Line Listing Report
Time run: 30/11/2022 03:16:53

| EU Local Number | EV Gateway Receipt Date | Report Type | Primary Source Qualification | Primary Source Country for Regulatory Purposes | Literature Reference | Patient Age Group | Patient Age Group (as per reporter) | Patient Sex | Parent Child Report | Reaction List PT (Duration – Outcome - Seriousness Criteria) | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) | Concomitant/Not Administered Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) | ICSR Form |
|-----------------------|----------------------------------|-------------|------------------------------------|---|-------------------------|-------------------------|--|----------------|---------------------------|---|--|--|--------------|
| EU-EC- 10012032333 | 28/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Abdominal pain (n/a - Recovered/Resolved -), Asthenia (n/a - Recovered/Resolved -), Crying (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved -), Unresponsive to stimuli (n/a - Recovered/Resolved -) | | | |
| EU-EC- 10012032611 | 28/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Male | No | Autoinflammatory disease (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10012033305 | 28/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | Insomnia (5d - Recovering/Resolving -), Pruritus (5d - Recovered/Resolved -), Rash papular (5d - Recovering/Resolving | COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 - n/a - [n/a3mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10012035013 | 28/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Male | No | -) Dermatitis allergic (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10012036953 | 28/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Adult | Female | No | Neuralgia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Visual impairment | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10012036965 | 28/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Male | No | (n/a - Unknown -) Chest pain (2d - Unknown - Other Medically Important Condition), Gastrointestinal pain (1d - Unknown - Other Medically Important Condition), Palpitations (2d - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10012037086 | 28/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10012037138 | 28/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Chest pain (n/a - Unknown -), Fatigue (n/a - Unknown -), Hemiparesis (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |

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| | | | | _ | | | | | | Muscular weakness (n/a - Unknown -) | | | |
| EU-EC- 10012038012 | 28/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Dyspnoea (4d - Recovered/Resolved - Other Medically Important Condition), Wheezing (4d - Recovered/Resolved - Other Medically | COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICSF |
| EU-EC- | 28/03/2022 | Spontaneous | Non | Non | Not | 3-11 | Not | Male | No | Important Condition) Alopecia (n/a - Not | .2mL - n/a]) TOZINAMERAN | Not reported | TCSD |
| 10012038463 | 28/03/2022 | Spontaneous | Healthcare Professional | European | Not available | Years | Specified | Маје | INO | Recovered/Not Resolved - Disabling, Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Emotional distress (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | | Madarosis (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition) | | | |
| EU-EC- 10012039045 | 28/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Balance disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Vertigo (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10012039270 | 28/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Chills (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | <u>ICSF</u> |
| | | | | | | | | | | Resolved -), Headache (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not | | | |
| EU-EC- | 28/03/2022 | Spontaneous | Non | Non | Not | 3-11 | Not | Male | No | Resolved -) Arthralgia (n/a - | COMIRNATY | Not reported | ICSR |
| 10012039760 | , , | · | Healthcare Professional | European | available | Years | Specified | | | Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | · | |
| | | | | | | | | | | Mobility decreased (n/a - Recovered/Resolved - Other Medically Important | | | |
| | | | | | | | | | | Condition), Paralysis (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved | | | |
| EU-EC- 10012039910 | 28/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | -) Guillain-Barre syndrome (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not reported | ICSR |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|---------------|------------------|----------|----------|--|---|--------------|------|
| EU-EC- 10012039957 | 28/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Chest pain (n/a - Recovering/Resolving -), Vaccination site pain (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10012040531 | 28/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Malaise (n/a - Recovering/Resolving -), Nasal congestion (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -) | COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular - | Not reported | ICSR |
| EU-EC- 10012027823 | 27/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Vaccination site lymphadenopathy (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10012028129 | 27/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Decreased appetite (1d - Recovered/Resolved -), Diarrhoea (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -) | COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 - n/a - [n/a1mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10012025231 | 26/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), Pericarditis (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10012009275 | 25/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Dry eye (n/a - Recovering/Resolving -), Eye pain (n/a - Recovering/Resolving -), Optic neuritis (n/a - Recovering/Resolving - Other Medically Important Condition), Vision blurred (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10012009967 | 25/03/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Chills (n/a - Recovered/Resolved -), Nasal congestion (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10012010007 | | Spontaneous | Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Croup infectious (n/a - Unknown - Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10012010008 | | Spontaneous | Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Myocarditis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10012010036 | 25/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |

| 20,003,000,000 20,000,000 | 0.11.2022 0 | | | | | | | | | Drug ineffective (n/a - Unknown - Other Medically Important | applicable - [n/a - n/a - n/a]) | | |
|--|-----------------------|------------|-------------|------------|----------------------|--|-------|--------|----|---|---|--------------|-----|
| 2-PEC Communication Processor Proc | EU-EC- 10012010066 | 25/03/2022 | Spontaneous | | European Economic | | | Male | No | Unknown - Other Medically Important | [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICS |
| Performance Company Performance Perf | | | | | | | | | | | | | |
| EU-EC- 091201072 25032022 Sportaneous Healthcare (No. Post Professional European Revolution Professional | EU-EC- 10012010070 | 25/03/2022 | Spontaneous | | European Economic | | | Female | No | Unknown - Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | Not reported | ICS |
| 2-001/2012 2-0 | | | | | | | | | | - Unknown - Other Medically Important | 1,70]) | | |
| Come sock abromated (in the properties of the pr | EU-EC- 10012010073 | 25/03/2022 | Spontaneous | | European Economic | | | Female | No | Bell's palsy (n/a - Recovered/Resolved - Other Medically Important | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Not reported | ICS |
| Beconversification (No. Beconversification) Beautification (No. Beautification) Beautification (No. Beau | | | | | | | | | | (n/a - Recovered/Resolved | 1,701) | | |
| - Other Medically Important Condition), Intracramal pressure increased (n/a = New York Recovered Recovered Recovered Recovered (n/a = New York Recovered Recovered Recovered Recovered (n/a = New York Recovered (n/a = New York Recovered | | | | | | | | | | | | | |
| ### Increased (n/a - Recovered/Recoved - Chief Medically Condition) Letharry (n/a - Recovered/Recoved - Chief Medically Condition) Letharry (n/a - Recovered/Recoved - Chief Medically Condition) | | | | | | | | | | - Other Medically Important | | | |
| BLEC. 25/03/2022 Spontaneous Professional Conomic. Area Professional Economic Professional Economic Professional Resolution Pr | | | | | | | | | | increased (n/a - Recovered/Resolved - Other Medically Important | | | |
| ELFEC 25/03/2022 Spontaneous Non Professional European (2012) 112011262 Spontaneous Non Professional Area (2012) 112011262 Spontaneous Non Not Professional Non Not Professional Area (2012) 112011262 Spontaneous Non Not Professional Area (2012) 112011262 Spontaneo | | | | | | | | | | Recovered/Resolved | | | |
| EU-EC- 10012010083 | | | | | | | | | | encephalopathy syndrome (n/a - Recovered/Resolved - Other Medically Important | | | |
| Recovered/Resolved - - - - - - - - - | | | | | | | | | | Recovered/Resolved - Other Medically Important | | | |
| EU-EC- CO12010083 COMIRANTY COMIRA | | | | | | | | | | Recovered/Resolved | | | |
| Professional European Economic Area Professional European Economic Area Professional European Economic Area Professional Area Profession | | | | | | | | | | Recovered/Resolved | | | |
| EU-EC- 10012011262 25/03/2022 Spontaneous Non Healthcare Professional European (2012011262) EU-EC- 10012011264 Spontaneous Healthcare Professional Secondic (2012011262) EU-EC- 10012012148 Spontaneous Healthcare Professional Secondic (2012011262) EU | EU-EC- 10012010083 | 25/03/2022 | Spontaneous | | European Economic | | | Male | No | Unknown - Other Medically Important | [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICS |
| EU-EC- (10012011262 Spontaneous Spontane | | | | | | | | | | - Unknown - Other Medically Important | | | |
| EU-EC-10012012148 Spontaneous Healthcare Professional European Economic Area Healthcare Professional European Economic Area Healthcare Professional European Economic Area Not Recovered/Not Resolved - Other Medically Important Condition), Staphylococcus bacteraemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Staphylococcus bacteraemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Staphylococcus bacteraemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Staphylococcus test Staphylococc | EU-EC- 10012011262 | 25/03/2022 | Spontaneous | Healthcare | Economic | | Child | Male | No | Ageusia (n/a - Not Recovered/Not | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a | Not reported | ICS |
| Osteomyelitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Staphylococcal bacteraemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Staphylococcus test | EU-EC- 10012012148 | 25/03/2022 | Spontaneous | | European Economic | | | Female | No | aggravated (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICS |
| bacteraemia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Staphylococcus test | | | | | | | | | | Not Recovered/Not Resolved - Other Medically Important | | | |
| | | | | | | | | | | bacteraemia (n/a - Not Recovered/Not Resolved - Other Medically Important | | | |
| | | | | | | | | | | | | | |

| | | | | | | | | | | Recovered/Not Resolved -) | | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|---------------|------------------|--------|----|--|--|--------------|------|
| EU-EC- 10012012159 | 25/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | COVID-19 (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10012012372 | 25/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Generalised tonic- clonic seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10012012386 | 25/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Anaphylactic reaction (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Cough (n/a - Unknown -), Dyspnoea (n/a - Unknown -), Pyrexia (n/a - Hospitalisation) | [TOZINAMERAN] (S - | Not reported | ICSR |
| EU-EC- 10012013611 | 25/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Unknown -) Blood pressure decreased (n/a - Unknown - Other Medically Important Condition), Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Pallor (n/a - Unknown - Other Medically Important Condition) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10012015340 | 25/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Cardiac murmur (n/a - Recovering/Resolving -), Cardiomegaly (n/a - Recovering/Resolving -), Inflammatory marker increased (n/a - Recovering/Resolving -), Kawasaki's disease (n/a - Recovering/Resolving - Other Medically Important Condition), Lethargy (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving -), | [TOZINAMERAN] (S - | Not reported | ICSR |
| EU-EC- 10012015352 | 25/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 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 | ICSR |
| EU-EC- 10012015393 | 25/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Bell's palsy (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10012015398 | 25/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Hypothyroidism (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10012015401 | 25/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10012018911 | 25/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Arthralgia (3d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |

