown -), Platelet disorder (n/a - Unknown -), Post lumbar puncture syndrome (n/a -Unknown -),

Contusion (n/a - Not Recovered/Not Resolved -

Fall (n/a - Unknown -

Loss of consciousness

Postural orthostatic tachycardia syndrome (n/a - Unknown -),

Skin abrasion (n/a -Unknown -),

Somnolence (n/a -Unknown -),

Syncope (6min -Unknown -

| | | | | | | | | | | Caused/Prolonged Hospitalisation), Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Tachycardia (n/a - Unknown -), Tension headache (n/a - Unknown -), Tremor (n/a - Unknown -), | | |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|--------|----|--|--|--------------|
| | | | | | | | | | | Vision blurred (n/a - Unknown -), Visual impairment (2h - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Visual impairment (n/a - Unknown -), Vomiting (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation), Weight decreased | | |
| EU-EC- 10014024513 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | (n/a - Unknown - Caused/Prolonged Hospitalisation), White blood cell count increased (n/a - Unknown -) Arthralgia (n/a - Not Recovered/Not Resolved -), Chronic fatigue syndrome (n/a - Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Sylution (I/Ja - Not Recovered/Not Resolved -), Depressed mood (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not | | |
| EU-EC- 10014024609 | 16/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Resolved -), Respiratory distress (n/a - Not Recovered/Not Resolved -) Amenorrhoea (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported |
| EU-EC- 10014025119 | 16/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Seizure (0d - Recovered/Resolved - Other Medically | immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| EU-EC- 10014025217 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Important Condition) Lymphadenopathy (n/a - Not Recovered/Not | n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| EU-EC- 10014025218 | 16/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | | Not Specified | Female | No | Resolved -) Epistaxis (1d - Recovered/Resolved -), Headache (1d - | n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014025304 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Recovered/Resolved -) Nausea (0d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014025672 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | | Not Specified | Female | No | Dysmenorrhoea (n/a - Unknown -), Heavy menstrual bleeding (n/a - Not | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |

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| | | | | | | | | | | Recovered/Not Resolved -), | | |
| | | | | | | | | | | Menstruation irregular (n/a - Not Recovered/Not Resolved -) | | |
| EU-EC- 10014025716 | 16/11/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Not Specified | Female | No | Cyanosis (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| 10014025716 | | | Professional | Area | | rears | specified | | | | | |
| | | | | | | | | | | Peripheral coldness | | |
| EU-EC- | 16/11/2022 | Spontaneous | | European | Not available | 12-17 | Not | Male | No | (n/a - Unknown -) Urticaria (n/a - | COMIRNATY | Not reported |
| 10014025763 | | | | Economic Area | | Years | Specified | | | Recovering/Resolving -) | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | |
| EU-EC- 10014025773 | 16/11/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Heavy menstrual bleeding (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014025811 | 16/11/2022 | Spontaneous | Healthcare | Economic | Not available | 12-17 Years | Not Specified | Female | No | Mobility decreased (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | Professional | Area | | | | | | Pain in extremity (n/a - Unknown -), | n/a - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Peripheral swelling (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Skin discolouration (n/a - Unknown -), | | |
| | | | | | | | | | | Tenderness (n/a - Unknown -) | | |
| EU-EC- 10014025815 | 16/11/2022 | Spontaneous | Healthcare | European Economic | Not available | 12-17 Years | Not Specified | Female | No | Fatigue (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | Professional | Area | | | | | | Nausea (n/a - Not Recovered/Not Resolved -), | n/a - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Vomiting (n/a - Unknown -) | | |
| EU-EC- 10014025819 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Dizziness (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Hypoaesthesia (n/a - Unknown -), | 11,41,5 | |
| | | | | | | | | | | Nausea (n/a - Recovering/Resolving -), | | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown -), | | |
| | | | | | | | | | | Presyncope (n/a - Unknown -), | | |
| EU-EC- | 16/11/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Female | No | Vomiting (n/a - Unknown -) Epilepsy (n/a - | COMIRNATY | Not reported |
| 10014025865 | ,, | | Professional | Economic Area | | Years | Specified | | | Unknown - Other Medically Important Condition), | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition) | | |
| EU-EC- 10014025923 | 16/11/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (41d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014025970 | 16/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Headache (8d - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | [DICLOFENAC, DICLOFENAC DIETHYLAMINE, |
| | | | | | | | | | | Nausea (8d - Recovered/Resolved -) | n/a]) | DICLOFENAC EPOLAMINE, DICLOFENAC POTASSIUM, DICLOFENAC RESINATE, DICLOFENAC SODIL DICLOFENAC SODIL PH. EUR.] (C - n/a - n/a - [n/a - n/a - Rectal use]), |
| | | | | | | | | | | | | [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM DIHYDRATE, ESOMEPRAZOLE SODIUM] (C - n/a - n/a - [n/a - n/a - Or use]), |
| | | | | | | | | | | | | [METOCLOPRAMIDE HYDROCHLORIDE, METOCLOPRAMIDE HYDROCHLORIDE ANHYDROUS] (C - r - n/a - [n/a - n/a - (use]), |
| | | | | | | | | | | | | [SERTRALINE] (C - - n/a - [n/a - n/a - (use]) |
| EU-EC- 10014025984 | 16/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest discomfort (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | | | | | | | | | | |

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| | | | | | | | | | | Chest pain (n/a - Unknown -), | n/a - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Headache (1d - Recovered/Resolved - | | |
| | | | | | | | | | |), | | |
| | | | | | | | | | | Nausea (1d - Recovered/Resolved -), | | |
| | | | | | | | | | | Pyrexia (1d - Recovered/Resolved -), | | |
| | | | | | | | | | | Vaccination site pain | | |
| | | | | | | | | | | (3d - Recovered/Resolved -) | | |
| EU-EC- 100140259 | | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Not Specified | Male | No | Chills (1d - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | | Area | | | | | | Headache (1d - Recovered/Resolved - | n/a - n/a - [n/a - n/a - n/a]) | |
| EU-EC- | | Spontaneous | | European | Not available | 12-17 | Not | Female | No |) Nausea (n/a - | COMIRNATY | Not reported |
| 100140260 | 38 | | Healthcare Professional | Economic Area | | Years | Specified | | | Unknown -), | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved -) | n/a]) | |
| EU-EC- 100140260 | 16/11/2022 | Spontaneous | Non Healthcare Professional | European Economic | Not available | 12-17 Years | Not Specified | Male | No | Poor quality sleep (n/a - Unknown - Other Medically | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| | | | Froressional | Aica | | | | | | Important Condition), | n/a]) | |
| | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), | | |
| | | | | | | | | | | Syncope (n/a - | | |
| | | | | | | | | | | Unknown - Other Medically Important Condition) | | |
| EU-EC- 100140261 | | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12 - 17 Years | Not Specified | Female | No | Ageusia (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | [DRIED FERROUS SULFATE, FERROUS SULFATE] (C - n/a - |
| | | | | | | | | | | Dizziness (n/a - Recovering/Resolving | n/a]) | n/a - [n/a - n/a - Or use]) |
| | | | | | | | | | | -), | | |
| | | | | | | | | | | Pain (n/a - Unknown -), | | |
| | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving -), | | |
| | | | | | | | | | | Vaccination site pain | | |
| | | | | | | | | | | Recovering/Resolving -) | | |
| EU-EC- 100140261 | | Spontaneous | Non Healthcare Professional | Economic | Not available | 12-17 Years | Not Specified | Male | No | Cough (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | [ESCITALOPRAM, ESCITALOPRAM |
| | | | Troicssional | Aicu | | | | | | Eye pain (n/a - Unknown -), | n/a]) | n/a - [n/a - n/a - Or use]), |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved -), | | [MELATONIN] (C - r - n/a - [n/a - n/a - (use]), |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | | [METHYLPHENIDAT HYDROCHLORIDE] - n/a - n/a - [n/a - r |
| | | | | | | | | | | Photophobia (n/a - | | - Oral use]), |
| | | | | | | | | | | Not Recovered/Not Resolved -), | | [PROPIOMAZINE, PROPIOMAZINE MALEATE] (C - n/a - |
| | | | | | | | | | | Vaccination site swelling (n/a - Not Recovered/Not | | n/a - [n/a - n/a - Or use]) |
| EU-EC- 100140261 | | Spontaneous | Healthcare Professional | European Economic | Not available | 12-17 Years | Not Specified | Male | No | Resolved -) Myalgia (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | | Area | | | | | | Resolved -), Pain (n/a - Unknown - | n/a - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | |), | | |
| EU-EC- | 16/11/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Adolescent | Male | No | Pyrexia (n/a - Unknown -) Dyspnoea (n/a - | COMIRNATY | Not reported |
| 100140275 | | Sportaneous | Professional | | Not available | Years | Adolescent | i i i i i i | | Unknown -), | [TOZINAMERAN] (S - COVID-19 | Not reported |
| | | | | | | | | | | Headache (n/a - Unknown -), | immunisation - Not applicable - [1d - 1{DF} - n/a]) | |
| | | | | | | | | | | Increased viscosity of upper respiratory secretion (n/a - | 1,000 | |
| | | | | | | | | | | Unknown -), Sneezing (n/a - | | |
| EU-EC- 100140277 | | Spontaneous | Non Healthcare | Non European | Not available | 12-17 Years | Not Specified | Male | No | Unknown -) Aggression (n/a - Unknown - | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| 1301702// | | | Professional | Economic Area | | Icqi2 | Specified | | | Caused/Prolonged Hospitalisation, | COVID-19 immunisation - Not | |
| | | | | | | | | | | Disabling), Chronic fatigue | applicable - [1d - n/a - Intramuscular use]) | |
| | | | | | | | | | | syndrome (n/a - Not Recovered/Not | | |
| | | | | | | | | | | | | |

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| | | | | | | | | | | Resolved - Caused/Prolonged Hospitalisation, Disabling), | | |
| | | | | | | | | | | Freezing phenomenon (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling), | | |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), | | |
| | | | | | | | | | | Panic attack (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling), | | |
| | | | | | | | | | | Tremor (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling) | | |
| EU-EC- 10014002719 | 15/11/2022 | Spontaneous | Non Healthcare Professional | | Not available | 12-17 Years | Not Specified | Female | No | Pulmonary embolism (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | [DIENOGEST, ETHINYLESTRADIOI LACTOSE, LACTOSE ANHYDROUS] (C - Amenorrhoea - n/a [n/a - n/a - n/a]) |
| EU-EC- 10014002999 | 15/11/2022 | Spontaneous | Non Healthcare Professional | | Not available | 12 - 17 Years | Not Specified | Female | No | Syncope (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014004116 | 15/11/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Not Specified | Female | No | Fatigue (n/a - Not Recovered/Not Resolved -), Hypoaesthesia (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular | Not reported |
| | | | | | | | | | | Resolved -), Peripheral swelling (n/a - Not Recovered/Not Resolved -), | use]) | |
| | | | | | | | | | | Swelling of eyelid (n/a - Unknown -) | | |
| EU-EC- 10014004802 | 15/11/2022 | Spontaneous | Non Healthcare Professional | | Not available | 12-17 Years | Not Specified | Male | No | Axillary pain (n/a - Recovering/Resolving -), Chills (1d - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | |), Swelling (n/a - Recovering/Resolving -) | | |
| EU-EC- 10014005395 | 15/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Pescosolido, E Clinical and immunological data from chronic urticaria onset after mRNA SARS-CoV-2 vaccines. Clinical and Experimental Allergy, 2022;52(11):1343-1346. doi:10.1111/cea.14214 | 12-17 Years | Not Specified | Male | No | Urticaria chronic (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014006432 | 15/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Abdominal pain (n/a - Unknown -), Condition aggravated (n/a - Unknown -), Depressed level of consciousness (n/a - Unknown -) Caused/Prolonged Hospitalisation, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| | | | | | | | | | | Diabetes mellitus (36d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Diabetic ketoacidosis (36d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Hyperglycaemia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Interchange of vaccine products (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| ttps://dap.e | ema.euro | pa.eu/ana | alytics/sav | v.dll?Go | | | | | | Condition), | | 36/7 |