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| | | | | | | | | | | Movement disorder (n/a - Recovered/Resolved -), | immunisation - Not applicable - [n/a - n/a - Intramuscular]) | | |
| | | | | | | | | | | Pain (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Pain in extremity (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Vaccination site erythema (60h - Recovered/Resolved -), | | | |
| | | | | | | | | | | Vaccination site induration (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Vaccination site pain (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Vaccination site warmth (n/a - Recovered/Resolved -) | | | |
| EU-EC- 10012018917 | 25/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | Croup infectious (n/a - Unknown - Other Medically Important Condition), | applicable - [n/a - n/a - n/a]) | | |
| | | | | | | | | | | Drug ineffective (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10012018928 | 25/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Pain in extremity (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | Not reported | ICSR |
| | | | | | | | | | | Rash (n/a - Recovered/Resolved -), | - n/a]) | | |
| | | | | | | | | | | Rash vesicular (n/a - Recovered/Resolved -), Somnolence (n/a - | | | |
| | | | | | | | | | | Recovering/Resolving -), Swelling (n/a - Recovered/Resolved | | | |
| EU-EC- 10012021355 | 25/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Not Specified | No | -) Peroneal nerve palsy (3d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported | <u>ICSR</u> |
| EU-EC- 10012021359 | 25/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Erythema multiforme (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10012023705 | 25/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Hypoacusis (0d - Recovered/Resolved -), Presyncope (0d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | -), Scleral discolouration (n/a - Recovering/Resolving | anti antiscular j) | | |
| EU-EC- 10011994030 | 24/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Erythema (n/a - Unknown -), Pruritus (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - | Not reported | ICSR |
| EU-EC- 10011994556 | 24/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Unknown -) Herpes zoster (n/a - Recovered/Resolved -) | [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011994592 | 24/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Blister (58d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | Dermatitis bullous (58d - | applicable - [n/a - | | |

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| | | | | | | | | | | Recovered/Resolved -), Hyperaemia (58d - | .2mL - Intramuscular]) | | |
| | | | | | | | | | | Recovered/Resolved -), Oedema (58d - Recovered/Resolved | | | |
| | | | | | | | | | | Pain (58d - Recovered/Resolved | | | |
| | | | | | | | | | | Pustule (58d - Recovered/Resolved | | | |
| EU-EC- 10011995199 | 24/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Not Specified | No | Rash (n/a - Unknown - Other Medically Important Condition) | [TOZINAMERAN] (S - | Not reported | ICS |
| EU-EC- 10011996697 | 24/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Fatigue (5d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - | Not reported | ICS |
| | | | | | | | | | | Headache (5d - Recovered/Resolved -), | [n/a - n/a - Intramuscular]) | | |
| | | | | | | | | | | Injection site pain (5d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Loss of personal independence in daily activities (5d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Pyrexia (5d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Wrong dose (5d - Recovered/Resolved -) | | | |
| EU-EC- 10011996887 | 24/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Epilepsy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Epilepsy (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10011998615 | 24/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Herpes zoster (7d - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - | Not reported | ICS |
| | | | | | | | | | | Neuralgia (1mo - Recovered/Resolved - Other Medically Important Condition) | COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | | |
| U-EC- .0011999223 | 24/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Dizziness (3d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 10ug - | Not reported | ICS |
| | | | | | | | | | | Headache (3d - Recovered/Resolved -) | Intramuscular]) | | |
| EU-EC- 10011999831 | 24/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Headache (2d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Malaise (2d - Recovering/Resolving -) | | | |
| EU-EC- 10012000759 | 24/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Headache (52d - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- L0012001499 | 24/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | <u>ICS</u> |
| | | | | | | | | | | Loss of consciousness (7h - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Nasopharyngitis (n/a | | | |
| | | | | | | | | | | Recovered/Resolved -), | | | |

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| | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Syncope (7h - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10012002503 | 24/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Not Specified | No | Exposure via breast milk (n/a - Recovered/Resolved -), Pyrexia (18h - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Recovered/Resolved | - ilya]) | | |
| EU-EC- 10012004374 | 24/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Adult | Male | No | Arthralgia (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intravenous (not otherwise specified)]) | Not reported | ICSR |
| | | | | | | | | | | -), Influenza (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving -) | | | |
| EU-EC- 10012004382 | 24/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Elderly | Male | No | Asthenia (n/a - Unknown -), Cardiac failure (n/a - | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | [[]] | | |
| | | | | | | | | | | Oedema peripheral (n/a - Unknown -) | | | |
| EU-EC- 10012004627 | 24/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Product administered to patient of inappropriate age (n/a - Unknown -), Vaccination site pain | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | Not reported | ICSR |
| | 24/03/2022 | Spontaneous | | European | Not | 3-11 | Child | Female | No | (n/a - Unknown -) Abdominal pain (3d - | - n/a]) COMIRNATY | Not reported | ICSR |
| 10012005020 | | | Healthcare Professional | Economic Area | available | Years | | | | Recovered/Resolved -), Dyspepsia (3d - Recovered/Resolved -), | [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) | | |
| | | | | | | | | | | Fatigue (3d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Headache (3d - Recovered/Resolved -) | | | |
| EU-EC- 10012005441 | 24/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Vomiting (n/a - Recovered/Resolved -) | | | |
| EU-EC- 10012006185 | 24/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Multisystem inflammatory syndrome in children (11d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Pyrexia (11d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Rash (11d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10012007597 | 24/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Axillary pain (n/a - Unknown -), Lymphadenopathy | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| FILES | 24/02/25=: | Caratt | 11 | F | Net | 24. | Child | No. 1 | NI - | (n/a - Unknown -) | applicable - [1d - 1{DF} - Unknown]) | Net and the | 705- |
| EU-EC- 10012007646 | 24/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Headache (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |

| | | | | | | | | | | Pyrexia (0d - Recovered/Resolved | | | |
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| EU-EC- 10012007706 | 24/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Myopericarditis (n/a - Recovering/Resolving - Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - | Not reported | ICSR |
| EU-EC- 10012007724 | 24/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Abdominal pain (n/a - Not Recovered/Not Resolved -), Arthralgia (4d - Recovered/Resolved -), Cold sweat (1d - Recovered/Resolved -), Dizziness (1d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (4d - Recovered/Resolved -), Malaise (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10012007792 | 24/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Somnolence (n/a - Recovering/Resolving -) Antiphospholipid syndrome (26d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d2mL - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011981110 | 23/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Atypical haemolytic uraemic syndrome (26d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation) Type III immune complex mediated reaction (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - | Not reported | ICSF |
| EU-EC- 10011981120 | 23/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Resolved -) Fatigue (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved Recovered/Resolved | [n/a - 1{DF} - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011982393 | 23/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | -) COVID-19 (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011982558 | 23/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Bone pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Somnolence (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011983807 | 23/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Resolved -) Lymphadenopathy (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - | Not reported | ICSR |
| EU-EC- 10011984164 | 23/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Pyrexia (0d - Recovered/Resolved -) | [n/a - 10ug - n/a]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- | 23/03/2022 | Spontaneous | Non | Non | Not | 3-11 | Not | Male | No | Aggression (n/a - | TOZINAMERAN | Not reported | ICSR |

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| 10011984663 | | | Healthcare Professional | | available | Years | Specified | | | Not Recovered/Not Resolved -), Autism spectrum disorder (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Delusional disorder, unspecified type (n/a - Not Recovered/Not | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | | |
| EU-EC- 10011984664 | 23/03/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Resolved -), Eating disorder symptom (n/a - Not Recovered/Not Resolved -) Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged | [TOZINAMERAN] (S - COVID-19 immunisation - Not | [GABAPENTIN] (C - n/a - n/a - [n/a - 100mg - n/a]) | ICSR |
| | | | | | | | | | | Hospitalisation, Other Medically | applicable - [n/a - n/a - n/a]) | | |
| EU-EC- 10011985582 | 23/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Important Condition) Diarrhoea (1d - Recovered/Resolved -), Fatigue (1d - Recovered/Resolved -), Nausea (1d - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 10ug - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -) | | | |
| EU-EC- 10011986034 | 23/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | COVID-19 (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011986886 | 23/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Adult | Female | No | Disturbance in attention (18d - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Dizziness (18d - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Dizziness (6d - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Fatigue (18d - Not Recovered/Not Resolved -), Feeling hot (7d - Not | | | |
| | | | | | | | | | | Recovered/Not Resolved -), Headache (17d - Not | | | |
| | | | | | | | | | | Recovered/Not Resolved -), Headache (18d - Not | | | |
| | | | | | | | | | | Recovered/Not Resolved -), Hot flush (18d - Not Recovered/Not | | | |
| | | | | | | | | | | Resolved -), Somnolence (18d - Not Recovered/Not | | | |
| EU-EC- 10011989704 | 23/03/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Resolved -) Asthenia (3d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | 71100 | | | | | | Blister (1h - Recovered/Resolved - Other Medically Important Condition), | applicable - [n/a - n/a - n/a]) | | |
| | | | | | | | | | | Body temperature decreased (3d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Decreased appetite (3d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Erythema (1h - Recovered/Resolved - Other Medically Important Condition), | | | |

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| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Feeling abnormal (n/a - Unknown -), | | | |
| | | | | | | | | | | Headache (3d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Hyperhidrosis (3d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Hypersensitivity (1h - Recovered/Resolved | | | |
| | | | | | | | | | | -), Malaise (3d - Recovered/Resolved | | | |
| | | | | | | | | | | -), Nausea (3d - Recovered/Resolved | | | |
| | | | | | | | | | | -), Somnolence (n/a - | | | |
| | | | | | | | | | | Not Recovered/Not Resolved -), Vomiting (1d - | | | |
| EU-EC- | 22/02/2022 | Spontaneous | Non | European | Not | 3-11 | Child | Female | No | Recovered/Resolved - Other Medically Important Condition) Ear pain (n/a - | COMIRNATY | Not reported | ICSR |
| 10011990803 | 23/03/2022 | Spontaneous | Healthcare | Economic Area | available | Years | Critica | remaie | No | | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICSIX |
| EU-EC- 10011991776 | 23/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011992661 | 23/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | Bronchitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10011993225 | 23/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Headache (1d - Recovered/Resolved - Other Medically Important Condition), Syncope (1d - Recovered/Resolved - Other Medically Important Condition), Vaccination site pain (2d - Recovered/Resolved - Other Medically | [Inya T(b) / Inya) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011993252 | 23/03/2022 | Spontaneous | | European Economic | Not available | 3-11 Years | Child | Male | No | Important Condition) Nephrotic syndrome (n/a - | COMIRNATY [TOZINAMERAN] (S - | Not reported | ICSR |
| | | | | Area | | | | | | Recovering/Resolving - Caused/Prolonged Hospitalisation) | COVID-19 immunisation - Not applicable - [1d - n/a - n/a]), [HEPATITIS A VACCINE] (S - n/a - Not applicable - [1d - | | |
| EU-EC- 10011962556 | 22/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Polymenorrhoea (n/a - Recovering/Resolving | n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |
| | | | | | | | | | | -) | immunisation - n/a - [n/a - n/a - Intramuscular]) | | |
| EU-EC- 10011963341 | 22/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011964916 | 22/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Important Condition) Decreased appetite (n/a - Recovering/Resolving -), Fatigue (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 10ug - Intramuscular]) | Not reported | ICSR |

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| | | | | | | | | | | Recovering/Resolving -), | | | |
| | | | | | | | | | | Myalgia (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Vomiting (n/a - Recovered/Resolved -) | | | |
| EU-EC- 10011965944 | 22/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Epistaxis (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | 7 60 | | | | | | Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | applicable - [n/a - n/a - n/a]) | | |
| EU-EC- 10011966162 | 22/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Kawasaki's disease (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Lethargy (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Multisystem inflammatory syndrome in children (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Myalgia (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Oropharyngeal pain (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Rhinorrhoea (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Thrombocytopenia (n/a - Recovered/Resolved | | | |
| | | | | | | | | | | - Other Medically Important Condition) | | | |
| EU-EC- 10011966452 | 22/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Croup infectious (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011968067 | 22/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Alopecia (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | COMIRNATY [TOZINAMERAN] (C - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | ICSR |
| EU-EC- 10011968326 | 22/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Blepharitis (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |
| | | | | | | | | | | Eyelid oedema (n/a - Unknown -), Myalgia (n/a - | immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | | |
| | | | | | | | | | | Unknown -), Pyrexia (n/a - | Thu amusculal J) | | |
| EU-EC- | 22/03/2022 | Spontaneous | Healthcare | European | Not | 3-11 | Child | Female | No | Unknown -) Fatigue (1wk - | COMIRNATY | Not reported | ICSR |
| 10011968362 | | | Professional | | available | Years | | | | Recovered/Resolved -), Insomnia (1wk - | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [5s - | | |
| | | | | | | | | | | Recovered/Resolved -), Sleep disorder (1wk - | 1{DF} - Intramuscular]) | | |
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| | | | | | | | | | | Recovered/Resolved -) | | | |
| EU-EC- 10011969377 | 22/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported | ICSF |
| EU-EC- 10011970486 | 22/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Vomiting (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported | ICSF |
| EU-EC- 10011971165 | 22/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Abdominal pain (n/a - Fatal - Results in Death), Cardiac arrest (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSF |
| | | | | | | | | | | Dyspnoea (n/a - Fatal - Results in Death), | | | |
| | | | | | | | | | | Haematemesis (n/a - Fatal - Results in Death), | | | |
| | | | | | | | | | | Headache (n/a - Fatal - Results in Death), | | | |
| | | | | | | | | | | Heart rate increased (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Oxygen saturation decreased (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (n/a - Fatal - Results in Death) | | | |
| EU-EC- 10011971179 | 22/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Ankle fracture (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | Not reported | ICSR |
| EU-EC- | 22/03/2022 | Spontaneous | | European | Not | 3-11 | Not | Male | No | COVID-19 (n/a - | - n/a]) COMIRNATY | Not reported | ICSF |
| 10011976224 | | | Healthcare Professional | Economic Area | available | Years | Specified | | | Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | | |
| | | | | | | | | | | Medically Important Condition) | | | |
| EU-EC- 10011976301 | 22/03/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Abdominal pain upper (n/a - Unknown -), Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | [NIMESULIDE] (C - n/a - n/a - [n/a - 40mL - n/a]) | ICSR |
| | | | | | | | | | | Dehydration (n/a - Unknown -), Haematuria (n/a - | | | |
| | | | | | | | | | | Unknown -), Headache (3h - Recovered/Resolved | | | |
| | | | | | | | | | | Vomiting (n/a - Unknown -) | | | |
| EU-EC- 10011976310 | 22/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Not reported | ICSR |
| | | | | | | | | | | Rash (n/a - Unknown - Caused/Prolonged Hospitalisation) | - | | |
| EU-EC- 10011978463 | 22/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Application site pain (n/a - Unknown -), Headache (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSE |
| | | | | | | | | | | Pyrexia (n/a - Unknown -) | | | |
| EU-EC- 10011978472 | 22/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Rash (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- | 22/03/2022 | Spontaneous | Non | European | Not | 3-11 | Child | Female | No | Diarrhoea (n/a - | COMIRNATY | Not reported | ICSR |

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| 10011978916 | | | Healthcare Professional | Economic Area | available | Years | | | | Recovered/Resolved -) | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | | |
| EU-EC- 10011979277 | 22/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Male | No | Lymphadenopathy (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011979708 | 22/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | Anaphylactic shock (0d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011979713 | 22/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Lymphadenopathy (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Vaccination site pain (n/a - Not Recovered/Not Resolved -), Vaccination site reaction (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - n/a]) | Not reported | ICSR |
| EU-EC- 10011979714 | | Spontaneous | Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Headache (5d - Recovered/Resolved -), Musculoskeletal pain (5d - Recovered/Resolved -), Pyrexia (5d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011980047 | 22/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Male | No | Cerebrovascular accident (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011980076 | | Spontaneous | Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Diarrhoea (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) | Not reported | ICSR |
| EU-EC- 10011980696 | 22/03/2022 | Spontaneous | Professional | European Economic Area | Not available | 3-11 Years | Child | Male | Yes | Arthralgia (n/a - Unknown - Other Medically Important Condition), Lip oedema (n/a - Unknown - Other Medically Important Condition), Oedema peripheral (n/a - Unknown -), Urticaria (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - .3mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011946081 | 21/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Electrolyte imbalance (3220min - Recovered/Resolved - Caused/Prolonged Hospitalisation), Feeling abnormal (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Guillain-Barre syndrome (3220min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotonia (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011946114 | 21/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011948920 | 21/03/2022 | Spontaneous | | European Economic | Not available | 3-11 Years | Not Specified | Male | No | Axillary pain (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - | Not reported | ICSR |

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| | | | | | | | | | | | applicable - [1d - n/a - n/a]) | | |
| EU-EC- 10011949033 | 21/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Abdominal pain (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10011950280 | 21/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Male | No | Injection site pain (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Rash (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10011950313 | 21/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Vomiting (1d - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10011950314 | 21/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Adult | Female | No | Dizziness (n/a - Not Recovered/Not Resolved -), Tachycardia (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10011950315 | 21/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Resolved -) Rash (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10011950318 | 21/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Vomiting (0d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a]) | Not reported | ICS |
| EU-EC- 10011950320 | 21/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Vomiting (0d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10011950406 | 21/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Fatigue (n/a - Unknown -), Headache (n/a - Unknown -), Injection site pain | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | (n/a - Unknown -), Pyrexia (n/a - Unknown -) | | | |
| EU-EC- 10011950457 | 21/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Injection site pain (1d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Rash (1d - Recovered/Resolved | | | |
| EU-EC- 10011950518 | 21/03/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | Yes | Abdominal pain (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Abdominal pain upper (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | COVID-19 (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Contusion (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Disease recurrence (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Epistaxis (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Condition), | | | |
| | | | | | | | | | | Henoch-Schonlein purpura (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |

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| EU-EC- 10011950542 | 21/03/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Important Condition) Inappropriate schedule of product administration (n/a - Unknown -), Loss of | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - | [METHYLPHENIDATE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]), [RUPATADINE] (C - n/a | ICSF |
| | | | | | | | | | | consciousness (n/a - Unknown - Other Medically Important Condition), Respiratory arrest | Intramuscular]) | - n/a - [n/a - n/a - n/a]) | |
| EU-EC- 10011950629 | 21/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | (n/a - Unknown - Life Threatening) Haematuria (n/a - Not Recovered/Not Resolved -), IgA nephropathy (n/a - Not Recovered/Not Resolved - Other Medically Important | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10011951767 | 21/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Syncope (n/a - Recovered/Resolved -) | COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2mL - n/a]) | Not reported | ICS |
| EU-EC- 10011951889 | 21/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Nausea (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSI |
| EU-EC- 10011954704 | 21/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Eczema (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported | ICSF |
| EU-EC- 10011956934 | 21/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Not Specified | No | Abdominal pain (n/a - Unknown -), Lip oedema (n/a - Unknown -), Rash (n/a - Unknown -), Rash macular (n/a - Unknown -), Vomiting (n/a - Unknown -) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE | Not reported | ICS |
| EU-EC- 10011957698 | 21/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Asthenia (n/a - Recovered/Resolved -), Chills (n/a - Recovered/Resolved -), Disorientation (n/a - Recovered/Resolved -), Malaise (n/a - Recovered/Resolved -), Oropharyngeal pain (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Throat tightness (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10011959713 | 21/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Anaphylactic reaction (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chills (0d - Recovered/Resolved - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | [DERMATOPHAGOIDES PTERONYSSINUS, DERMATOPHAGOIDES FARINAE] (C - n/a - n/a - [487d - n/a - Subcutaneous]) | ICSF |

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| | | | | | | | | | | Hospitalisation), | | | |
| | | | | | | | | | | Dyspnoea (30min - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Tachycardia (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10011959993 | 21/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Arrhythmia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Somnolence (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Unknown -), Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation, | iyajy | | |
| | | | | | | | | | | Other Medically Important Condition) | | | |
| EU-EC- 10011960563 | 21/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Pain in extremity (n/a - Recovered/Resolved -), Product administered | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not ampulicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | to patient of inappropriate age (n/a - Unknown -) | , | | |
| EU-EC- 10011961052 | 21/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Not Specified | No | Myalgia (n/a - Unknown -), Pain in extremity | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | (n/a - Unknown -) | applicable - [n/a - n/a - n/a]) | | |
| EU-EC- 10011961120 | 21/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Hepatitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Transaminases increased (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Vomiting (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10011961449 | 21/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Dysphagia (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Not reported | ICSR |
| | | | | | | | | | | Palatal oedema (n/a | - n/a]) | | |
| | | | | | | | | | | Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10011961486 | 21/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | Henoch-Schonlein purpura (35d - Recovered/Resolved - Other Medically | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - | Not reported | ICSR |
| | | | | | | | | | | Important Condition) | .2mL - Intramuscular]) | | |
| EU-EC- 10011961521 | 21/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Male | No | Lymphadenopathy (2d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Not reported | ICSR |
| | | | | | | | | | | Petit mal epilepsy (1d - Recovered/Resolved - Caused/Prolonged | - n/a]) | | |
| EU-EC- 10011961650 | 21/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Hospitalisation) Menstrual disorder (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - | Not reported | ICSR |
| | | | | | | | | | | | .2mL - Intramuscular]) | | |
| EU-EC- 10011961657 | 21/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Diarrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a | Not reported | ICSR |
| EU-EC- 10011961669 | 21/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Lymphadenopathy (n/a - Recovering/Resolving -) | - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - | Not reported | ICSR |

| | | | | | | | | | | | .2mL - Intramuscular]) | | |
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| EU-EC- 10011961676 | 21/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Chills (n/a - Unknown -), Headache (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d3mL - | Not reported | ICSI |
| | | | | | | | | | | Pyrexia (n/a - Unknown -) | Intramuscular]) | | |
| EU-EC- 10011961687 | 21/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Rhinitis (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .2mL - Intramuscular]) | Not reported | ICSF |
| | | | | | | | | | | Recovering/Resolving | | | |
| EU-EC- 10011961695 | 21/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Nausea (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving | COVID-19 immunisation - Drug withdrawn - [1d - | Not reported | <u>ICSR</u> |
| EU-EC- 10011944840 | 20/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Aphthous ulcer (n/a - Recovering/Resolving -), Erythema nodosum (n/a - Recovering/Resolving -), Pain in extremity (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - .2mL - | Not reported | ICSR |
| EU-EC- 10011945003 | 20/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Application site pain (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011945004 | 20/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Application site pain (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011945039 | 20/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Rash (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011945555 | 20/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | Haematuria (n/a - Recovering/Resolving - Other Medically Important Condition), Pyrexia (7d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011945689 | 20/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Cerebral haemorrhage (2d - Fatal - Results in Death) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011939281 | 19/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Lymphadenopathy (n/a - Recovered/Resolved -), Vertigo (n/a - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011928885 | 18/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | -) Chest pain (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Dyspnoea (n/a - Not Recovered/Not Resolved -), Oropharyngeal discomfort (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |