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| U.11.2022 | 13.22 | | | | | Kun Li | ne Listine | g Kepo | rt | Off label use (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oropharyngeal pain (n/a - Unknown -), Peripheral circulatory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation), Tachypnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Type 1 diabetes mellitus (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Vomiting (n/a - Unknown - | | |
| | | | | | | | | | | Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Weight decreased (n/a - Unknown -) | | |
| EU-EC- 10014006452 | 15/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| EU-EC- 10014006850 | 15/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Visual field defect (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition) | applicable - [1d - 1{DF} - Intramuscular use]) | COMIRNATY [TOZINAMERAN] (C COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscu use]), [DOXYCYCLINE, DOXYCYCLINE HYCLATE, DOXYCYCLINE |
| EU-EC- | 15/11/2022 | Spontaneous | Non | European | Not available | 12-17 | Adolescent | Female | No | Autoimmune | | MONOHYDRATE] (O Acne - Dose not changed - [n/a - n/a n/a]) Not reported |
| 10014006890 | | | Healthcare Professional | Economic | | Years | | | | | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | |
| 10014006915 | | Spontaneous | Healthcare Professional | | Not available | Years | Not Specified | Male | No | Arthralgia (n/a - Recovering/Resolving -), Chills (1d - Recovered/Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Nasal congestion (n/a - Unknown -), Oropharyngeal pain (n/a - Unknown -), Pyrexia (2d - Recovered/Resolved -), Vaccination site pain (3d - Recovered/Resolved -), Vaccination site swelling (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014006935 | 15/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adult | Male | No | Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| | | | Healthcare Professional | Economic Area | Not available | | Adult | Male | No | swelling (n/a - Recovering/Resolving -) Acute kidney injury (n/a - Unknown - Caused/Prolonged Hospitalisation), Cough (n/a - Unknown - Caused/Prolonged | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not |

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| | | | | | | | | | | Unknown - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10014007098 | 15/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Immunisation reaction (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10014007139 | 15/11/2022 | Spontaneous | Non 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 reported |
| EU-EC- 10014008041 | 15/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Pain (n/a - Not Recovered/Not Resolved -), Pruritus (n/a - Not Recovered/Not Resolved -), Vaccination site swelling (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014008274 | 15/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Enlarged uvula (1d - Recovered/Resolved -), Oropharyngeal pain (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| 10014008515 | | Spontaneous | Healthcare Professional | | Not available | Years | Not Specified | Male | No | Back pain (n/a - Unknown -), Headache (4d - Recovered/Resolved -), Limb discomfort (4d - Recovered/Resolved -), Myalgia (6d - Recovered/Resolved -), Pain (4d - Recovered/Resolved -), Pyrexia (5d - Recovered/Resolved -), Rash (1d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014008585 | 15/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Lymphadenitis (n/a - Not Recovered/Not Resolved -), Neck pain (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014008646 | 15/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Fatigue (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Palpitations (n/a - Not Recovered/Not Resolved -), Sleep disorder (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014008676 | 15/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (n/a - Not Recovered/Not Resolved -), Chills (n/a - Recovering/Resolving -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), Hypoaesthesia (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |

| | | | | | | | | | |), Illness (n/a - | | |
|-----------------------|-----------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|---|---|--------------|
| | 5/11/2022 | Spontaneous | | European | Not available | | Not | Female | No | Unknown -), Pyrexia (n/a - Not Recovered/Not Resolved -), Rash (0d - Recovered/Resolved -), Swelling (n/a - Recovered/Resolved -), Urticaria (n/a - Unknown -) Urticaria (n/a - | COMIRNATY | Not reported |
| 10014008982 | | | Professional | Economic Area | | Years | Specified | | | Recovering/Resolving -) | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | |
| EU-EC- 10014009676 | 5/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Menstrual disorder (n/a - Unknown -), Menstruation irregular (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014009875 | 5/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Menstrual disorder (n/a - Not Recovered/Not Resolved -), Menstruation delayed | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014009933 | 5/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | (n/a - Unknown -) Epistaxis (0d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (0d - Recovered/Resolved -), Nausea (0d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| 10014010383 | | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | Years | Not Specified | | No | Condition), Haemorrhagic ovarian cyst (n/a - Unknown - Caused/Prolonged Hospitalisation), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Intermenstrual bleeding (n/a - Unknown - Other Medically Important Condition), Menstrual disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Menstruation delayed (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Menstruation irregular (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Menstruation irregular (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ovarian cyst (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ovarian cyst (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Ovarian cyst (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014010512 | 5/11/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Drug ineffective (n/a - Unknown - Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014010549 | 5/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Dissociation (5d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |

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|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|--------|----|---|--|--------------|
| | | | | | | | | | | Recovered/Resolved -), | | |
| | | | | | | | | | | Malaise (n/a - Unknown -), | | |
| | | | | | | | | | | Swelling (5d - | | |
| | | | | | | | | | | Recovered/Resolved -), | | |
| | | | | | | | | | | Vaccination site oedema (n/a - | | |
| EU-EC- | 15/11/2022 | Spontaneous | Non | European | Not available | 12-17 | Not | Female | No | Unknown -) Intermenstrual | COMIRNATY | Not reported |
| 10014010616 | , , | · | Healthcare Professional | Economic | | Years | Specified | | | bleeding (n/a - Not Recovered/Not Resolved -), | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | · |
| | | | | | | | | | | Menstrual disorder (n/a - Not Recovered/Not | | |
| EU-EC- | 15/11/2022 | Spontaneous | | European | Not available | 12-17 | Not | Female | No | Resolved -) Malaise (n/a - | COMIRNATY | Not reported |
| 10014010641 | | | Healthcare Professional | Economic Area | | Years | Specified | | | Recovering/Resolving -), | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved -) | اارام | |
| EU-EC- 10014010713 | 15/11/2022 | Spontaneous | Healthcare | European Economic | Not available | 12-17 Years | Not Specified | Male | No | Chills (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | Professional | Area | | | | | | Fatigue (n/a - Recovering/Resolving | n/a - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Headache (n/a - Recovering/Resolving | | |
| | | | | | | | | | | -), Pyrexia (n/a - | | |
| | | | | | | | | | | Recovering/Resolving -), | | |
| | | | | | | | | | | Vaccination site pain (1d - Recovered/Resolved - | | |
| EU-EC- 10014010856 | 15/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dizziness (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| | | | | | | | | | | Fatigue (n/a - Recovering/Resolving -) | n/a]) | |
| EU-EC- 10014011015 | 15/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chills (2d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| | | | | | | | | | | Erythema (n/a - Recovered/Resolved -), | n/a]) | |
| | | | | | | | | | | Headache (2d - Recovered/Resolved - | | |
| | | | | | | | | | | Influenza like illness | | |
| | | | | | | | | | | Recovered/Resolved -), Malaise (2d - | | |
| | | | | | | | | | | Recovered/Resolved -), Nausea (2d - | | |
| | | | | | | | | | | Recovered/Resolved - | | |
| | | | | | | | | | | Pyrexia (2d - Recovered/Resolved -), | | |
| | | | | | | | | | | Vaccination site pain (n/a - Recovering/Resolving -) | | |
| EU-EC- 10014011111 | 15/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chills (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |
| | | | | | | | | | | Ear pain (n/a - Unknown -), | n/a]) | |
| | | | | | | | | | | Headache (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Ocular hyperaemia (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Oropharyngeal pain (n/a - Recovering/Resolving | | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown -) | | |
| EU-EC- 10014011136 | | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Injection site erythema (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| https://dap. | | | 1.44 1 | 4000 | | | | | | Pyrexia (1d - Recovered/Resolved - | | 40/= |
| attno://don | ama alira | na outana | INTICE /COM | v all:2(20 | | | | | | | | 40/7 |

| | | | | | | | | | |), Vaccination site pain | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|-----|--|--|---|
| | | | | | | | | | | (1d - Recovered/Resolved -), | | |
| | | | | | | | | | | Vaccination site swelling (1d - Recovered/Resolved - | | |
| EU-EC- 10014011236 | 15/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Headache (2d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Nausea (2d - Recovered/Resolved -), Pyrexia (2d - | | |
| | | | | | | | | | | Recovered/Resolved -), Rash (n/a - Not Recovered/Not | | |
| EU-EC- 10014011243 | 15/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Resolved -) Abdominal pain (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | LEVEMIR [INSULIN DETEMIR] (C - n/a - n/a - [n/a - n/a - |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved -) | n/a]) | n/a]), NOVORAPID PENFII [INSULIN ASPART] - n/a - n/a - [n/a - r - n/a]) |
| EU-EC- 10014011278 | 15/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Lymphadenopathy (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Vaccination site pain (n/a - Recovering/Resolving -) | | |
| EU-EC- 10014011281 | | Spontaneous | Professional | Area | Not available | Years | Not Specified | Male | No | Hypoaesthesia (7d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014011339 | 15/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | COVID-19 immunisation (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Headache (n/a - Recovering/Resolving -), | | |
| | | | | | | | | | | Mobility decreased (n/a - Recovering/Resolving -), | | |
| | | | | | | | | | | Myalgia (n/a - Recovering/Resolving -), | | |
| | | | | | | | | | | Pain (n/a - Recovering/Resolving -), | | |
| | | | | | | | | | | Pain in extremity (n/a - Recovering/Resolving -) | | |
| EU-EC- 10014011623 | 15/11/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Anxiety (n/a - Unknown -), Paralysis (n/a - | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported |
| | | | | | | | | | | Unknown - Other Medically Important Condition), | applicable - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Visual impairment (n/a - Unknown -), Wheelchair user (n/a | | |
| EU-EC- 10014011733 | 15/11/2022 | Spontaneous | Healthcare Professional | European | Not available | 12-17 Years | Not Specified | Female | No | Skin discolouration (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | | Area | | | | | | | COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | |
| EU-EC- 10014011913 | | Spontaneous | Healthcare Professional | European Economic Area | Not available | Years | Not Specified | Male | No | Taste disorder (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014011998 | 15/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chills (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| ELL EC | 15/11/2022 | Constant | 1114 | F | N.A Table | 12.17 | NI-t | Male | No | Pyrexia (n/a - Not Recovered/Not Resolved -) | COMIRNATY | Networked |
| EU-EC- 10014012131 | 15/11/2022 | Spontaneous | Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | INO | Chest discomfort (n/a - Recovering/Resolving -), | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Erythema of eyelid (n/a - Recovering/Resolving -), | | |
| EU-EC- | 15/11/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Male | No | Palpitations (n/a - Unknown -) Dizziness (n/a - | COMIRNATY | Not reported |
| 10014012144 | | | Professional | | | | Specified | | | Recovering/Resolving | | |