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| | | | | | | | | | | Resolved -), Palpitations (n/a - Not Recovered/Not Resolved -), Pericarditis (n/a - Not Recovered/Not Resolved - Others | | | |
| EU-EC- 10011928903 | 18/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Resolved - Other Medically Important Condition) Empyema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | Not reported | ICSR |
| | | | | | | | | | | Pneumonia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | - n/a]) | | |
| EU-EC- 10011929078 | 18/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011929082 | 18/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Dizziness (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Increased appetite (n/a - Recovering/Resolving -), | COVID-19 immunisation - Not applicable - [1d - n/a | Not reported | ICSR |
| | | | | | | | | | | Photophobia (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Vision blurred (n/a - | | | |
| | | | | | | | | | | Recovering/Resolving -), Vomiting (n/a - Recovering/Resolving -) | | | |
| EU-EC- 10011929108 | 18/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Basedow's disease (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011929109 | 18/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Croup infectious (n/a - Unknown - Other Medically Important Condition) | | Not reported | ICSR |
| EU-EC- 10011929294 | 18/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Administration site pain (2d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 10ug - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011929512 | 18/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Rash (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011929543 | 18/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Female | No | Nausea (0d - Recovering/Resolving -) | COMIRNATY | Not reported | ICSR |
| EU-EC- 10011929751 | 18/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Administration site pain (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 10ug - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011930973 | 18/03/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Discomfort (n/a - Unknown -), Drug ineffective (n/a - Unknown - Other | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Medically Important Condition), Pyrexia (n/a - Unknown -) | | | |
| EU-EC- | 18/03/2022 | Spontaneous | Healthcare | Non | Not | 3-11 | Not | Female | No | Abdominal pain (n/a | COMIRNATY | Not reported | ICSR |

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| 10011931026 | | | Professional | European Economic Area | available | Years | Specified | | | - Recovering/Resolving -), Appendicitis (n/a - Recovering/Resolving - Other Medically Important Condition), | [TOZINAMERAN] (5 - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | | |
| | | | | | | | | | | Malaise (n/a - Recovering/Resolving -) | | | |
| EU-EC- 10011931089 | 18/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011932219 | 18/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Administration site pain (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 10ug - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011932443 | 18/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Petechiae (n/a - Unknown - Caused/Prolonged Hospitalisation), Thrombocytopenia | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a2mL - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10011932697 | 18/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Eye inflammation (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Subcutaneous]) | Not reported | ICSR |
| | | | | | | | | | | Papilloedema (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | | |
| EU-EC- | 18/03/2022 | Spontaneous | Healthcare | European | Not | 3-11 | Not | Female | No | Uveitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) C-reactive protein | COMIRNATY | Not reported | ICSR |
| 10011932868 | 10,03,2022 | Sportaireous | Professional | | available | Years | Specified | remale | | increased (n/a - Unknown - Caused/Prolonged Hospitalisation), | [TOZINAMERAN] (S - n/a - n/a - [n/a - .2mL - Intramuscular]) | not reported | 1001 |
| | | | | | | | | | | Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Lymphopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Multisystem inflammatory syndrome in children (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Procalcitonin increased (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| EU-EC- | 19/03/2022 | Spontaneous | Hoalthcaro | European | Not | 3-11 | Not | Male | No | Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY | Not reported | ICCD |
| 10011932975 | 10/03/2022 | Sportanieous | Professional | | available | Years | Specified | male | INU | Anaphylactic shock (n/a - Unknown - Life Threatening), Asthenia (n/a - | [TOZINAMERAN] (S - n/a - n/a - [n/a - .3mL - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Unknown - Life Threatening), Blood pressure decreased (n/a - | | | |
| | | | | | | | | | | Unknown - Life Threatening), | | | |

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| | | | | | | | | | | Headache (n/a - Unknown - Life Threatening), | | | |
| | | | | | | | | | | Hypotonic- hyporesponsive episode (n/a - Unknown - Life Threatening), | | | |
| | | | | | | | | | | Loss of consciousness (n/a - Unknown - Life Threatening), | | | |
| | | | | | | | | | | Muscle spasticity (n/a - Unknown - Life Threatening), | | | |
| | | | | | | | | | | Muscle tightness (n/a - Unknown - Life Threatening), | | | |
| | | | | | | | | | | Vomiting (n/a - Unknown - Life Threatening) | | | |
| EU-EC- 10011934351 | 18/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Application site pain (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Arthralgia (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10011934353 | 18/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Application site pain (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Fatigue (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Headache (n/a - Recovered/Resolved -) | | | |
| EU-EC- 10011935982 | 18/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Accidental overdose (n/a - Unknown -), Product administered to patient of inappropriate age | applicable - [n/a - | Not reported | ICSR |
| EU-EC- | 18/03/2022 | Spontaneous | | Non | Not | 3-11 | Not | Female | No | (n/a - Unknown -) Febrile convulsion | COMIRNATY | Not reported | ICSR |
| 10011936421 | | | Professional | European Economic Area | available | Years | Specified | | | (1min - Recovered/Resolved - Life Threatening) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular]) | | |
| EU-EC- 10011937224 | 18/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Cardiac arrest (n/a - Fatal - Results in Death, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011915775 | 17/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Asthenia (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |
| | | | | | | | | | | Lymphadenitis (n/a - Recovering/Resolving -), | immunisation - Not applicable - [n/a - .1mL - Intramuscular]) | | |
| | | | | | | | | | | Vertigo (n/a - Recovering/Resolving -) | | | |
| EU-EC- 10011916082 | 17/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), | COVID-19 immunisation - Unknown - [n/a - | Not reported | ICSR |
| | | | | | | | | | | Pericarditis (n/a - Recovering/Resolving - Other Medically | 1{DF} - Intramuscular]) | | |
| EU-EC- 10011916667 | 17/03/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Important Condition) COVID-19 (n/a - Unknown - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | Drug ineffective (n/a - Unknown - Other Medically Important | applicable - [n/a - n/a - n/a]) | | |
| EU-EC- | 17/03/2022 | Spontaneous | Healthcare | European | Not | 3-11 | Not | Male | No | Condition) Urticaria (n/a - Not | COMIRNATY | Not reported | ICSR |

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| 10011917146 | | | Professional | Economic Area | available | Years | Specified | | | Recovered/Not Resolved - Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | | |
| EU-EC- 10011918240 | 17/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY | Not reported | ICSR |
| EU-EC- 10011918449 | 17/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Chills (6d - Recovered/Resolved -), Nausea (6d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Palpitations (6d - Recovered/Resolved -), Vomiting (6d - | | | |
| | | | | | | | | | | Recovered/Resolved -) | | | |
| EU-EC- 10011918562 | 17/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Skin exfoliation (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011918592 | 17/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Abdominal pain upper (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011918650 | 17/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | <u>ICSR</u> |
| EU-EC- 10011919117 | 17/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Female | No | Uveitis (19d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011919139 | 17/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Female | No | Diabetes mellitus inadequate control (1d - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Headache (1d - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Pyrexia (1d - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Type 1 diabetes mellitus (1d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10011919149 | 17/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Dizziness (126d - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | <u>ICSR</u> |
| EU-EC- 10011919636 | 17/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Vasculitis (21d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported | <u>ICSR</u> |
| EU-EC- 10011919810 | 17/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Fatigue (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - | Not reported | ICSR |
| | | | | | | | | | | General physical health deterioration (n/a - Recovered/Resolved -), | Intramuscular]) | | |
| | | | | | | | | | | Somnolence (n/a - Recovered/Resolved -) | | | |
| EU-EC- 10011919858 | | Spontaneous | Healthcare Professional | | Not available | 3-11 Years | Child | Male | No | Injection site pain (0d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011920779 | 17/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Seizure (0d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a - n/a - Intramuscular]) | [OXCARBAMAZEPINE] (C - Epilepsy - n/a - [n/a - 600mg - Oral]), [VALPROIC ACID, SODIUM VALPROATE] | ICSR |
| | | | | | | | | | | | | (C - Epilepsy - n/a - [n/a - 1000mg - Oral]) | |
| EU-EC- 10011921413 | 17/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Chills (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - | Not reported | <u>ICSR</u> |

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| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | 10ug - Intramuscular]) | | |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10011922104 | 17/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Administration site pain (12h - Recovered/Resolved -), Chills (12h - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 10ug - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | -), Pyrexia (12h - Recovered/Resolved | | | |
| EU-EC- 10011922173 | 17/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Pyrexia (3h - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 10ug - n/a]) | Not reported | ICSR |
| EU-EC- 10011922543 | 17/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | Abdominal pain (n/a - Unknown -), Decreased appetite (n/a - Unknown -), Fatigue (14d - | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]), COMIRNATY [TOZINAMERAN] (S - | Not reported | ICSR |
| EU-EC- | 17/03/2022 | Spontaneous | | European | Not | 3-11 | Not | Female | No | Recovered/Resolved -) Asthenia (1d - | Immunisation - n/a - [n/a - 2{DF} - n/a]) COMIRNATY | Not reported | ICSR |
| 10011922819 | | | Healthcare Professional | Economic Area | available | Years | Specified | | | Recovered/Resolved -), Body temperature increased (1d - Recovered/Resolved -), Ear pain (1d - | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | | |
| | | | | | | | | | | Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved | | | |
| | | | | | | | | | | -), Somnolence (1d - Recovered/Resolved | | | |
| EU-EC- 10011923317 | 17/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | -) Loss of consciousness (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Pruritus (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Respiratory arrest (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Seizure (n/a - Recovering/Resolving - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | | |
| EU-EC- | | Spontaneous | | | Not | 3-11 | Child | Female | _ | Angioedema (3d - | COMIRNATY | | ICSR |

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| EU-EC- 10011923451 | 17/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Male | No | Chills (1d - Recovered/Resolved -), Fatigue (0d - Unknown -), Rash (7d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSF |
| EU-EC- : | 17/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSI |
| EU-EC- : | 17/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | (n/a - Unknown - Other Medically Important Condition) Headache (3d - Recovered/Resolved -), Injection site pain (2d - | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSI |
| | | | | | | | | | | Recovered/Resolved | | | |
| EU-EC- 10011924824 | 17/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Male | No | Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported | ICSI |
| EU-EC- 10011925953 | 17/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSI |
| EU-EC- 10011926262 | 17/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Guillain-Barre syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiratory failure | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) | Not reported | ICSF |
| | | | | | | | | | | (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10011926574 | 17/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Abdominal pain (n/a - Not Recovered/Not Resolved -), COVID-19 (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | Not reported | ICS |
| | | | | | | | | | | Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- : 10011926869 | 17/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | Urticaria (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011926870 | 17/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Headache (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a]) | [HYDROCORTISONE BUTYRATE] (C - Eczema - n/a - [n/a - n/a - Cutaneous]), [SODIUM HYDROGEN CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - Oral]) | ICSF |
| EU-EC- 10011926875 | 17/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Headache (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSF |
| EU-EC- : | 17/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Rash erythematous (n/a - Recovering/Resolving -), Rash pruritic (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - | Not reported | ICSF |
| | | | | | | | | | | Recovering/Resolving -) | Intramuscular]) | | |