| | | | | Area | | | | | | -) | n/a - n/a - [n/a - n/a - n/a]) | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|---|--|--|
| EU-EC- 10014012209 | 15/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | | Not Specified | Male | No | Cold sweat (n/a - Unknown -), Headache (2d - Recovered/Resolved -), Illness (n/a - Unknown -), Nausea (2d - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014012228 | 15/11/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | | Not Specified | Female | No | Recovered/Resolved -) Persistent postural- perceptual dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation, Disabling) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | Not reported |
| EU-EC- 10014012611 | 15/11/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | | Not Specified | Female | No | Hypertension (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition) | - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | [NORETHISTERONE ACETATE, ETHINYLESTRADIO (C - n/a - n/a - [n/a n/a - n/a]) |
| EU-EC- 10014012775 | 15/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Pyrexia (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | [METHYLPHENIDAT HYDROCHLORIDE] - n/a - n/a - [n/a - 1 - Oral use]) |
| EU-EC- 10014012832 | 15/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | | Not Specified | Male | No | Unknown -) Headache (1d - Recovered/Resolved -), Malaise (n/a - Unknown -), Pyrexia (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014012927 | 15/11/2022 | Spontaneous | | European Economic Area | Not available | | Not Specified | Female | No | Resolved -) Chills (n/a - Recovering/Resolving -), Dizziness (0d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Vaccination site erythema (n/a - Not Recovered/Not Resolved -), Vaccination site pruritus (n/a - Not Recovered/Not Resolved -), Vaccination site pruritus (n/a - Not Recovered/Not Resolved -), Vaccination site pruritus (n/a - Not Recovered/Not Resolved -), Vaccination site pruritus (n/a - Not Recovered/Not Resolved -), Vaccination site swelling (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - n/a - n/a - n/a - n/a - | Not reported |
| EU-EC- 10014012966 | 15/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | | Not Specified | Female | No | Chest pain (n/a - Recovering/Resolving -), Electrocardiogram T wave inversion (n/a - Recovering/Resolving -), Nausea (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10014013527 | 15/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Unknown -) Pyrexia (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not reported |
| EU-EC- 10014013832 | 15/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Pyrexia (n/a - Unknown -), Vomiting (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not reported |

| EU-EC- 10013993272 | | Spontaneous | Healthcare Professional | European | Not available | 12-17 | Not Specified | | No | Abdominal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Abdominal pain upper (n/a - Not Recovered/Not Resolved - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|--|----------------|------------------|--------|----|--|---|---|
| | | | | | | | | | | Caused/Prolonged Hospitalisation), Arthralgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Diarrhoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Eye swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Eyelid oedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Henoch-Schonlein purpura (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Joint swelling (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Myalgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Rash (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10013994089 | 14/11/2022 | Spontaneous | Professional | Non European Economic Area | Kukita, S Two Cases of Young Patients Presenting with Acute Perimyocarditis Due to Post-COVID-19 Vaccination Adverse Reaction. The 70th Annual Scientific Session of the Japanese College of Cardiology, 2022;70th:56 | 12-17 Years | Not Specified | Male | No | Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013995104 | 14/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Headache (n/a - Recovering/Resolving -), Pyrexia (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | [BUDESONIDE, BUDESONIDE, MICRONISED] (C - I - n/a - [n/a - n/a - n/a]), |
| | | | | | | | | | | Recovering/Resolving | | [HYDROXYZINE DIHYDROCHLORIDE HYDROXYZINE HYDROCHLORIDE] - n/a - n/a - [n/a - r - Oral use]), |
| | | | | | | | | | | | | [MELATONIN] (C - r - n/a - [n/a - n/a - (use]), |
| EU-EC- 10013995250 | 14/11/2022 | Spontaneous | Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | - n/a - [n/a - n/a - (use]) Not reported |
| | | | | | 1 | 1 | 1 | 1 | | ı | 1 | |

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|-----------------------|------------|-------------|----------------------------|------------------------------|---|----------------|------------------|---------|-----|---|--|-------------------|
| | | | | | | | | | | Localised oedema (4d - Recovered/Resolved -), | | |
| | | | | | | | | | | Lymphadenopathy (n/a - Not Recovered/Not | | |
| | | | | | | | | | | Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Pain (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Pain in extremity (n/a - Not Recovered/Not Resolved -), | | |
| EU-EC- | 14/11/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Male | No | Vomiting (n/a - Not Recovered/Not Resolved -) Pallor (n/a - Unknown | COMIRNATY | Not reported |
| 10013996596 | 14/11/2022 | | | Economic Area | The available | | Specified | riaic | 140 | -), | [TOZINAMERAN] (S - COVID-19 | Not reported |
| EU EC | 14/11/2022 | Constant | Non | F | N.A Walls | 12.17 | Note | FI- | | Syncope (0d - Recovered/Resolved - Other Medically Important Condition) | immunisation - n/a - [n/a - 1{DF} - n/a]) | Nick was subsided |
| EU-EC- 10013997113 | 14/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Specified | Female | No | Body temperature increased (48h - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | Not reported |
| | | | | | | | | | | Chills (48h - Recovered/Resolved -), Headache (48h - | - n/a]) | |
| EU-EC- | 14/11/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Female | No | Recovered/Resolved -) Chest pain (3d - | COMIRNATY | Not reported |
| 10013997380 | 11,11,2022 | | Professional | Economic Area | The distillation | | Specified | Terrore | | Recovered/Resolved - Caused/Prolonged Hospitalisation), | [TOZINAMERAN] (S - Immunisation - Unknown - [n/a3mL - Intramuscular use]) | Not reported |
| | | | | | | | | | | Myocarditis (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10013998192 | 14/11/2022 | Spontaneous | Healthcare Professional | Non European | Horino, T Newly diagnosed IgA nephropathy with gross haematuria | | Not Specified | Male | No | IgA nephropathy (n/a - Not Recovered/Not | TOZINAMERAN [TOZINAMERAN] (S - | Not reported |
| 511.50 | 14/44/2022 | | N | Economic Area | following COVID-19 vaccination, QJM, 2022;115(1):28-29, doi:10.1093/qjmed/hcab305 | 12.17 | Notes | F1. | | Resolved - Other Medically Important Condition) | COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | No. |
| EU-EC- 10013998331 | 14/11/2022 | | | European Economic Area | Not available | | Not Specified | Female | No | Dermatitis allergic (0d - Recovered/Resolved -), Lip swelling (0d - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Recovered/Resolved -), Pruritus (0d - | | |
| EU EO | 444442022 | | | - | N | 10.17 | | | | Recovered/Resolved -) | COMPANY | <u> </u> |
| EU-EC- 10013998537 | | | Healthcare Professional | European Economic Area | Not available | Years | Adolescent | | No | Menstrual cycle management (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported |
| EU-EC- 10013998567 | 14/11/2022 | Spontaneous | | European Economic Area | Not available | | Not Specified | Male | No | Chills (1d - Recovered/Resolved -), Dizziness (1d - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Recovered/Resolved -), Fatigue (1d - | | |
| | | | | | | | | | | Recovered/Resolved -), Headache (1d - Recovered/Resolved - | | |
| | | | | | | | | | |), Hyperhidrosis (n/a - Unknown -), | | |
| | | | | | | | | | | Malaise (1d - Recovered/Resolved -), | | |
| | | | | | | | | | | Malaise (n/a - Unknown -), | | |
| | | | | | | | | | | Pyrexia (1d - Recovered/Resolved -), | | |
| | | | | | | | | | | Vaccination site pain (2d - Recovered/Resolved -) | | |
| EU-EC- 10013998683 | 14/11/2022 | Spontaneous | | European Economic | Not available | | Not Specified | Female | No | Pruritus (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | riolessional | Aica | | | | | | Rash (5d - Recovered/Resolved - | n/a - n/a - [n/a - n/a - n/a]) | |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|---|---|--|
| EU-EC- 10013998876 | 14/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Epistaxis (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013999256 | 14/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Lymphadenopathy (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013999554 | 14/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Abdominal pain (n/a - Unknown -), Blister (n/a - Unknown -), Herpes zoster (n/a - Not Recovered/Not Resolved -), Malaise (n/a - | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- | 14/11/2022 | Spontaneous | Non | European | Not available | 12-17 | Adult | Male | No | Unknown -) Peripheral swelling | COMIRNATY | Not reported |
| 10014001203 | | · | Healthcare | Economic | | Years | | | | (4d - Recovered/Resolved -) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | · |
| EU-EC- 10013987882 | 12/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Headache (4d - Recovered/Resolved -), Pyrexia (24h - Recovered/Resolved -), Vaccination site pain (1wk - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013977939 | 11/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | | Not Specified | Female | No |) COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013977966 | 11/11/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | | Not Specified | Male | No | Epistaxis (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| EU-EC- 10013978351 | 11/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Post vaccination syndrome (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013978990 | 11/11/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Disturbance in attention (n/a - Unknown -), Memory impairment (n/a - Unknown -), Muscular weakness (n/a - Recovering/Resolving -), Pain in extremity (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Subcutaneous use]) | Not reported |
| EU-EC- 10013979561 | 11/11/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (7d - Recovered/Resolved - Other Medically Important Condition), Peripheral swelling (4d - Recovered/Resolved - Other Medically Important Condition), Skin temperature (5d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| EU-EC- 10013979605 | 11/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 30ug - Intramuscular use]) | Not reported |
| EU-EC- 10013981160 | 11/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | | Not Specified | Male | No | Chest pain (n/a - Recovered/Resolved -), Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | ABILIFY [ARIPIPRAZOLE] (C Autism spectrum disorder - n/a - [n/a n/a - Oral use]), [LITHIUM CARBONATE] (C - Autism spectrum disorder - n/a - [n/a n/a - Oral use]), [RISPERIDONE] (C Autism spectrum disorder - n/a - [n/a n/a - Oral use]) |
| EU-EC- 10013981668 | 11/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Headache (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013982248 | 11/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Arthralgia (n/a - Recovered/Resolved With Sequelae - Disabling), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|--|----------------|------------------|--------|----|--|--|---|
| | | | | | | | | | | Arthritis (152d - Recovered/Resolved With Sequelae - | applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | Disabling), Disturbance in attention (48d - Recovered/Resolved - Disabling, Other Medically Important Condition), | | |
| | | | | | | | | | | Dysstasia (48d - Recovered/Resolved - Disabling, Other Medically Important Condition), | | |
| | | | | | | | | | | Feeling abnormal (48d - Recovered/Resolved - Disabling, Other Medically Important Condition), | | |
| | | | | | | | | | | Headache (48d - Recovered/Resolved - Disabling, Other Medically Important Condition), | | |
| | | | | | | | | | | Juvenile idiopathic arthritis (n/a - Recovered/Resolved With Sequelae - Disabling, Other Medically Important Condition), | | |
| | | | | | | | | | | Malaise (48d - Recovered/Resolved - Disabling, Other Medically Important Condition), | | |
| | | | | | | | | | | Pyrexia (48d - Recovered/Resolved - Disabling, Other Medically Important Condition) | | |
| EU-EC- 10013982258 | 11/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | | Not Specified | Female | No | Chills (n/a - Recovered/Resolved -), Feeling cold (n/a - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | [SOMATROPIN] (C - n/a - n/a - [n/a - 1.35mg - n/a]) |
| | | | | | | | | | |), Nasopharyngitis (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Oropharyngeal pain (n/a - Recovered/Resolved -), Rhinorrhoea (n/a - | | |
| | | | | | | | | | | Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved - | | |
| EU-EC- 10013983606 | 11/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Nakayama, M COVID-19 vaccination- related intraocular inflammation in Japanese patients. Graefe's Archive for Clinical and Experimental Ophthalmology. 2022;1-3. doi:10.1007/s00417-022-05866-5 | 12-17 Years | Not Specified | Female | No | Autoimmune retinopathy (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | Not reported |
| EU-EC- 10013983627 | 11/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), | - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported |
| | | | | | | | | | | Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition) | Intramuscular use]) | |
| EU-EC- 10013984596 | 11/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | -), Headache (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a]) | Not reported |
| | | | | | | | | | | Recovered/Resolved -), Hyperhidrosis (n/a - Recovered/Resolved -), | | |
| | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved -), | | |
| FILEC | 10/11/2022 | Spontons | Non | Non | Not available | 12.17 | Not | Male | No | Tonsillitis (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIDNATY | Not reported |
| EU-EC- 10013965169 | | Spontaneous | Healthcare Professional | Area | Not available | Years | Not Specified | Male | No | Encephalitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| EU-EC- 10013965473 | 10/11/2022 | | Healthcare Professional | | Not available | 12-17 Years | Adolescent | Female | No | Body temperature increased (3d - | COMIRNATY [TOZINAMERAN] (S - | Not reported |

| | | | | Area | | | | | | Recovered/Resolved - | COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|--|----------------|------------------|--------|----|--|---|--------------|
| EU-EC- 10013967617 | 10/11/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Disturbance in attention (n/a - Not Recovered/Not Resolved -), Dyspnoea exertional | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Post vaccination syndrome (n/a - Not Recovered/Not Resolved -) | | |
| 10013971062 | | Spontaneous | Professional | Area | Not available | Years | Adolescent | | No | Myopericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013971064 | 10/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Extrasystoles (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013972780 | 10/11/2022 | Spontaneous | | European Economic | Not available | 12-17 Years | Adolescent | Male | No | Caused/Prolonged Hospitalisation) COVID-19 (n/a - Unknown - Other | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | | Area | | | | | | Medically Important Condition), Vaccination failure (n/a - Unknown - | n/a - n/a - [n/a - n/a - Intramuscular use]) | |
| EU-EC- 10013972790 | 10/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Other Medically Important Condition) Colitis ulcerative (n/a - Not Recovered/Not Resolved - Other Medically Important | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - | Not reported |
| | | | | | | | | | | Condition), Crohn's disease (n/a - Not Recovered/Not Resolved - Other Medically Important | [n/a - 1{DF} - n/a]) | |
| | | | | | | | | | | Condition), Diarrhoea (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | | Inflammatory bowel disease (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | |
| EU-EC- 10013972968 | 10/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Kitazawa, T A case of acute pericarditis that developed after the second novel corona virus vaccination. The 222nd Chiba Regional Meeting of the Japan Pediatric Society [The 1463rd. 2022;222nd:9 | 12-17 Years | Not Specified | Male | No | Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported |
| | | | | | | | | | | Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | n/a]) | |
| | | | | | | | | | | Electrocardiogram ST segment elevation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important | | |
| | | | | | | | | | | Condition), Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Supraventricular extrasystoles (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Ventricular extrasystoles (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | | |
| | 10/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Headache (n/a - Unknown -), Lacrimation increased | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported |
| 10013973905 | | | | | | | | | | (n/a - Unknown -), | applicable - [1d - | |
| 10013973905 | | | | | | | | | | (n/a - Unknown -), Pyrexia (n/a - Unknown -), Rhinorrhoea (n/a - | applicable - [1d - 1{DF} - n/a]) | |

|).11.2022 | | | | Area | | | ne Listinç | | | Lymphadenopathy (n/a - Unknown -) | COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use]) | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|--|----------------|------------------|--------|----|---|--|--|
| EU-EC- 10013955301 | 09/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition), Interchange of vaccine products (n/a - Unknown - Other Medically Important Condition) | Intramiscular designation of the continuous of t | Not reported |
| EU-EC- 10013955361 | 09/11/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Guillain-Barre syndrome (27d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Inappropriate schedule of product administration (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular use]) | DULOXETINE [DULOXETINE, DULOXETINE, DULOXETINE, HYDROCHLORIDE] - n/a - n/a - [n/a - 60mg - n/a]), PREGABALIN [PREGABALIN] (C - n/a - 75mg n/a]), [DROSPIRENONE, ETHINYLESTRADIC LACTOSE, LACTOSE MONOHYDRATE] (CONTRACEPTION - n/a) - n/a] |
| EU-EC- 10013957373 | 09/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Pyrexia (n/a - Recovered/Resolved -), Vaccination site erythema (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013958624 | 09/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Lymphadenitis (10d - Recovering/Resolving -), Lymphadenopathy (10d - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10013959472 | 09/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Rash (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013959996 | 09/11/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Adult | Female | No | Diarrhoea (5d - Recovered/Resolved -), Migraine (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY | Not reported |
| EU-EC- 10013960928 | 09/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Gomes, S HERPES ZOSTER AND COVID- 19 VACCINE: APURPOSE OF A CASE REPORT. Rev Port Med Geral Fam. 2022;38 (suppl 8):S53 Gomes, S HERPES ZOSTER E VACINA COVID-19: A PROPOSITO DE UM RELATO DE CASO. Rev Port Med Geral Fam. 2022;38 (suppl 8):S53 | 12-17 Years | Not Specified | Female | No | Herpes zoster (n/a - Unknown -), Vaccination site pain (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013962363 | 09/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Hypomenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 in munisation - Unknown - [n/a - 1{DF} - n/a]) | Not reported |
| EU-EC- 10013962411 | 09/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Pyrexia (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not reported |
| EU-EC- 10013962488 | 09/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Vaccination site pain (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular | Not reported |
| EU-EC- 10013962500 | 09/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Vision blurred (n/a - Not Recovered/Not Resolved -) | use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported |
| EU-EC- 10013962510 | 09/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Hypomenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a]) | DESLORATADINE I [DESLORATADINE] - Urticaria - n/a - [n - n/a - Oral use]), [BUDESONIDE] (C- Asthma - n/a - [n/a n/a - Inhalation use [DESLORATADINE] - Seasonal allergy - - [n/a - n/a - Oral |

| 0.11.2022 | ·OILL | | | | · | (dii _i | IIC LISTIN | gilopo | | | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|--|----------------|------------------|--------|----|--|---|---|
| | | | | | | | | | | | | use]), [MOMETASONE FUROATE] (C - Ecze - n/a - [n/a - n/a - Cutaneous use]), [SALBUTAMOL, SALBUTAMOL |
| | | | | | | | | | | | | SULFATE] (C - Asthr - n/a - [n/a - n/a - Inhalation use]) |
| EU-EC- 10013963001 | 09/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Abdominal pain (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Vaccination site inflammation (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular use]) | Not reported |
| EU-EC- | 00/11/2022 | Caastanaaus | Lianithanea | European | Not available | 12-17 | Adolescent | Mala | No | Recovering/Resolving -) Abdominal discomfort | COMIRNATY | Not vanastad |
| 10013963051 | 09/11/2022 | Spontaneous | Professional | Economic Area | NUL available | Years | Adolescent | Male | NO | (n/a - Unknown -), Asthenia (n/a - Unknown -), Headache (n/a - Unknown -), Pyrexia (n/a - | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not reported |
| EU-EC- 10013942723 | 08/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Unknown -) Pyrexia (n/a - Unknown -), Tachycardia (2d - Recovered/Resolved -), Vomiting (2d - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013944233 | 08/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | OVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |
| | | | | | | | | | | Headache (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition), Vomiting (n/a - Recovered/Resolved - | | |
| EU-EC- 10013944515 | 08/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Other Medically Important Condition) Axillary pain (2d - Recovered/Resolved -), Pain in extremity (2d - Recovered/Resolved -), Vaccination site eedema (2d - Recovered/Resolved -), Vaccination site pain | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1min - .3mL - Intramuscular use]) | Not reported |
| | | | | | | | | | | (2d - Recovered/Resolved -) | | |
| EU-EC- 10013944750 | 08/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Chimatapu, S., TWO CASES OF GRAVES' DISEASE IN ADDLESCENTS FOLLOWING COVID-19 VACCINATIONS. Thyroid. 2022;32 (Supple1):A111. doi:10.1089/thy.2022.29140.lb,abstracts | 12-17 Years | Not Specified | Female | No | Basedow's disease (n/a - Recovering/Resolving - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013945076 | 08/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Nasopharyngitis (1d - Recovering/Resolving -), Vomiting (1d - Recovering/Resolving -) | COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1,[DF] - Intramuscular use]) | Not reported |
| EU-EC- 10013945274 | 08/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Administration site erythema (3d - Recovered/Resolved -), Administration site pain (2d - Recovered/Resolved -) | COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 jmmunisation - Not applicable - [n/a - 1,[DF} - Intramuscular use]) | Not reported |
| EU-EC- 10013948905 | 08/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Child | Male | No | Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported |

| 0 | 7.11.2022 | 10.22 | | | | 1 | Curr Lii | ic Listing | y repo | | | | |
|---|-----------------------|------------|-------------|----------------------------|-------------------------------------|---|----------------|------------------|--------|----|---|---|--------------|
| | | | | | | | | | | | Hospitalisation), Disturbance in attention (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), Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Performance status decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | immunisation - n/a - [n/a - 2{DF} - n/a]) | |
| | EU-EC- 10013950459 | 08/11/2022 | Spontaneous | Professional | Non European Economic Area | Chimatapu, S TWO CASES OF GRAVES' DISEASE IN ADOLESCENTS FOLLOWING COVID-19 VACCINATIONS, Thyroid. 2022;32(Suppl 1):A111. doi:10,1089/thy,2022,29140.lb,abstracts | | Not Specified | Male | No | Basedow's disease (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| | 10013934046 | | Spontaneous | Healthcare Professional | European Economic Area | Not available | Years | Not Specified | Female | No | (n/a - Recovering/Resolving - Other Medically Important Condition), Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (14d - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (18d - Recovered/Resolved - Other Medically Important Condition), Nausea (16d - Recovered/Resolved - Other Medically Important Condition), Nausea (16d - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | EU-EC- | | Spontaneous | Healthcare Professional | European | Not available Not available | | Not Specified | Female | No | Body temperature increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chills (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Lymphadenopathy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pain in extremity (3d - Recovering/Resolving - Caused/Prolonged Hospitalisation), Tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) COVID-19 (n/a - Utberower - Other | COMIRNATY COMIRNATY COMIRNATY COMIRNATY COMIRNATY | Not reported |
| | 10013934749 | | | Professional | Economic Area | | Years | | | | Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | |
| | EU-EC- 10013936072 | 07/11/2022 | 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 reported |

| | | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|---|--|--|
| EU-EC- 10013936777 | 07/11/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | BUDESONIDE [BUDESONIDE] ((n/a - n/a - [n/a - n/a]), [CETIRIZINE |
| | | | | | | | | | | Unknown - Other Medically Important Condition) | | DIHYDROCHLORI (C - n/a - n/a - [n n/a - n/a]), [MONTELUKAST, MONTELUKAST, SODIUM] (C - n/a n/a - [n/a - n/a - n/a]), [SALBUTAMOL |
| EU-EC- 10013936792 | 07/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Soft tissue swelling (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | SULFATE] (C - n/a n/a - [n/a - n/a - Not reported |
| | 07/11/2022 | Spontaneous | | European | Not available | 12-17 | Not | Male | No | Myocarditis (n/a - | applicable - [1d - n/a - n/a]) COMIRNATY | Not reported |
| 10013936803 | | | | | | Years | Specified | | | Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | |
| EU-EC- 10013936985 | 07/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chills (1d - Recovered/Resolved -), Pain in extremity (1d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use]) | [BENFOTIAMINE, CYANOCOBALAMI BENFOTIAMINE, PYRIDOXINE HYDROCHLORIDE - n/a - n/a -) |
| | | | | | | | | | | Pyrexia (1d - Recovered/Resolved -) | | |
| EU-EC- 10013937524 | 07/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10013937780 | 07/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Headache (n/a - Not Recovered/Not Resolved -), Rash (n/a - Recovering/Resolving - Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{OF} - Intramuscular use]) | Not reported |
| EU-EC- 10013937910 | 07/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Resolved -) Substance-induced psychotic disorder (n/a - Not Recovered/Not Resolved - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [28d - | Not reported |
| EU-EC- 10013939778 | 07/11/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Caused/Prolonged Hospitalisation) Intracranial pressure increased (n/a - Unknown - Other Medically Important Condition) | 2{DF} - Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | Not reported |
| EU-EC- 10013941671 | 07/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adult | Female | No | Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -) | - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | [INFLUENZA VIRI (C - n/a - n/a - [r n/a - n/a]) |
| EU-EC- 10013932337 | 05/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Pruritus (n/a - Not Recovered/Not Resolved -), Rash (n/a - Unknown -), Urticaria (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013932378 | 05/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Resolved -) Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Syncope (1d - Recovered/Resolved - Other Medically | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | AERIUS 5 MG FIL COATED TABLET [DESLORATADINI - n/a - n/a - [n/a - Oral use]) |
| EU-EC- 10013932381 | 05/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Important Condition) Asthenia (n/a - Recovering/Resolving - Other Medically | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported |