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| EU-EC- 10011927064 | 17/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Lymphadenopathy (n/a - Recovering/Resolving -) | - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSF |
| EU-EC- 10011927109 | 17/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY | Not reported | ICSF |
| EU-EC- 10011927130 | 17/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Menstruation normal (4d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011927177 | 17/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Pruritus allergic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash scarlatiniform (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not reported | ICSF |
| EU-EC- 10011927183 | 17/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | Lymphadenopathy (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular - More in ICSR]) | Not reported | ICSF |
| EU-EC- 10011927187 | 17/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Pruritus allergic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Rash scarlatiniform (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not reported | ICSF |
| EU-EC- 10011927194 | 17/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | Musculoskeletal chest pain (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular - More in ICSR]) | Not reported | ICSF |
| EU-EC- 10011903486 | 16/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Palatal oedema (n/a - Recovering/Resolving -), Pruritus (n/a - Recovering/Resolving -), Tongue oedema (n/a - Recovering/Resolving -), Urticaria (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 30ug - | Not reported | ICSF |
| EU-EC- 10011905416 | 16/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Injection site pain (2d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011905434 | 16/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 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 | ICSF |
| EU-EC- 10011905443 | 16/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - - Recovering/Resolving - Other Medically Important | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|---------------|------------------|------------|-------|--|---|--------------|-------|
| | | | | | | | | | | Condition), | | | |
| | | | | | | | | | | Malaise (n/a - Recovering/Resolving | | | |
| | | | | | | | | | | -), | | | |
| | | | | | | | | | | Nausea (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Vomiting (n/a - Recovering/Resolving -) | | | |
| EU-EC- 10011905448 | 16/03/2022 | Spontaneous | | Non European Economic | Not available | 3-11 Years | Not Specified | Male | No | Abdominal pain (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |
| | | | | Area | | | | | | COVID-19 (n/a - Unknown -), | immunisation - Not applicable - [1d - n/a - Intramuscular]) | | |
| | | | | | | | | | | Cold sweat (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Diarrhoea (n/a - Unknown -), | | | |
| | | | | | | | | | | Fall (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Foaming at mouth (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown -), | | | |
| | | | | | | | | | | Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Pyrexia (n/a - Unknown -), | | | |
| | | | | | | | | | | Seizure (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Tachycardia (830min | | | |
| | | | | | | | | | | Recovered/Resolved - Life Threatening, Other Medically | | | |
| EU-EC- 10011905470 | 16/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Important Condition) Injection site pain (6d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - | Not reported | ICSR |
| EU-EC- | 16/03/2022 | Spontaneous | | European | Not | 3-11 | Child | Male | No | -) Injection site pain | [n/a - n/a - n/a]) COMIRNATY | Not reported | ICSR |
| 10011905517 | 10/03/2022 | Sportaneous | Healthcare Professional | Economic | available | Years | Cinia | riaje | No | (1d - Recovered/Resolved -) | [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSIX |
| EU-EC- 10011905522 | 16/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Injection site pain (1d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - | Not reported | ICSR |
| EU-EC- | 16/03/2022 | Spontaneous | | European | Not | 3-11 | Child | Male | No | Rash (7d - | [n/a - n/a - n/a]) COMIRNATY | Not reported | ICSR |
| 10011905524 | | | Healthcare Professional | | available | Years | | | | Recovered/Resolved -) | [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | | |
| EU-EC- 10011906018 | 16/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Injection site pain (1d - Unknown -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011906566 | 16/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Not reported | ICSR |
| | | | | | | | | | | Drug ineffective (n/a - Unknown - Other Medically Important Condition), | - n/a]) | | |
| | | | | | | | | | | Multisystem inflammatory | | | |

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| | | | | | | | | | | syndrome in children (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | SARS-CoV-2 test positive (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Sepsis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important | | | |
| | | | | | | | | | | Condition), Troponin increased (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10011906939 | 16/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Pyrexia (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011907202 | 16/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Injection site erythema (3d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Injection site pain (33d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Nausea (0d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Pyrexia (0d - Recovering/Resolving -), Vomiting (0d - | | | |
| | | | | | | | | | | Recovered/Resolved | | | |
| EU-EC- 10011907227 | 16/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Male | No | Fatigue (0d - Recovering/Resolving -), Nausea (0d - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | -), Vomiting (0d - Recovered/Resolved -) | | | |
| EU-EC- 10011907951 | 16/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Male | No | Fatigue (1d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Injection site pain (0d - Recovered/Resolved -) | | | |
| EU-EC- 10011907968 | | Spontaneous | Healthcare Professional | | Not available | 3-11 Years | Child | Female | No | Henoch-Schonlein purpura (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10011908458 | 16/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | [VITAMIN D] (C - n/a - n/a -) | ICSR |
| | | | | | | | | | | Menstruation irregular (n/a - Not Recovered/Not Resolved -), | | | |
| EILEC | 16/02/2022 | Cnontra | Non | Europe | Not | 2 11 | Adult | Eomal- | Ne | Polymenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIDNATY | Not reported | ICCD |
| EU-EC- 10011908701 | 10/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Adult | Female | No | Asthenia (n/a - Not Recovered/Not Resolved -), Circulatory collapse (n/a - Not Recovered/Not Resolved - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |

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| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Headache (62d - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Hypotension (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Palpitations (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Restlessness (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Sleep disorder (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Syncope (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Tachycardia (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10011908707 | 16/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | Chest pain (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - | Not reported | <u>ICSR</u> |
| | | | | | | | | | | Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition) | [n/a - n/a - n/a]) | | |
| EU-EC- 10011910288 | 16/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Chills (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |
| | | | | | | | | | | Fatigue (n/a - Unknown -), | immunisation - Not applicable - [1d - n/a - n/a]) | | |
| | | | | | | | | | | Headache (n/a - Unknown -), | | | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown -), | | | |
| EU-EC- | 16/03/2022 | Spontaneous | Healthcare | European | Not | 3-11 | Not | Male | No | Pyrexia (n/a - Unknown -) Arthralgia (9d - | COMIRNATY | Not reported | ICSR |
| 10011910295 | | · | | Economic Area | available | Years | Specified | | | Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | · | |
| | | | | | | | | | | Gait disturbance (n/a | | | |
| | | | | | | | | | | Recovered/Resolved - Caused/Prolonged Hospitalisation, Disabling), | | | |
| | | | | | | | | | | Headache (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Inflammation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Mycoplasma test positive (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Neutropenia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (7d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10011910416 | 16/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Personality change (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Restlessness (n/a - Not Recovered/Not Resolved -), | | | |

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| | | | | | | | | | Sleep disorder (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | Taste disorder (n/a - Not Recovered/Not Resolved -) | | | |
| 16/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | Not reported | ICSF |
| | | | | | | | | | Drug ineffective (n/a - Unknown - Other Medically Important Condition) | - n/a]) | | |
| 16/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSI |
| | | | | | | | | | Drug ineffective (n/a - Unknown - Other Medically Important Condition) | , . . , | | |
| 16/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Abdominal pain (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSI |
| | | | | | | | | | Not Recovered/Not Resolved -), | - Intramuscular]) | | |
| | | | | | | | | | Unknown -), Swelling (n/a - Not Recovered/Not | | | |
| 16/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Resolved -) Pruritus (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICS |
| | | | | | | | | | Pustule (n/a - Unknown -), Rash erythematous | applicable - [n/a - n/a - n/a]) | | |
| 16/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | (n/a - Unknown -) Asthenia (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), Decreased appetite (n/a - Not Recovered/Not | COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | [BENZYDAMINE HYDROCHLORIDE] (C - Pain - n/a -), [PARACETAMOL, PARACETAMOL PH. EUR.] (C - Pain, Symptomatic treatment - n/a - [n/a - n/a - n/a]) | ICSF |
| | | | | | | | | | Exercise tolerance decreased (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | Impaired quality of life (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | Loss of personal independence in daily activities (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | 1 | i contraction of the contraction | | | |
| | | | | | | | | | Neck pain (n/a - Not Recovered/Not Resolved -), | | | |
| | 16/03/2022 16/03/2022 16/03/2022 | 16/03/2022 Spontaneous 16/03/2022 Spontaneous 16/03/2022 Spontaneous | 16/03/2022 Spontaneous Healthcare Professional 16/03/2022 Spontaneous Healthcare Professional 16/03/2022 Spontaneous Non Healthcare Professional 16/03/2022 Spontaneous Non Healthcare Professional | 16/03/2022 Spontaneous Healthcare Professional European Economic Area 16/03/2022 Spontaneous Healthcare Professional European Economic Area 16/03/2022 Spontaneous Non European Economic Area 16/03/2022 Spontaneous Professional Professional Professional Professional Professional Professional Professional Professional Professional Economic Area 16/03/2022 Spontaneous Professional Professional Professional Professional Economic Area | 16/03/2022 Spontaneous Healthcare Professional European Economic Area Non European Economic Area Not European Economic Area 16/03/2022 Spontaneous Healthcare Professional Economic Area Non European Economic Area Not available 16/03/2022 Spontaneous Professional Economic Area Not available Area 16/03/2022 Spontaneous Professional | 16/03/2022 Spontaneous Healthcare Professional Professional Professional Area Non European Economic Area 3-11 Years 16/03/2022 Spontaneous Healthcare Professional Healthcare Professional Professional Professional Area Non European Roomic Area Not available Professional Area 16/03/2022 Spontaneous Professional Profes | 16/03/2022 Spontaneous Healthcare Professional European Economic Area Non European Economic Area Not available Years Specified Not available Years Specified Not available Years Specified Not European Economic Area Not European Economic Area Not European Economic Area Not Area Not Specified 16/03/2022 Spontaneous Non Healthcare Professional Economic Area Not Specified Not Specified Not Specified Not Specified Not Specified Not Area Not Specified Not Specified | 16/03/2022 Spontaneous Healthcare Professional Economic Area Not European Economic Area Not available Specified Male 16/03/2022 Spontaneous Healthcare Professional Economic Area Not European Economic Area Not available Specified Spocified Female 16/03/2022 Spontaneous Professional Area Not Healthcare Professional Economic Area Not available Specified Not Specified Male Specified 16/03/2022 Spontaneous Professional Area Not Area Not Area Not Specified Not Specified Male Specified 16/03/2022 Spontaneous Professional Area Not Area Not Area Not Specified Not Specified Male Specified 16/03/2022 Spontaneous Professional Professional Healthcare Professional Economic Area Not Specified Not Specified Not Specified Male Specified | 16/03/2022 Spontaneous Healthcare Professional European Economic Area Non European Economic Area Non Burden Professional European Economic Area Non European Economic Area Not Specified Female No Specifi | Siego disorder (n/a - Not Recovered/Not Received -) Taste disorder (n/a - Not Recovered/Not Received -) Taste disorder (n/a - Not Recovered/Not Received -) Taste disorder (n/a - Not Recovered/Not Received -) Taste disorder (n/a - Not Recovered/Not Received -) Taste disorder (n/a - Not Recovered/Not Received -) Taste disorder (n/a - Not Recovered/Not Received -) Taste disorder (n/a - Not Recovered/Not Received -) Taste disorder (n/a - Not Recovered/Not Received -) Taste disorder (n/a - Not Recovered/Not Received -) Taste disorder (n/a - Not Recovered/Not Received -) Taste disorder (n/a - Not Recovered/Not Received -) Taste disorder (n/a - Not Recovered/Not Received -) Taste disorder (n/a - Not Recovered/Not Received -) Taste disorder (n/a - Not Recovered/Not Received -) Taste (n/a - Not Recove | Info3/2022 Sportlaneous Neathcase Non Description Professional Profes | Separation Sep |