| | | | | | | | | | | - Other Medically Important Condition), | | |
|---------------------|------------|-------------|-----------------------------------|-------------------------------------|---|----------------|------------------|--------|----|---|---|--|
| | | | | | | | | | | Syncope (n/a - Recovering/Resolving - Other Medically Important Condition) | | |
| J-EC- 0013921016 | 04/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Application site pain (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | 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 - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved -), Restlessness (n/a - | | |
| | | | | | | | | | | Not Recovered/Not Resolved -) | | |
| U-EC- 0013921361 | 04/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Jongvilaikasem, P., CHILDHOOD NEPHROTIC SYNDROME AND ACUTE KIDNEY INJURY FOLLOWING THE SARS- COV-2 BNT162B2 VACCINE, Pediatric Nephrology, 2022;37(11):2865-2866. doi:10,1007/s00467-022-05630-1 | 12-17 Years | Not Specified | Male | No | Acute kidney injury (n/a - Unknown - Life Threatening, Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Nephrotic syndrome (n/a - Unknown - Life Threatening, Other Medically Important Condition) | | |
| U-EC- 0013923799 | 04/11/2022 | Spontaneous | Non Healthcare Professional | Economic | Not available | 12-17 Years | Adolescent | Male | No | Body temperature increased (2d - Recovered/Resolved -), Chills (1d - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular | Not reported |
| | | | | | | | | | | Recovered/Resolved -), Headache (2d - Recovered/Resolved - | use]) | |
| U-EC- 0013925037 | 04/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Abnormal loss of weight (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - | Not reported |
| | | | | | | | | | | Coeliac disease (n/a - Unknown - Caused/Prolonged Hospitalisation), | Intramuscular use]) | |
| | | | | | | | | | | Fatigue (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Muscle discomfort (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Nasopharyngitis (n/a - Unknown - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Paraesthesia (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Somnolence (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation) | | |
| U-EC- 0013925051 | 04/11/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Alopecia areata (n/a - Not Recovered/Not Resolved - Disabling), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not | [LEVOTHYROXIN LEVOTHYROXINI SODIUM] (C - n/ n/a - [n/a - 75uc |

| | | | | | | | | | | Resolved - Disabling) | | [METHYLPHENIDA (C - n/a - n/a - [n/ 20mg - n/a]) |
|-----------------------|------------|-------------|----------------------------|------------------------------|---|----------------|------------------|--------|----|--|--|--|
| EU-EC- 10013926054 | 04/11/2022 | Spontaneous | | Economic | Not available | 12-17 Years | Adolescent | Female | No | Abdominal pain lower (n/a - Unknown -), Fatigue (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Headache (n/a - Unknown -), Heavy menstrual bleeding (n/a - Not Recovered/Not | | |
| U-EC- 0013926565 | 04/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Petruzzelli, L Nephritis following SARS-COV-2 Vaccine: Causal or incidental correlation?. Pediatric Nephrology, 2022;37 (11):2910-2911 Petruzzelli, L Nephritis following SARS-COV-2 Vaccine: Causal or incidental correlation?. Pediatric Nephrology. 2022;37 (11):2911-2912. doi:10.1007/s00467-022-05630-1 | 12-17 Years | Not Specified | Male | No | Resolved -) Acute kidney injury (n/a - Unknown - Other Medically Important Condition), Nephritis (n/a - Unknown - Life Threatening, Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a]) | Not reported |
| U-EC- 0013926807 | 04/11/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Not Specified | Female | No | Weight increased (n/a - Unknown -) Alopecia (n/a - Not Recovered/Not Resolved -), Anxiety (n/a - Unknown -), Cardiovascular | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| | | | | | | | | | | disorder (n/a - Not Recovered/Not Resolved -), Decreased appetite (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Disturbance in attention (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved - Not Recovered/Not | | |
| | | | | | | | | | | Resolved -), Dyspnoea exertional (n/a - Unknown -), Fatigue (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Headache (1wk - Recovered/Resolved -), Nausea (1wk - Recovered/Resolved -), | | |
| | | | | | | | | | | Performance status decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Post viral fatigue syndrome (n/a - Unknown -), Pyrexia (1wk - Recovered/Resolved - | | |
| | | | | | | | | | |), Sense of oppression (n/a - Not Recovered/Not Resolved -) | | |
| EU-EC- 10013926819 | 04/11/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Not Specified | Male | No | Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation), Blood prolactin increased (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMENATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| | | | | | | | | | | Disturbance in attention (n/a - Unknown - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Dizziness (n/a - Unknown - | | |

| | | | | | | | | | | Caused/Prolonged Hospitalisation), Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Labile hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Obesity (n/a - Unknown - Caused/Prolonged Hospitalisation), Post viral fatigue syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure (n/a - Unknown - Caused/Prolonged Hospitalisation), Throat irritation (n/a - Unknown - Caused/Prolonged Hospitalisation), Throat irritation (n/a - Unknown - Caused/Prolonged Hospitalisation), Throat irritation (n/a - Unknown - Caused/Prolonged | | |
|-----------------------|------------|-------------|----------------------------|------------------------------|---------------|----------------|------------------|--------|----|--|--|--------------|
| EU-EC- 10013926839 | 04/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Hospitalisation) Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -) Tremor (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013927357 | 04/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Anaemia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10013929954 | 04/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Lymphadenitis (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not reported |
| EU-EC- 10013908327 | 03/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Injection site pain (5d - Recovered/Resolved -), Pyrexia (5d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10013909836 | 03/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Body temperature increased (n/a - Unknown -), Chest pain (n/a - Unknown -), Chills (n/a - Unknown -), Headache (n/a - Unknown -), Malaise (n/a - Unknown -), Tachycardia (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular use]) | Not reported |
| EU-EC- 10013911165 | 03/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013911705 | 03/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Important Condition) Anaemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported |

| | | | | | | | | | | Condition), Heavy menstrual | | |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|--|----------------|------------------|--------|----|---|---|--|
| | | | | | | | | | | bleeding (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Not Recovered/Not Resolved - Other Medically Important | | |
| EU-EC- 10013913043 | 03/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Condition) COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | Not reported |
| | | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10013913800 | 03/11/2022 | Spontaneous | | | Saito, C A Case of Thyroid Crisis That Occurred After COVID-19 Vaccination. Folia Endocrinologica Japonica. 2022;98(2):585 | 12-17 Years | Not Specified | Female | No | Hyperthyroidism (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Thyrotoxic crisis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | |
| EU-EC- 10013915251 | 03/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Acne (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- | 03/11/2022 | Spontaneous | Non | European | Not available | 12-17 | Adolescent | Male | No | Resolved - Other Medically Important Condition) Herpes zoster (n/a - | COMIRNATY | Not reported |
| 10013915331 | | | Healthcare Professional | Economic Area | | Years | | | | Recovering/Resolving -), Influenza like illness (n/a - Recovering/Resolving -), | [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use]) | |
| | | | | | | | | | | Nausea (n/a - Recovering/Resolving -), Palpitations (n/a - | | |
| | | | | | | | | | | Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving | | |
| EU-EC- 10013919308 | 03/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Pruritus (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a]) | [AMOXICILLIN TRIHYDRATE] (C - - n/a - [7d - n/a - n/a]) |
| EU-EC- 10013919389 | 03/11/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Encephalitis autoimmune (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported |
| EU-EC- 10013919906 | 03/11/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| | | | | | | | | | | Flank pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | 11/4]) | |
| | | | | | | | | | | Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10013895816 | 02/11/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain upper (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| 1 | | | | 1 | Í. | 1 | I | I | 1 | Gastrointestinal | I | I |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---|----------------|------------------|---------|----|--|--|--|
| | | | | | | | | | | Hospitalisation, Disabling), | | |
| | | | | | | | | | | Liver disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), | | |
| | | | | | | | | | | Nerve injury (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), | | |
| | | | | | | | | | | Nervous system disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Disabling), | | |
| | | | | | | | | | | Skin disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10013897901 | | Spontaneous | Professional | European Economic Area | Silis, P. Early experience with myocarditis and pericarditis in adolescents following vaccination against COVID-19 in latvia Cardiol-Young. 2022;32 (Suppl. 2):S228 | 12-17 Years | Not Specified | Female | No | Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013899670 | 02/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Mohamed, S Case Report: Retinal vasculitis in two adolescents after COVID-19 vaccination. Ocular Immunology and Inflammation. 2022;10.1080/09273948.2022.2129694. doi:10.1080/09273948.2022.2129694 | 12-17 Years | Not Specified | Female | No | Periphlebitis (n/a - Recovered/Resolved - Other Medically Important Condition), Retinal vasculitis (n/a - Recovered/Resolved - Other Medically | TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013899773 | 02/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Recovered/Resolved - Other Medically Important Condition), Drug ineffective (1412min - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]), | Not reported |
| | | | | | | | | | | Recovered/Resolved - Other Medically Important Condition) | [COVID-19 VACCINE] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | |
| EU-EC- 10013901343 | | Spontaneous | Professional | European Economic Area | Sills, P. Early experience with myocarditis and pericarditis in adolescents following vaccination against COVID-19 in latvia. Cardiol-Young, 2022;32 (Suppl. 2):S228 | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013902634 | 02/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Mohamed, S., Case Report: Retinal vasculitis in two adolescents after COVID-19 vaccination. Ocular Immunology and Inflammation. 2022;10.1080/09273948.2022.2129694. doi:10.1080/09273948.2022.2129694 | 12-17 Years | Not Specified | Male | No | Periphlebitis (n/a - Recovered/Resolved - Other Medically Important Condition), Retinal vasculitis (n/a - Recovered/Resolved - Other Medically Important Condition) | TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013903688 | 02/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Amenorrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), Menstruation irregular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id - 1{DF} - Intramuscular use]) | COMIRNATY [TOZINAMERAN] (C COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscu use]) |
| EU-EC- 10013903689 | 02/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id - 1{OF} - Intramuscular use]) | Not reported |
| EU-EC- 10013903860 | 02/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Immunisation reaction (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10013903986 | 02/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), Cardiovascular disorder (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Nervous system disorder (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| | | | | | | | | | | Unknown -), | | |

| .11.2022 | | | | | | | | 9 ((C)O | | Despiratory failure | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---|----------------|------------------|-------------|----|---|---|---|
| | | | | | | | | | | Respiratory failure (n/a - Unknown - Other Medically | | |
| U-EC- 0013905280 | 02/11/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Important Condition) Abdominal pain (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported |
| | | | | | | | | | | Diarrhoea (n/a - Unknown -), | immunisation - Not applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | Dry mouth (n/a - Unknown -), | | |
| | | | | | | | | | | Dyspepsia (n/a - Unknown -), | | |
| | | | | | | | | | | General physical health deterioration (n/a - Unknown -), | | |
| | | | | | | | | | | Skin swelling (n/a - Unknown -), | | |
| U-EC- | 02/11/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Adolescent | Female | No | Vomiting (n/a - Unknown -) Decreased immune | COMIRNATY | Not reported |
| 0013907184 | | · | Professional | Economic Area | | Years | | | | responsiveness (n/a - Unknown -), Herpes zoster (n/a - | [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | · |
| | | | | | | | | | | Unknown -), Infection (n/a - | [iva = iva = iva]) | |
| | 01/11/2022 | Spontaneous | | Non | Not available | 12-17 | | Female | No | Unknown -) Loss of consciousness | COMIRNATY | Not reported |
| 0013888693 | | | Healthcare Professional | European Economic Area | | Years | Specified | | | (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | |
| | | | | | | | | | | Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | |
| J-EC- 0013889109 | 01/11/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported |
| | | | | | | | | | | Disorientation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | Intramuscular use]) | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Pyrexia (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Restlessness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | | |
| :U-EC- 0013891811 | 01/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Silis, P Early experience with myocarditis and pericarditis in adolescents following vaccination against COVID-19 in latvia. Cardiol-Young. 2022;32 (Suppl. 2):S228 | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | |
| U-EC- 0013893520 | 01/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Fatigue (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | [BUDESONIDE] (C - n/a - n/a - [n/a - n/ Inhalation use]), |
| | | | | | | | | | | Heart rate increased (n/a - Not Recovered/Not Resolved -), | ~1, | [ISOTRETINOIN] (C n/a - n/a - [n/a - n/ Oral use]), |
| 71.50 | 01/11/2005 | Canada | Health - | Fame at | City D. Fords on the Control of the | 12.42 | Net | Mal- | Ne | Malaise (n/a - Unknown -) | COMIDNATIO | [SALBUTAMOL, SALBUTAMOL SULFATE] (C - n/a - n/a - [n/a - n/a - Inhalation use]) |
| EU-EC- 10013893630 | 01/11/2022 | Spontaneous | Professional | European Economic Area | Silis, P Early experience with myocarditis and pericarditis in adolescents following vaccination against COVID-19 in latvia. Cardiol-Young. 2022;32 (Suppl. 2):S228 | 12-17 Years | Not Specified | Male | No | Myocardial fibrosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|--|----------------|------------------|-------------|--------|---|--|---|
| | | | | | | | | | | Condition), | applicable - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Pericardial fibrosis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | |
| EU-EC- 10013894040 | 01/11/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Disabling), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Menstrual disorder (n/a - Not Recovered/Not Resolved - Disabling) | | |
| EU-EC- 10013895094 | 01/11/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Dyspnoea (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - | [ADAPALENE, BENZOYL PEROXIDI (C - Acne - n/a - [n/ n/a - Cutaneous use |
| | | | | | | | | | | Recovered/Not Resolved -) | 1{DF} - n/a]) | [IBUPROFEN] (C - F - n/a - [n/a - n/a - (use]) |
| EU-EC- 10013880048 | 31/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Ahmed, T A report on short-term follow- up cardiac imaging and dinical outcomes of myocarditis after coronavirus disease 2019 vaccination. Journal of Cardiovascular Medicine. 2022;23(10):691-693. doi:10.2459/JCM.000000000001341 | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013880205 | 31/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Muscular weakness (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013881247 | 31/10/2022 | Spontaneous | Healthcare Professional | European Economic Area | Petruzzelli, L Nephritis following SARS- COV-2 Vaccine: Causal or incidental correlation?. Pediatric Nephrology, 2022;37 | 12-17 Years | Not Specified | Male | No | Henoch-Schonlein purpura nephritis (n/a | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 | Not reported |
| | | | | | (11):2911-2912, doi:10.1007/s00467-022- 05630-1 | | | | | Recovering/Resolving - Other Medically Important Condition), Proteinuria (n/a - | immunisation - Not applicable - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Recovering/Resolving - Other Medically Important Condition) | | |
| EU-EC- 10013883192 | 31/10/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Chest discomfort (n/a - Not Recovered/Not Resolved -), Dyspnoea exertional (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), Palpitations (n/a - Not | | |
| | | | | | | | | | | Recovered/Not Resolved -) | | |
| EU-EC- 10013883958 | 31/10/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Disturbance in attention (n/a - Unknown -), Dizziness (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported |
| | | | | | | | | | | Unknown -), Headache (n/a - Unknown -), | n/a]) | |
| | | | | | | | | | | Tonsillitis (n/a - Unknown -) | | |
| EU-EC- 10013885044 | 31/10/2022 | Spontaneous | Healthcare Professional | Non European Economic | Smith, E Multiple Evanescent White Dot Syndrome following COVID-19 mRNA Vaccination in Two Patients, Ocular | 12-17 Years | Not Specified | Male | No | Headache (n/a - Unknown -), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 | Not reported |
| | | | | Area | Immunology and Inflammation, 2022;1-4, doi:10.1080/09273948.2022.2032198 Smith, E Multiple Evanescent White Dot Syndrome following COVID-19 mRNA | | | | | Myalgia (n/a - Unknown -), Retinal white dots | immunisation - Not applicable - [n/a - n/a - n/a]) | |
| | | | | | Vaccination in Two Patients. Ocular Immunology and Inflammation. 2022;30 (5):1240-1243. doi:10.1080/09273948.2022.2032198 | | | | | syndrome (n/a - Recovered/Resolved - Other Medically Important Condition) | | |
| EU-EC- 10013885137 | 31/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Dizziness (2h - Recovered/Resolved -), Loss of consciousness | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported |
| | | | | | | | | | | (2h - Recovered/Resolved - Other Medically Important Condition) | Intramuscular use]) | |
| EU-EC- 10013885709 | 31/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (99h - Recovered/Resolved - Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported |
| | | | | | | | | | | Dizziness (99h - Recovered/Resolved - Other Medically Important Condition), | applicable - [1d - n/a - Intramuscular use]) | |
| | | | | | | | | | | Headache (99h - Recovered/Resolved - Other Medically Important Condition), | | |

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|-----------------------|-------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|--|--|--|
| | | | | | | | | | | Vomiting (99h - Recovered/Resolved - Other Medically Important Condition) | | |
| EU-EC- 10013886174 | 31/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea exertional (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | [ERYTHROMYCIN, ERYTHROMYCIN ETHYLSUCCINATE, ERYTHROMYCIN ETHYLSUCCINATE F EUR., ERYTHROMYC STEARATE] (C - Abscess limb - n/a - [n/a - n/a - Oral use |
| | | | | | | | | | | Myocarditis (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Myopericarditis (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | |
| EU-EC- 10013886489 | 31/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Conversion disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| | | | | | | | | | | Dehydration (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Eating disorder (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Gait disturbance (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | Pyrexia (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | |
| EU 50 | 24 (40/2022 | | | | N | 12.17 | | | | White blood cell count increased (n/a - Unknown -) | | |
| 10013887237 | | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Hypoaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013887379 | 31/10/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Lymphadenopathy (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013878570 | 30/10/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest pain (1d - Recovered/Resolved -), Dyspnoea (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Unknown -), Palpitations (1d - Recovered/Resolved -), | | |

| | | | | | | | | | | Palpitations (n/a - Unknown -) | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|--|----------------|------------------|--------|----|---|--|--|
| EU-EC- .0013859843 | 28/10/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Asthenia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use]) | Not reported |
| | | | | | | | | | | Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Hypertension (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Pain in extremity (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Paraesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | |
| | | | | | | | | | | Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | |
| J-EC- 0013861192 | 28/10/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Haematoma (7d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| J-EC- 0013861521 | 28/10/2022 | Spontaneous | Healthcare Professional | European Economic Area | Kounisa, N Encephalitis, myocarditis, and thrombocytopenia after COVID-19 mRNA vaccination: Clinical and pathophysiological considerations. Journal of | | Not Specified | Female | No | Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported |
| | | | | | Neuroimmunology, 2022;373:10.1016/j.jneuroim.2022.577988. doi:10.1016/j.jneuroim.2022.577988 | | | | | Myocarditis (n/a - Unknown - Other Medically Important Condition), | applicable - [n/a - n/a - n/a]) | |
| | | | | | | | | | _ | Thrombocytopenia (n/a - Unknown - Other Medically Important Condition) | | |
| J-EC- 013861666 | 28/10/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | [SALBUTAMOL SULFATE] (C - Asth - n/a - [n/a - n/a - n/a]) |
| | | | | | | | | | | Headache (n/a - Unknown - Other Medically Important Condition), | n/a]) | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | | Pyrexia (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | | Renal pain (n/a - Unknown - Other Medically Important Condition), | | |
| J-EC- | 20/40/2022 | | lu lu | | | 10.17 | | | | Vomiting (n/a - Unknown - Other Medically Important Condition) | | |
| 0013863601 | 28/10/2022 | Spontaneous | Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Electroencephalogram abnormal (n/a - Unknown -), Epilepsy (n/a - Not | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported |
| | | | | | | | | | | | Intramuscular use]) | |
| | | | | | | | | | | Seizure (n/a - Recovering/Resolving - Caused/Prolonged | | |

| | | | | | | | | | | Hospitalisation, Other Medically Important Condition) | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---|----------------|------------------|--------|----|---|--|--|
| EU-EC- 10013865402 | 28/10/2022 | Spontaneous | | Non European Economic Area | Kojima, N Case Report: Myocarditis Associated With COVID-19 mRNA Vaccination Following Myocarditis Associated With Campylobacter Jejuni, Frontiers in Cardiovascular Medicine. 2022;9:10.3389/fcvm.2022.837759 doi:10.3389/fcvm.2022.837759 | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013866374 | 28/10/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain (n/a - Recovering/Resolving -), Chills (2d - Recovered/Resolved -), Diarrhoea (n/a - Recovering/Resolving -), Myalgia (3d - Recovered/Resolved -), Nausea (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013866763 | 28/10/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Recovering/Resolving -) Headache (1d - Recovered/Resolved -), Nausea (n/a - Recovering/Resolving), Rhinorrhoea (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (5 - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013866902 | 28/10/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Resolved -) Abdominal pain (n/a - Not Recovered/Not Resolved -), Chills (0d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Recovering/Resolving -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Presyncope (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | [CYPROTERONE ACETATE, ETHINYLESTRADIO (C - n/a - n/a - [n/a n/a - Oral use]) |
| EU-EC- 10013867000 | 28/10/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Pruritus (n/a - Not Recovered/Not Resolved -), Rash (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013867063 | 28/10/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Lymphadenopathy (7d - Recovered/Resolved -), Oral pain (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Throat irritation (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013867476 | 28/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Drug ineffective (108d - Recovered/Resolved - Other Medically Important Condition), Suspected COVID-19 (108d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| EU-EC- 10013867504 | 28/10/2022 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Acute respiratory distress syndrome (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | ICETIRIZINE, CETIRIZINE DIHYDROCHLORID (C - Rash erythematous - n/a [n/a - n/a - n/a]), [CHLORMEZANONE |