| | | | | | | | | | | Pain in extremity (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Taste disorder (n/a - Not Recovered/Not Resolved -) | | | |
|-----------------------|------------|-------------|------------|------------------------------|------------------|---------------|------------------|------|----|---|---|--------------|------|
| EU-EC- .0011912410 | 16/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- .0011912704 | 16/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | abdominal discomfort (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Abdominal distension (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Abdominal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Constipation (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovered/Not Resolved - Other Medically Important Condition), Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dyschezia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Dysuria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Faecal volume increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Faecal volume increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Flatulence (n/a - Recovered/Resolved - Other Medically Important Condition), Gastrointestinal hyportant Condition), Constructed - Other Medically Important Condition), Malaise (n/a - Recovered/Resolved - Other Medically Important Condition), Malaise (n/a - Recovered/Resolved - Other Medically Important Condition), Malaise (n/a - Recovered/Resolved - Other Medically Important Condition), Malaise (n/a - Recovered/Resolved - Other Medically Important Condition), | CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |

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| | | | | | | | | | | - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10011912743 | 16/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Rash (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011913080 | 16/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011914210 | 16/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Condition) Dizziness postural (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011914548 | 16/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Syncope (0d - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Dose not changed - [n/a - 1{DF} - n/a]), | Not reported | ICSR |
| | | | | | | | | | | Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | | |
| EU-EC- 10011887246 | 15/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Herpes zoster (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a3mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011887412 | 15/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Infusion site erythema (2d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | <u>ICSR</u> |
| EU-EC- 10011887415 | 15/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Administration site swelling (3d - Recovered/Resolved -), Injection site erythema (3d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011887417 | 15/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Arthralgia (10d - Recovered/Resolved - Other Medically Important Condition), Diarrhoea (10d - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Hyperpyrexia (10d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Myalgia (10d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | 15/00/0000 | | | | | | | | | Vomiting (10d - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10011887507 | 15/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Chest pain (2d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (2d - Recovered/Resolved - Other Medically | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Important Condition), Tachycardia (2d - Recovered/Resolved | | | |

| | | | | | | | | | | - Other Medically | | | |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|------------------|---------------|------------------|--------|----|--|--|---|------|
| EU-EC- 10011887513 | 15/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Important Condition) Headache (n/a - Recovering/Resolving -) | COVID-19 immunisation - n/a - [n/a2mL - | Not reported | ICS |
| EU-EC- 10011887521 | 15/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Hyperpyrexia (n/a - Recovering/Resolving - Other Medically | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | ICS |
| | | | | | | | | | | Important Condition), Pharyngitis (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10011887706 | 15/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Aphasia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Asthenia (n/a - Recovered/Resolved - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - n/a]) | [SOMATROPIN] (C - Short stature - n/a - [n/a8mg - Subcutaneous]) | ICS |
| | | | | | | | | | | Hospitalisation), Facial asymmetry (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Hypoaesthesia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Ischaemic stroke (n/a - Recovered/Resolved | | | |
| EU-EC- 10011889490 | 15/03/2022 | Spontaneous | Non Healthcare Professional | European Economic | Not available | 3-11 Years | Child | Male | No | - Caused/Prolonged Hospitalisation) Diarrhoea (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - | Not reported | ICS |
| | | | Professional | Area | | | | | | Resolved -), Haematochezia (n/a - Not Recovered/Not Resolved -) | n/a - n/a - [n/a - n/a - n/a]) | | |
| EU-EC- 10011889496 | 15/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Male | No | Lymph node pain (4d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported | ICS |
| EU-EC- 10011889498 | 15/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Application site pain (n/a - Unknown -), Headache (n/a - Unknown -), Pyrexia (n/a - | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Recovered/Resolved | | | |
| EU-EC- 10011889661 | 15/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Headache (2d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSI |
| EU-EC- 10011890298 | 15/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Type 1 diabetes mellitus (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10011890696 | 15/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Vomiting (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10011890834 | 15/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Injection site pain (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10011891881 | 15/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Pyrexia (0d - Recovering/Resolving -), Vomiting (0d - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10011891898 | 15/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Fatigue (0d - Recovered/Resolved -), Injection site pain | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | (1d - Recovered/Resolved -), | | | |

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| | | | | | | | | | | Pyrexia (0d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved | | | |
| EU-EC- 10011893087 | 15/03/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | -) COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | Not reported | ICSR |
| | | | | | | | | | | Drug ineffective (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | - n/a]) | | |
| | | | | | | | | | | Infection (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10011893701 | 15/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Adolescent | Female | No | Purpura (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10011894265 | 15/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Headache (n/a - Unknown -), Pain (n/a - Unknown -), Vaccination site | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | erythema (n/a - Unknown -) | | | |
| EU-EC- 10011894564 | 15/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Male | No | Rash (2d - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | <u>ICSR</u> |
| EU-EC- 10011894582 | 15/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Nausea (0d - Recovered/Resolved -), Vomiting (0d - | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Recovered/Resolved | | | |
| EU-EC- 10011895416 | 15/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Female | No | Injection site pain (3d - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011895487 | 15/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Abdominal pain (2d - Recovered/Resolved -), Chills (0d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved | | | |
| EU-EC- 10011895491 | 15/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Abdominal pain (37d - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - | Not reported | ICSR |
| | | | | | | | | | | -), Disturbance in attention (37d - Recovering/Resolving -), | [n/a - n/a - n/a]) | | |
| | | | | | | | | | | Fatigue (37d - Recovering/Resolving -), | | | |
| | | | | | | | | | | Nausea (37d - Recovering/Resolving -) | | | |
| EU-EC- 10011895499 | 15/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Male | No | Injection site pain (2d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011895527 | 15/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Fatigue (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011895532 | 15/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Injection site pain (2d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Pain in extremity (0d | | | |

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| | | | | | | | | | | - Recovered/Resolved | | | |
| EU-EC- 10011896070 | 15/03/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Drug ineffective (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10011896097 | 15/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Overdose (n/a - Unknown -), Product preparation error (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10011896099 | 15/03/2022 | Spontaneous | Non Healthcare Professional | Non European Economic | Not available | 3-11 Years | Not Specified | Male | No | Cough (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |
| | | | | Area | | | | | | Dyspnoea (n/a - Unknown - Other Medically Important Condition), | immunisation - Not applicable - [1d - n/a - n/a]) | | |
| | | | | | | | | | | Eye pruritus (n/a - Unknown -), | | | |
| | | | | | | | | | | Nasal pruritus (n/a - Unknown -), | | | |
| EU-EC- | 15/03/2022 | Spontaneous | Non | European | Not | 3-11 | Not | Female | No | Ocular hyperaemia (n/a - Unknown -) Headache (n/a - | COMIRNATY | Not reported | ICSR |
| 10011897529 | 10/03/2022 | Sportaineous | Healthcare Professional | Economic | available | Years | Specified | , emais | | Unknown -), Pyrexia (n/a - Unknown -), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Tion reported | 2001 |
| | | | | | | | | | | Vaccination site pain (n/a - Unknown -) | - n/a]) | | |
| EU-EC- 10011875145 | 14/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Anaphylactoid reaction (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011875660 | 14/03/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Drug ineffective (n/a - Unknown - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]) | ICSR |
| | | | | | | | | | | Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition) | - n/a]) | | |
| EU-EC- 10011876249 | 14/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Injection site pain (0d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Rash (1d - Recovered/Resolved -) | | | |
| EU-EC- 10011876263 | 14/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Injection site pain (2d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011876321 | 14/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Injection site pain (1d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011877008 | 14/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Anaphylactic reaction (0d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) | [MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma - n/a - [n/a - n/a - n/a]) | ICSR |
| EU-EC- 10011877415 | 14/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Rash (30min - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Not reported | ICSR |
| EU-EC- 10011877519 | 14/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Anaphylactoid reaction (n/a - Recovering/Resolving - Other Medically Important Condition) | - Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011878085 | 14/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Injection site pain (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011878118 | 14/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Injection site erythema (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |

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|-----------------------|------------|-------------|-----------------------------------|------------------------------|------------------|---------------|------------------|------------|----------|---|---|--------------|--------------|
| EU-EC- 10011878140 | 14/03/2022 | Spontaneous | Non Healthcare Professional | Economic | Not available | 3-11 Years | Child | Male | No | Headache (0d - Recovered/Resolved -), Injection site pain (3d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011878153 | 14/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Headache (Od - Not Recovered/Not Resolved -), Injection site pain (2d - Not Recovered/Not Resolved -), Pyrexia (Od - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011878610 | 14/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Resolved -) Plantar fasciitis (48h - Recovered/Resolved -) | COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a] | Not reported | ICSF |
| EU-EC- 10011879064 | 14/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Abdominal pain (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Vomiting (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSF |
| EU-EC- 10011879966 | 14/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Chills (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSF |
| EU-EC- 10011880622 | 14/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Abdominal lymphadenopathy (14d - Recovered/Resolved -), Abdominal pain (14d - Recovered/Resolved -), Diarrhoea (10d - Recovered/Resolved -), Diarrhoea (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 10ug - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011880871 | 14/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Erythema (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011881669 | 14/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Erythema (n/a - Unknown -), Headache (n/a - Unknown -), Pain (n/a - Unknown -), Vaccination site swelling (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| 10011882019 | | Spontaneous | Healthcare Professional | Area | Not available | 3-11 Years | Not Specified | Male | No | Arthralgia (n/a - Unknown -), Asthenia (n/a - Unknown -), Gait disturbance (n/a | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR 35/5 |

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| Public P | | | | - Unknown -), | | | | | | | | | | |
| EB-EC 14/03/2022 Spontaneous Peatlineare No | | | | | | | | | | | | | | |
| EB EEC 14/83/2022 Spontamental New Yorks and Phythosome Spontamental New Yorks Spontam | | | | | | | | | | | | | | |
| REFC 1403/2022 Sportamenus Realthcare Removement | | | | | | | | | | | | | | |
| | | | | Unknown - Other Medically Important | | | | | | | | | | |
| | | | | | | | | | | | | | | |
| EU-EC 14/03/2022 Spontaneous Montroller Resilhicate Resilhic | ICSF | Not reported | [TOZINAMERAN] (S - COVID-19 immunisation - Not | Rash (n/a - Recovering/Resolving - Other Medically | No | Female | | | | European Economic | | Spontaneous | 14/03/2022 | |
| | ICSF | Not reported | - Intramuscular]) | Diplopia (p/a | No | Mala | Child | 2 11 | Not | Furancan | Non | Cnontanagus | 14/02/2022 | EU EC |
| BU-EC- 14/03/2022 Sportaneous Healthcare Consomination Continues | ICSF | Not reported | [TOZINAMERAN] (S - Immunisation - n/a - | Recovered/Resolved - Caused/Prolonged Hospitalisation), | INO | Male | Crilla | | | Economic | Healthcare | Spontaneous | 14/03/2022 | |
| EU-EC- 1011883761 14/03/2022 Spontaneous Healthcare Non | | | | Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | | | | | | | | |
| Professional European Professional European Professional European Professional Economic Prof | | | | Recovered/Resolved - Caused/Prolonged | | | | | | | | | | |
| EU-EC- 10011883944 14/03/2022 Spontaneous Healthcare Non Professional European Professional European Professional Secondinic | ICSF | Not reported | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Recovered/Resolved - Other Medically Important | No | Male | | | | European Economic | | Spontaneous | 14/03/2022 | |
| EU-EC- 10011886033 14/03/2022 Spontaneous Healthcare Commic European Economic Professional More Mor | | | - Indamuscular J) | | | | | | | | | | | |
| EU-EC- 14/03/2022 Spontaneous Healthcare Professional European European Not Professional European Not European Not Professional European Not European Not Professional Not Professional Professional Professional Not Professional Professional Not Professional | ICSF | Not reported | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Syncope (n/a - Recovered/Resolved - Other Medically | No | Male | | | | European Economic | | Spontaneous | 14/03/2022 | |
| EU-EC- 14/03/2022 Spontaneous Non Healthcare Professional Non Healthcare Professional Area Not Specified Specifi | ICSF | Not reported | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | reaction (n/a - Recovered/Resolved - Other Medically | No | Female | | | | European Economic | | Spontaneous | 14/03/2022 | |
| EU-EC- 10011886033 | | HYDROGEN FUMARATE] (C - Grunting - n/a - [n/a | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Recovered/Resolved -), Vaccination site pain (0d - Recovered/Resolved | No | Female | | | | Economic | Healthcare | Spontaneous | 14/03/2022 | |
| Professional Professional Professional Professional Professional Professional EU-EC- 10011886044 Professional | ICSF | Not reported | | Axillary pain (n/a - | No | Male | Child | | | | | Spontaneous | 14/03/2022 | |
| EU-EC- 10011886044 14/03/2022 Spontaneous Healthcare Professional European Recovering/Resolving Informunisation - Not applicable - [Id - n/a - n/a]) EU-EC- 10011886837 EU-EC- 10011886837 EU-EC- 10011886837 EU-EC- 10011886837 EU-EC- 10011886837 EU-EC- 10011886837 EU-EC- 10011874540 EU-EC- 10011874 | | | COVID-19 immunisation - Not applicable - [1d - | Vaccination site lymphadenopathy | | | | Years | avallable | | | | | 10011886033 |
| EU-EC- 10011886093 14/03/2022 Spontaneous Healthcare Professional European Area Not available Area Not reported (1d - Fatal - Results in Death) Not applicable - [1d - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 in munisation - Not applicable - [1d - n/a - n/a]) Not reported (14/03/2022 Spontaneous Area Not reported (14/03/2022 Spontaneous Area) Not reported (14/03/2022 Spontaneous Area Not reported (14/03/2022 Spontaneous Area) | ICSF | Not reported | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a | Vaccination site lymphadenopathy (n/a - Recovering/Resolving | No | Female | Child | | | Economic | | Spontaneous | 14/03/2022 | |
| EU-EC- 10011886837 14/03/2022 Spontaneous Non Healthcare Professional Healthcare Professional Healthcare Professional Healthcare Professional Healthcare Professional Healthcare Professional Spontaneous Healthcare Professional Healthcare Professional Spontaneous Healthcare Professional Healthcare Professional Spontaneous Spont | ICSF | Not reported | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | arrest (1d - Fatal - | No | Male | Child | | | Economic | | Spontaneous | 14/03/2022 | |
| EU-EC- 13/03/2022 Spontaneous Healthcare Professional Care Professional Real Real Real Real Real Real Real Re | ICSF | Not reported | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Unknown -), Vaccination site mass | No | Female | Child | | | Economic | Healthcare | Spontaneous | 14/03/2022 | |
| 10011874540 Professional Economic Area Professional Economic Area Professional Area Recovered/Resolved TOZINAMERAN] (S - COVID-19 | ICSF | Not reported | 1{DF} - n/a]) | , | No | Female | Child | 3-11 | Not | Furonean | Healthcare | Spontaneous | 13/03/2022 | FU-FC- |
| immunisation - Drug withdrawn - [n/a - n/a - n/a] | 1031 | st reported | [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - | Recovered/Resolved | | Tande | J. mu | | | Economic | | Sportanicous | -5, 05, 2022 | |
| EU-EC- 13/03/2022 Spontaneous Healthcare Professional Economic Area Spontaneous Healthcare Profe | ICSF | Not reported | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - | (n/a - Recovering/Resolving | No | Male | Child | | | Economic | | Spontaneous | 13/03/2022 | |
| EU-EC- 13/03/2022 Spontaneous Healthcare Professional Economic available Years | ICSF | Not reported | COMIRNATY | | No | Male | Child | | | | | Spontaneous | 13/03/2022 | |

|).11.2022 0 | | | | Area | | | | | | Recovered/Not Resolved -) | COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|---------------|------------------|--------|----|---|---|---|------|
| EU-EC- 10011868635 | 12/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Urticaria (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011870890 | 12/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Hepatitis viral (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), [BECLOMETASONE] (C - n/a - n/a - [n/a - n/a - n/a]) | ICSF |
| EU-EC- 10011873353 | 12/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Headache (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011854520 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Pain in extremity (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011854521 | 11/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Fatigue (3d - Recovered/Resolved -), Headache (3d - Recovered/Resolved -), Pain in extremity (3d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{OF} - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011854522 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Headache (3d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011854523 | 11/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Pain in extremity (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011854524 | 11/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Pain in extremity (3d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011854525 | 11/03/2022 | Spontaneous | Healthcare Professional | | Not available | 3-11 Years | Not Specified | Male | No | Pain in extremity (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011854526 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Pain in extremity (4d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011854527 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Pain in extremity (2d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011854528 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Headache (6d - Recovered/Resolved -), Pain in extremity (6d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011854918 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Haematuria (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011855058 | 11/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Fatigue (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSF |

| | | | | | | | | | | Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|---------------|------------------|--------|----|---|--|--|------|
| EU-EC- 10011855071 | 11/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSF |
| | | | | | | | | | | - Other Medically Important Condition) | | | |
| EU-EC- 10011856449 | 11/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Pruritus (0d - Recovered/Resolved - Disabling), Rash macular (0d - Recovered/Resolved - Disabling), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | [SOMATROPIN] (C - n/a - Unknown - [n/a - n/a - n/a]) | ICSF |
| | | | | | | | | | | Skin disorder (0d - Recovered/Resolved - Disabling), | | | |
| | | | | | | | | | | Urticaria (0d - Recovered/Resolved - Disabling) | | | |
| EU-EC- 10011856869 | 11/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Rash (0d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011857080 | 11/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Hypoaesthesia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011857130 | 11/03/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011858322 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Condition) Abdominal pain (3wk - Recovered/Resolved -), Lymphadenopathy (3wk - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011859121 | 11/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | | 3-11 Years | Child | Male | No | -) Malaise (3d - Recovered/Resolved -), Vomiting (0d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011860759 | 11/03/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | 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 | ICSR |
| EU-EC- 10011861892 | 11/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Important Condition) Fatigue (5d - Unknown - Disabling), Headache (5d - Unknown - Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011862086 | 11/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Headache (n/a - Recovered/Resolved -), Pain in extremity (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011862375 | 11/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | -) Syncope (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011862988 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Medication error (n/a - Unknown -), Off label use (n/a - Unknown -) | | Not reported | ICSR |

| | | | | | | | | | | | 1{DF} - | | |
|-----------------------|------------|-------------|----------------------------|------------------------------|------------------|---------------|------------------|--------|----|---|--|--|------|
| EU-EC- 10011862989 | 11/03/2022 | Spontaneous | | European Economic | Not available | 3-11 Years | Child | Male | No | Medication error (n/a - Unknown -), | [TOZINAMERAN] (S - | Not reported | ICSF |
| | | | | Area | | | | | | Off label use (n/a - Unknown -) | COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]) | | |
| EU-EC- 10011862990 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Medication error (n/a - Unknown -), Off label use (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - | Not reported | ICSF |
| EU-EC- 10011862991 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Medication error (n/a - Unknown -), Off label use (n/a - Unknown -) | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011862992 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Medication error (n/a - Unknown -), Off label use (n/a - Unknown -) | | Not reported | ICSF |
| EU-EC- 10011862993 | 11/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Male | No | Medication error (n/a - Unknown -), Off label use (n/a - Unknown -) | | Not reported | ICSF |
| EU-EC- 10011865751 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 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 - [1d - n/a - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011865903 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Headache (0d - Recovered/Resolved -), Lymphadenopathy (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | [FLUTICASONE PROPIONATE] (C - Respiratory disorder - Not applicable - [n/a - n/a - Other]), [IBUPROFEN] (C - Product used for unknown indication - Not applicable - [n/a - n/a - Oral]), [PREDNICARBATE] (C - Dermatitis atopic - Not applicable - [n/a - n/a - Topical]), [PREDNISOLONE] (C - Product used for unknown indication - Not applicable - [n/a - n/a - Oral]), [SALBUTAMOL] (C - Product used for unknown indication - Not applicable - [n/a - n/a - Other]) | ICSF |
| EU-EC- 10011865907 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Seizure (1d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011865910 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Anaphylactic reaction (1d - (1d - Recovered/Resolved - Other Medically Important Condition), Cough (1d - Recovered/Resolved - Other Medically Important Condition), Rash macular (1d - Recovered/Resolved - Other Medically Important Condition), Throat irritation (1d - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .3mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- | 11/03/2022 | Spontaneous | Healthcare | European | Not | 3-11 | Child | Female | No | Recovered/Resolved - Other Medically Important Condition) Lymphadenopathy | COMIRNATY | Not reported | ICSF |