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|---------------|----------|-----------|------------|------------|---|---------|------------|---------|------------------------------|--|
| | | | | | | | | | R R | lister (n/a - Not ecovered/Not esolved - Life hreatening), |
| | | | | | | | | | ir R R C | reactive protein ncreased (n/a - Not lecovered/Not lesolved - laused/Prolonged lospitalisation), |
| | | | | | | | | | N R C | chromaturia (n/a - lot Recovered/Not esolved - aused/Prolonged lospitalisation), |
| | | | | | | | | | (i R R C | pecreased appetite n/a - Not ecovered/Not esolved - aused/Prolonged lospitalisation), |
| | | | | | | | | | N R C | Pengue fever (n/a - lot Recovered/Not lesolved - laused/Prolonged lospitalisation), |
| | | | | | | | | | R R C | oizziness (n/a - Not ecovered/Not esolved - aused/Prolonged lospitalisation), |
| | | | | | | | | | ly (i R R C H | laemophagocytic ymphohistiocytosis n/a - Not lecovered/Not lesolved - saused/Prolonged lospitalisation, Othe ledically Important condition), |
| | | | | | | | | | ir R R C | lepatic enzyme ncreased (n/a - Not lecovered/Not lesolved - laused/Prolonged lospitalisation), |
| | | | | | | | | | H R R T | lepatitis (n/a - Not lecovered/Not lesolved - Life threatening, Other ledically Important condition), |
| | | | | | | | | | N R | lypotension (n/a - lot Recovered/Not lesolved - Life 'hreatening), |
| | | | | | | | | | R R T | aundice (n/a - Not ecovered/Not esolved - Life hreatening), |
| | | | | | | | | | R R T | eukopenia (n/a - No lecovered/Not lesolved - Life hreatening, Other ledically Important condition), |
| | | | | | | | | | N R C | ip erythema (n/a - lot Recovered/Not lesolved - laused/Prolonged lospitalisation), |
| | | | | | | | | | R R C | ip swelling (n/a - No ecovered/Not esolved - aused/Prolonged lospitalisation), |
| | | | | | | | | | R R C | falaise (n/a - Not ecovered/Not esolved - aused/Prolonged lospitalisation), |
| | | | | | | | | | R R C | lyalgia (n/a - Not ecovered/Not esolved - aused/Prolonged lospitalisation), |
| | | | | | | | | | (i R R C | ocular hyperaemia n/a - Not ecovered/Not esolved - aused/Prolonged lospitalisation), |
| | | | | | | | | | R R | yrexia (n/a - Not ecovered/Not esolved - Life hreatening), |
| https://dap.e | ama ouro | na aulono | lytics/ss: | יי קוואַרי | | | | | (I R R | ash erythematous n/a - Not ecovered/Not esolved - Life hreatening), |

Not

- n/a - n/a - [3d - n, n/a]),

[DICLOFENAC, DICLOFENAC POTASSIUM, DICLOFENAC SODIL (C - n/a - n/a - [3d n/a - n/a]),

[MOSAPRIDE] (C - r - n/a - [3d - n/a -n/a]),

[PIPRINHYDRINATE (C - Rash pruritic - r - [6d - n/a - n/a])

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|----|-----------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|---------|----|---|---|--------------|
| | | | | | | | | | | | Serum ferritin increased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Skin exfoliation (n/a - Not Recovered/Not Resolved - Life Threatening), Stevens-Johnson syndrome (n/a - Not Recovered/Not Resolved - Life Threatening), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Thrombocytopenia (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), Toxic epidermal necrolysis (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), | | |
| | 10013867835 | | | Healthcare Professional | Economic Area | Not available | Years | Adolescent | | No | Asthenia (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Menstrual disorder (n/a - Not Recovered/Not Resolved -), Mental disorder (n/a - Not Recovered/Not Resolved -), Musde spasms (n/a - Not Recovered/Not Resolved -), Musde spasms (n/a - Not Recovered/Not Resolved -), Pain (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported |
| | EU-EC- 10013848235 | 27/10/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Burning sensation (n/a - Recovering/Resolving -), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular | Not reported |
| | EU-EC- 10013848250 | 27/10/2022 | Spontaneous | | European Economic Area | Not available | | Not Specified | Female | No | Alopecia (n/a - Recovering/Resolving -), Breakthrough COVID- 19 (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular use]) | Not reported |
| | EU-EC- 10013848630 | 27/10/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | | Not Specified | Male | | COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Cough (n/a - Unknown -), Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -), Vaccination failure (n/a - Recovered/Resolved - Other Medically | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id - n/a - Intramuscular use]) | Not reported |
| | EU-EC- 10013849043 | 27/10/2022 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Important Condition) Headache (n/a - Not Recovered/Not Resolved -), Injection site joint | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - | Not reported |

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|-----------------------|------------|-------------|----------------------------|------------------------------|---------------|----------------|------------------|--------|----|--|--|--------------|
| | | | | | | | | | | movement impairment (n/a - Not Recovered/Not Resolved -), | [n/a - n/a - Intramuscular use]) | |
| | | | | | | | | | | Pain in extremity (n/a - Not Recovered/Not Resolved -) | | |
| EU-EC- 10013850867 | 27/10/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Adolescent | Male | No | Contusion (n/a - Recovered/Resolved -), Rash (3d - Recovered/Resolved -) | COMIRNATY 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10013852687 | 27/10/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Adolescent | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | Not reported |
| | | | | | | | | | | (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10013853688 | 27/10/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Adolescent | Male | No | Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 0013854007 | 27/10/2022 | Spontaneous | | European Economic Area | Not available | | Not Specified | Male | No | Asthenia (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| :U-EC- 0013854178 | 27/10/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Adolescent | Female | No | Unknown -) COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular use]) | Not reported |
| | | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | | |
| EU-EC- 10013854436 | 27/10/2022 | Spontaneous | | Economic | Not available | | Not Specified | Female | No | Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| | | | | | | | | | | Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not | | |
| | | | | | | | | | | Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | Pain (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not | | |
| EU-EC- | 27/10/2022 | Spontaneous | Non | European | Not available | 12-17 | Not | Male | No | Recovered/Not Resolved -) Influenza (n/a - | COMIRNATY | Not reported |
| 10013855226 | 27,10,2022 | Sportaneous | | Economic | The drainage | | Specified | riale | | Recovered/Resolved - | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | The reported |
| EU-EC- 10013855244 | 27/10/2022 | Spontaneous | Healthcare Professional | | Not available | | Not Specified | Female | No | Angina pectoris (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | Not reported |
| | | | | | | | | | | Arrhythmia (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), | | |
| | | | | | | | | | | Body temperature decreased (n/a - Unknown -), | | |
| | | | | | | | | | | Bradycardia (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), | | |
| | | | | | | | | | | Brugada syndrome (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | | Cyanosis (n/a - Unknown -), Dyspnoea (n/a - Not Recovered/Not | | |
| | | pa.eu/ana | | | | | | | | Resolved - Life Threatening), | | |

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|----|-------------|------------|-------------|------------|------------------|---------------|----------|------------|-----------|-----|--|--|--------------|
| | | | | | | | | | | | Feeling cold (n/a - Not Recovered/Not Resolved - Life | | |
| | | | | | | | | | | | Threatening), Muscle disorder (n/a - Unknown -), | | |
| | | | | | | | | | | | Muscle spasms (n/a - Unknown - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | | Pancytopenia (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | | | Pulse absent (n/a - Unknown -), | | |
| | | | | | | | | | | | Seizure (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition), | | |
| | | | | | | | | | | | Speech disorder (n/a - Unknown -), | | |
| | | | | | | | | | | | Tachycardia (n/a - Not Recovered/Not Resolved - Life Threatening), | | |
| | EU-EC- | 27/10/2022 | Spontaneous | Healthcare | European | Not available | 12-17 | Not | Female | No | Tremor (n/a - Unknown -) Alopecia (n/a - Not | COMIRNATY | Not reported |
| | 10013856340 | 27/10/2022 | | | Economic Area | NOC available | Years | Specified | Temale | INO | Recovered/Not Resolved -), | [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported |
| | | | | | | | | | | | Altered state of consciousness (n/a - Unknown - Other Medically Important Condition), | applicable - [1d - n/a - n/a]) | |
| | | | | | | | | | | | Cardiovascular disorder (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | | Decreased appetite (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | | Depressive symptom (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | | Disturbance in attention (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | | Dizziness (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | | Dyspnoea (n/a - Not Recovered/Not Resolved -), | | |
| | | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | |
| | | | | | | | | | | | Female reproductive tract disorder (n/a - Unknown -), | | |
| | | | | | | | | | | | Headache (1wk - Recovered/Resolved -), | | |
| | | | | | | | | | | | Inappropriate schedule of product administration (n/a - Unknown -), | | |
| | | | | | | | | | | | Joint swelling (n/a - Unknown -), | | |
| | | | | | | | | | | | Loss of consciousness (n/a - Unknown - Other Medically Important Condition), | | |
| | | | | | | | | | | | Memory impairment (n/a - Unknown -), | | |
| | | | | | | | | | | | Menstrual disorder (n/a - Unknown -), | | |
| | | | | | | | | | | | Migraine (n/a - Unknown -), | | |
| | | | | | | | | | | | Nausea (1wk - Recovered/Resolved -), | | |
| | | | | | | | | | | | Nervous system disorder (n/a - Unknown -), | | |
| hí | tos://dap.e | ma euro | na eu/ana | lytice/eaw | , dll2Go | | 1 | | | 1 | | | 65/71 |

| | | | | | | | | | | Performance status decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pyrexia (1wk - Recovered/Resolved -), Respiratory failure (n/a - Unknown - Other Medically Important Condition), Sense of oppression (n/a - Not Recovered/Not Resolved -), Tremor (n/a - Unknown -) | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|---|---|---|
| 10013857241 | | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Not Specified | Male | No | Myalgia (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | [PARACETAMOL] (C n/a - n/a - [n/a - n/ Oral use]) |
| 10013857297 | | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Specified | Female | No | Rash (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |
| 10013857510 | | Spontaneous | Professional | European Economic Area | Not available | 12-17 Years | Adolescent | | No | Skin reaction (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular use]) | Not reported |
| EU-EC- 10013857528 | 27/10/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular use]) | Not reported |
| EU-EC- 10013857620 | 27/10/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Malaise (n/a - Unknown -), Pyrexia (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular use]) | Not reported |
| EU-EC- 10013838955 | 26/10/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dizziness (n/a - Not Recovered/Not Resolved -), Fall (n/a - Not Recovered/Not Resolved -), Pericardial effusion (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Tachycardia (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1(DF) - Intramuscular use]) | Not reported |
| EU-EC- 10013839246 | 26/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - Intramuscular use - More in ICSR]) | Not reported |
| 10013839267 | | Spontaneous | Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Heart rate increased (n/a - Unknown -), Nasal obstruction (n/a - Recovering/Resolving - Other Medically Important Condition), Oropharyngeal pain (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id3mL - Intramuscular use]) | Not reported |
| EU-EC- 10013839572 | 26/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Hypoaesthesia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013841080 | 26/10/2022 | Spontaneous | Non Healthcare Professional | Non European | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (n/a - Unknown - Other Medically Important | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported |

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|-----------------------|------------|-------------|----------------------------|----------------------|---|----------------|------------------|---------|----|---|--|----------------|
| | | | | Economic Area | | | | | | Condition), | immunisation - Not applicable - [1d - n/a - | |
| | | | | , | | | | | | Dysmenorrhoea (n/a - Not Recovered/Not | n/a]) | |
| | | | | | | | | | | Resolved - Other | | |
| | | | | | | | | | | Medically Important Condition) | | |
| EU-EC- | 26/10/2022 | Spontaneous | | Non | Not available | 12-17 | Not | Female | No | COVID-19 (5d - | COMIRNATY | Not reported |
| 10013841181 | | | Healthcare Professional | European Economic | | Years | Specified | | | Recovered/Resolved - Other Medically | [TOZINAMERAN] (S - COVID-19 | |
| | | | | Area | | | | | | Important Condition), | immunisation - Not applicable - [1d - n/a - | |
| | | | | | | | | | | Drug ineffective (n/a - Unknown - Other | n/a]), | |
| | | | | | | | | | | Medically Important | [COVID-19 VACCINE] | |
| | | | | | | | | | | Condition) | (S - COVID-19 immunisation - Not | |
| | | | | | | | | | | | applicable - [n/a - n/a - n/a]) | |
| EU-EC- | 26/10/2022 | Spontaneous | | European | Not available | 12-17 | Not | Male | No | Anxiety (n/a - | COMIRNATY | Not reported |
| 10013841426 | | | Healthcare Professional | Economic Area | | Years | Specified | | | Recovering/Resolving -), | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | |
| | | | | | | | | | | Cardiac discomfort | n/a]) | |
| | | | | | | | | | | (n/a - Recovering/Resolving | | |
| | | | | | | | | | | -), | | |
| | | | | | | | | | | Chest discomfort (n/a | | |
| | | | | | | | | | | Recovering/Resolving | | |
| | | | | | | | | | | -), | | |
| | | | | | | | | | | Headache (3d - Recovered/Resolved - | | |
| | | | | | | | | | |), | | |
| | | | | | | | | | | Pain in extremity (n/a | | |
| | | | | | | | | | | - Recovering/Resolving | | |
| | | | | | | | | | | -), | | |
| | | | | | | | | | | Productive cough (n/a | | |
| | | | | | | | | | | Recovering/Resolving | | |
| | | | | | | | | | | -), | | |
| | | | | | | | | | | Pyrexia (3d - Recovered/Resolved - | | |
| EU-EC- | 26/10/2022 | Spontaneous | Healthcare | Non | Ahmed, T A report on short-term follow- | 12-17 | Not | Male | No | Myocarditis (24h - | TOZINAMERAN | Not reported |
| 10013842337 | | | Professional | European Economic | up cardiac imaging and dinical outcomes of myocarditis after coronavirus disease 2019 | | Specified | | | Recovered/Resolved - Caused/Prolonged | [TOZINAMERAN] (S - COVID-19 | |
| | | | | Area | vaccination. Journal of Cardiovascular | | | | | Hospitalisation, Other | immunisation - Not | |
| | | | | | Medicine. 2022;23 (10):691-693. doi:10.2459/JCM.000000000001341 | | | | | Medically Important Condition) | applicable - [n/a - n/a - n/a]) | |
| EU-EC- 10013842429 | 26/10/2022 | Spontaneous | Healthcare Professional | Non European | Not available | 12-17 Years | Not Specified | Male | No | Condition aggravated (n/a - Unknown - | TOZINAMERAN [TOZINAMERAN] (S - | Not reported |
| | | | | Economic Area | | | ' | | | Caused/Prolonged Hospitalisation), | COVID-19 immunisation - Not | |
| | | | | Aica | | | | | | , , , , , | applicable - [1d - n/a - | |
| | | | | | | | | | | Deep vein thrombosis (n/a - | n/a]) | |
| | | | | | | | | | | Recovered/Resolved With Sequelae - Life | | |
| | | | | | | | | | | Threatening, Caused/Prolonged | | |
| | | | | | | | | | | Hospitalisation, Disabling, Other | | |
| | | | | | | | | | | Medically Important | | |
| | | | | | | | | | | Condition), | | |
| | | | | | | | | | | Muscle injury (n/a - Unknown -), | | |
| | | | | | | | | | | Pain in extremity (n/a | | |
| | | | | | | | | | | - Unknown -), | | |
| | | | | | | | | | | Peripheral swelling (n/a - Unknown - | | |
| | | | | | | | | | | Caused/Prolonged | | |
| | | | | | | | | | | Hospitalisation), | | |
| | | | | | | | | | | Surgery (n/a - Not Recovered/Not | | |
| | | | | | | | | | | Resolved - Life Threatening, | | |
| | | | | | | | | | | Caused/Prolonged Hospitalisation, | | |
| | | | | | | | | | | Disabling), | | |
| | | | | | | | | | | Thrombosis (n/a - Not | | |
| | | | | | | | | | | Recovered/Not Resolved - Life | | |
| | | | | | | | | | | Threatening, Caused/Prolonged | | |
| | | | | | | | | | | Hospitalisation, | | |
| | | | | | | | | | | Disabling, Other Medically Important | | |
| EU-EC- | 26/10/2022 | Spontaneous | | European | Not available | 12-17 | Adolescent | Male | No | Condition) Myocarditis (n/a - | COMIRNATY | Not reported |
| 10013842645 | | | Healthcare Professional | Economic Area | | Years | | | | Recovering/Resolving - Caused/Prolonged | [TOZINAMERAN] (S - COVID-19 | |
| | | | | | | | | | | Hospitalisation) | immunisation - n/a - [n/a - n/a - n/a]) | |
| EU-EC- | 26/10/2022 | Spontaneous | | European | Not available | 12-17 | Adolescent | Female | No | Arrhythmia (n/a - Not | COMIRNATY | Not reported |
| 10013842649 | | | Healthcare Professional | Economic Area | | Years | | | | Recovered/Not Resolved - | [TOZINAMERAN] (S - COVID-19 | |
| | | | | | | | | | | Caused/Prolonged Hospitalisation) | immunisation - n/a - [n/a - n/a - | |
| EU EC | 26/10/2022 | Cnort | Non | Nor | Not available | 12.17 | Not | For:-' | Ne | | Intramuscular use]) | Not your - it! |
| EU-EC- 10013842724 | 26/10/2022 | Spontaneous | Healthcare | Non European | Not available | 12-17 Years | Not Specified | Female | No | Drug ineffective (n/a - Recovering/Resolving | TOZINAMERAN [TOZINAMERAN] (S - | Not reported |
| | | | Professional | Economic Area | | | | | | - Other Medically Important Condition), | COVID-19 immunisation - Not | |
| | | | | | | | | | | Suspected COVID-19 | applicable - [n/a - n/a - Intramuscular use]) | |
| | | | | | | | | | | (n/a - | a.aascalal use]) | |
| I | 1 | I | I | I | I | 1 | I | I | I | Recovering/Resolving | I | I |

| FU FO | 26/40/2022 | C | 1110 | F | N. b 11-b.l | 42.47 | A d . 1 | F1- | | - Other Medically Important Condition) | COMIDNIATY | Not an and |
|-----------------------|--------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|--|--|--------------|
| EU-EC- 10013842908 | 26/10/2022 | Spontaneous | Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Epistaxis (5d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10013842984 | 26/10/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Oligomenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10013842988 | 26/10/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Menstruation irregular (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10013843164 | 26/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | | Not Specified | Male | No | Resolved -) Chest pain (1819h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chills (79d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dyspnoea (1819h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Electrocardiogram repolarisation abnormality (76d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Headache (79d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (1818h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Myocarditis (1818h - Recovered/Resolved - Caused/Prolonged Hospitalisation), Pericarditis (1818h - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| | 25.14.0/2222 | | | | | 40.47 | | | | Recovered/Resolved - Caused/Prolonged Hospitalisation), Pyrexia (79d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | |
| 10013843430 | | Spontaneous | Professional | Non European Economic Area | Not available | | Not Specified | Male | No | Hypersensitivity (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Rash erythematous (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Urticaria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Urticaria (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| EU-EC- 10013843552 | 26/10/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Administration site pain (3d - Recovered/Resolved -), Body temperature increased (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10013843559 | 26/10/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | | Not Specified | Female | No | Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Disabling), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Disabling), Iron deficiency anaemia (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported |

|).11.2022 | 13.22 | | | | Γ | Kuii Lii | ne Listing | g Kepo | 11 | | | |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|--|----------------|------------------|--------|----|--|---|--------------|
| | | | | | | | | | | Resolved - Disabling), Menstruation irregular (n/a - Not Recovered/Not | | |
| EU-EC- 10013843655 | 26/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Ahmed, T A report on short-term follow- up cardiac imaging and dinical outcomes of myocarditis after coronavirus disease 2019 vaccination. Journal of Cardiovascular Medicine, 2022;23(10):691-693. doi:10.2459/JCM.000000000001341 | 12-17 Years | Not Specified | Male | No | Resolved - Disabling) Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013843924 | 26/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition), Palpitations (n/a - Recovered/Resolved - Other Medically | - N/aJ) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013844251 | 26/10/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Important Condition) Hyperthyroidism (n/a Not Recovered/Not Resolved - Other Medically Important Condition), Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rhabdomyolysis (n/a - Not Recovered/Not Resolved - Other Medically Important Undersolved - Other Medically Important Medically Important Undersolved - Other Medically Important | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013844511 | 26/10/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Condition) Anaphylactic shock (n/a - Recovered/Resolved - Other Medically Important Condition), Angioedema (n/a - Recovered/Resolved - Other Medically Important Condition), Hypotension (n/a - Recovered/Resolved - Rec | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | Not reported |
| | | | | | | | | | | Other Medically Important Condition), Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition) | | |
| EU-EC- | | Spontaneous | Healthcare Professional | Non | Not available Not available | 12-17 Years | Not Specified | Male | No | Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), Limb discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Nasopharyngitis (n/a - Unknown - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation) Immunisation stress-related response (n/a - Inknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - | Not reported |
| 10013844572 | | | Professional | European Economic Area | | Years | Specified | | | related response (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | |
| 10013845921 | | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Immunodeficiency (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| 10013846654 | | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain upper (n/a - Unknown -), Cough (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| EU-EC- 10013846666 | 26/10/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Axillary pain (1d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported |

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| | | | | | | | | | | Vaccination site pain (2d - Recovered/Resolved - | | |
| EU-EC- 10013847012 | 26/10/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adult | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -), Lymphadenopathy (7d - Recovered/Resolved - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a]) | Not reported |
| EU-EC- 10013847016 | 26/10/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Pain in extremity (n/a - Recovering/Resolving -), Pain threshold decreased (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a]) | Not reported |
| EU-EC- 10013847120 | 26/10/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Heavy menstrual bleeding (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported |
| EU-EC- 10013847628 | 26/10/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Fatigue (n/a - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), COVID-19 MRNA VACCINE MODERNA (CX-024414) [COVID- 19 MRNA VACCINE MODERNA (CX- 024414)] (S - COVID- 19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| EU-EC- 10013847818 | 26/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Ahmed, T A report on short-term follow- up cardiac imaging and dinical outcomes of myocarditis after coronavirus disease 2019 vaccination. Journal of Cardiovascular Medicine. 2022;23(10):691-693. doi:10.2459/JCM.000000000001341 | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |
| 10013830162 | 25/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest discomfort (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013830182 | 25/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Not Specified | No | COVID-19 (10172min - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (10172min - Recovered/Resolved - Other Medically Important Condition), Headache (2833min - Recovered/Resolved - Other Medically Important Condition), Pyrexia (2702min - Recovered/Resolved - Other Medically Important Condition), Pyrexia (2702min - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use - More in ICSR]) | Not reported |
| EU-EC- 10013830295 | 25/10/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Epilepsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013831805 | 25/10/2022 | 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), Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013831935 | 25/10/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Arthralgia (n/a - Unknown -), Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Pyrexia (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
| EU-EC- 10013832342 | 25/10/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Arthralgia (8d - Recovered/Resolved -), Fatigue (8d - Recovered/Resolved -), Injection site pain (8d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported |

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| EU-EC- 10013832807 | 25/10/2022 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Not Specified | Female | No | Injection site reaction (8d - Recovered/Resolved -), Malaise (8d - Recovered/Resolved -) Chest discomfort (9d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - | Not reported |
| | | | | Economic Area | | | | | | - Other Medically Important Condition), Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (9d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition) | COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | |
| U-EC- 0013832852 | | Spontaneous | Professional | Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Alopecia areata (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013832951 | | Spontaneous | Professional | Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Drug ineffective (n/a - Unknown - Other Medically Important Condition), Dysmenorrhoea (n/a - Unknown -), Heavy menstrual bleeding (n/a - Recovering/Resolving -), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition) | | Not reported |
| EU-EC- 10013833231 | | Spontaneous | Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest pain (10d - Recovered/Resolved - Other Medically Important Condition), Dizziness (10d - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (10d - Recovered/Resolved - Other Medically Important Condition), Hypoaesthesia (10d - Recovered/Resolved - Other Medically Important Condition), Palpitations (10d - Recovered/Resolved - Other Medically Important Condition), Palpitations (10d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |
| EU-EC- 10013833401 | 25/10/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Recovering/Resolving - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |

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