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| 10011866098 | | | Professional | Economic Area | available | Years | | | | (n/a - Not Recovered/Not Resolved -) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | | |
| EU-EC- 10011866192 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Lymphadenopathy (10d - Recovered/Resolved -), Vaccination site | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not reported | ICSR |
| | | | | | | | | | | inflammation (4d - Recovered/Resolved -) | | | |
| EU-EC- 10011866352 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Hyperaesthesia (4d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011866357 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011866388 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Gianotti-Crosti syndrome (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011866418 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Lymphadenopathy (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011866426 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Vaccination site lymphadenopathy (4d - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011866651 | 11/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Vaccination site injury (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown]) | Not reported | ICSR |
| EU-EC- 10011840629 | 10/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Multisystem inflammatory syndrome in children (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Oropharyngeal pain (n/a - Recovering/Resolving Resolving Resolving Resolving Resolving Inflammation Inflammatical I | COMIRNATY [TOZINAMERAN] (5 - Immunisation - n/a - [n/a - 2{DF} - n/a]) | Not reported | ICSR |
| | | | | | | | | | | - Caused/Prolonged Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10011840834 | 10/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Vaccination site pain (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011840838 | 10/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Hunger (1d - Recovered/Resolved -), Vaccination site pain (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011840841 | 10/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Lymphadenopathy (4d - Recovered/Resolved -), Vaccination site pain (4d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | RISDIPLAM [RISDIPLAM] (C - n/a - n/a - [n/a - n/a - n/a]) | ICSR |
| | | | | | | | | | | Vaccination site swelling (4d - Recovered/Resolved | | | |
| EU-EC- 10011840855 | 10/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Vaccination site pain (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011840860 | 10/03/2022 | Spontaneous | Healthcare Professional | European Economic | Not available | 3-11 Years | Not Specified | Male | No | Vaccination site pain (2d - | COMIRNATY [TOZINAMERAN] (S - | Not reported | ICSR |

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| | | | | | Area | | | | | | | immunisation - n/a - [n/a2mL - | | |
| EU-SC 10/11/2002 Spiratenesis Intelligence Recognitive Processor | | 10/03/2022 | Spontaneous | | Economic | | | | Male | No | Recovered/Resolved -), Myalgia (3d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - | Not reported | ICSR |
| | | | | | | | | | | | (3d - Recovered/Resolved | | | |
| ELEC. 10/03/2022 Sportlaneaus Pealthcare Discovered Peals of Sportlaneaus Pealthcare Discovered Peals of Sportlaneaus Peals of Sport | | 10/03/2022 | Spontaneous | | Economic | | | | Male | No | Recovered/Resolved | [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - | Not reported | ICSR |
| ELEC. 10/03/2022 Sportaneous healthcare European Not Professional European Not Professional European Not Not Professional European Not Professional European Not Not Professional European Not Professional Professional European Not Professional European Not Professional Professional Professional European Not Professional Professional Professional European Not Professional Professional Professional Professional European Not Professional Professional Professional European Not Professional Professio | | | | | | | | | | | hyperaemia (n/a - Recovered/Resolved -), | 27 | | |
| Turn | | | | | | | | | | | Recovered/Resolved -), | | | |
| 10/03/2022 Sportlaneous Healthcare European Not 2-11 Not Pemale No Sportlaneous Healthcare European Not Professional Scoromic Area Not Professional Sportlaneous Healthcare European Not Professional Scoromic Area Not Professional Sportlaneous Healthcare Professional Scoromic Area Not Professional Sportlaneous Healthcare Not Professional Scoromic Area Not Professional Scoromic Not Professional Not Pr | | | | | | | | | | | -), Headache (n/a - | | | |
| | | | | | | | | | | | -) | | | |
| EU-EC- 10/03/2022 Sportaneous Healthcare Common Professional European More European More Professional European More Professional European More Europ | | 10/03/2022 | Spontaneous | | Economic | | | | Female | No | Recovered/Resolved | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .2mL - | Not reported | <u>ICSR</u> |
| Eu-EC- 10/03/2022 Spontaneous Non European Not Not Recovered/Not Recovered/N | | 10/03/2022 | Spontaneous | | | | | | Female | No | | COMIRNATY | Not reported | ICSR |
| EU-EC- 10/03/2022 Spontaneous Healthcare Non Professional European Not Recovered/Not Resolved -), Palato (v/a - Not Recovered/Not Resolved -), Palato (v/a | 10011841644 | | | Professional | Economic | available | Years | Specified | | | -), Dyspnoea (n/a - Recovered/Resolved | COVID-19 immunisation - Not applicable - [1d - n/a | | |
| ELI-EC- 10011841695 EU-EC- 10011841896 EU-EC- 10011841895 EU-EC | | | | | | | | | | | Nausea (n/a - Recovered/Resolved | | | |
| EU-EC- 10/13/2022 Spontaneous Healthcare Non Professional European European European European European Not Professional European | | | | | | | | | | | Pallor (n/a - Recovered/Resolved | | | |
| Professional European Candition Professional European In 1011841846 Professional European In 1011841846 Professional European In 1011841849 Professional European In | | | | | | | | | | | Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10/03/2022 Spontaneous Healthcare Professional European EU-EC- 100118418459 10/03/2022 Spontaneous Healthcare Professional European | | 10/03/2022 | Spontaneous | | European Economic | | | | Female | No | (n/a - Not Recovered/Not | [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| EU-EC- 10011841859 Diagram Dia | | | | | | | | | | | Recovered/Not Resolved -), | | | |
| EU-EC- 10011841859 10/03/2022 Spontaneous Healthcare 10011841859 10/03/2022 Spontaneous Healthcare 10011841849 10/03/2022 Spontaneous Healthcare 10011841849 10/03/2022 Spontaneous Healthcare 10011841849 10/03/2022 Spontaneous Healthcare 10011841859 Healthcare 10011841859 10/03/2022 Spontaneous Healthcare 10011841859 Healthcare 1001184184044 H | | | | | | | | | | | (n/a - Not Recovered/Not | | | |
| EU-EC- 10011841846 Divide a label l | | | | | | | | | | | Recovered/Not Resolved -), | | | |
| Healthcare Professional Not reported Professional Prof | | | | | | | | | | | Recovered/Not Resolved - Other Medically Important | | | |
| EU-EC- 10/03/2022 Spontaneous Healthcare Professional European Economic Area EU-EC- 10/03/2022 Spontaneous Healthcare Professional European Economic Area Non Not available Specified Sp | | 10/03/2022 | Spontaneous | Healthcare | Economic | | | | Male | No | Unknown - Other Medically Important | [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| 10011841859 Professional European Economic Area Professional European European European Indicate Professional European European Indicate Professional European Indicate Professional European Indicate Professional European Indicate Professional Indicate Professi | | | | | | | | | | | - Unknown - Other Medically Important Condition) | - n/a]) | | |
| EU-EC- 10/03/2022 Spontaneous Healthcare Professional Economic Healthcare Professional Economic Healthcare Professional Economic Healthcare Professional Economic Healthcare Professional Healthcare Professional Economic Healthcare Professional Hea | | 10/03/2022 | Spontaneous | | European Economic | | | | Male | No | clonic seizure (n/a - Recovered/Resolved - Other Medically | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | Not reported | ICSR |
| 10011843044 Professional Economic available Years Specified Recovered/Resolved [TOZINAMERAN] (S - | EU-EC- | 10/03/2022 | Spontaneous | Healthcare | European | Not | 3-11 | Not | Male | No | | COMIRNATY | Not reported | ICSR |
| Area - Life Threatening), COVID-19 | 10011843044 | | | | | available | Years | Specified | | | | [TOZINAMERAN] (S - COVID-19 | | |

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| EU-EC- 10011843203 | 10/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Chest pain (30min - Recovered/Resolved - Other Medically Important Condition), Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), Myocarditis (n/a - Recovered/Resolved - Other Medically Important Condition), Palpitations (30min - Recovered/Resolved - Life Threatening), Palpitations (30min - Recovered/Resolved - Other Medically Important Condition), Troponin increased (n/a - Recovered/Resolved - Uffer Threatening) Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Myopericarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Unknown - Caused/Prolonged Hospitalisation), Pericardial effusion (n/a - Unknown - Other Medically Important Condition), Troponin increased (n/a - Unknown - Other Medically Important Condition), | immunisation - n/a - [n/a - n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011843258 | 10/03/2022 | Spontaneous | Healthcare Professional | | Not available | 3-11 Years | Not Specified | Male | No | Important Condition) Pericarditis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011844560 | 10/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Erythema (n/a - Not Recovered/Not Resolved -), Pruritus (n/a - Not Recovered/Not Resolved -), Swelling (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011844717 | 10/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Palpitations (n/a - Not Recovered/Not Resolved - Life Threatening, Other Medically Important Condition) | COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a] | Not reported | ICSR |
| EU-EC- 10011844779 | 10/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Male | No | Injection site pain (2d - Recovered/Resolved -), Vomiting (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011846528 | 10/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Application site pain (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10011846595 | 10/03/2022 | Spontaneous | Healthcare Professional | Non European | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Unknown - Disabling, Other Medically | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |

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| | | | | Economic Area | | | | | | Important Condition), Drug ineffective (n/a - Unknown - Disabling, Other | immunisation - Not applicable - [n/a - n/a - n/a]) | | |
| | | | | | | | | | | Medically Important Condition) | | | |
| EU-EC- 10011847383 | 10/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Injection site pain (2d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011848922 | 10/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Fatigue (1d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved | [n/a - n/a - n/a]) ComirnATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011849368 | 10/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | -) Lethargy (n/a - Recovered/Resolved -), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011849782 | 10/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Male | No | Urticaria (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - 1{DF} - n/a]) | [PHLEUM PRATENSE, PHLEUM PRATENSE (225), PHLEUM PRATENSE POLLEN EXTRACT, TIMOTHY GRASS POLLEN EXTRACT] (C - n/a - n/a -) | ICSR |
| EU-EC- 10011852012 | 10/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Local reaction (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10011852307 | 10/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Angioedema (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10011852835 | 10/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Eye pain (3d - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown]) | Not reported | ICSR |
| EU-EC- 10011852845 | 10/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Headache (0d - Recovered/Resolved -), Pyrexia (0d - Recovered/Resolved -), Vaccination site lymphadenopathy (n/a - Recovering/Resolving -) | COVID-19 immunisation - Not | [IBUPROFEN] (C - Product used for unknown indication - Not applicable - [n/a - n/a - Oral]), [MOMETASONE FUROATE] (C - Product used for unknown indication - Not applicable - [n/a - n/a - Nasal]), [PARACETAMOL] (C - Product used for unknown indication - Not applicable - [n/a - n/a - Oral]), [PREDNISOLONE] (C - Product used for unknown indication - Not applicable - [n/a - n/a - Oral]), | ICSR |
| EU-EC- 10011852846 | 10/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Headache (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Petechiae (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | n/a - Oral]) Not reported | ICSR |
| EU-EC- 10011852939 | 10/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Vaccination site lymphadenopathy (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011852941 | 10/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | Erythema (2d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011852948 | 10/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Hypersensitivity (3d - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a]) | Not reported | ICSR |

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| 10/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Dizziness (0d - Recovered/Resolved -), Headache (0d - Recovered/Resolved -), Vaccination site pain (0d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [0d - n/a - n/a]) | Not reported | ICSR |
| 10/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | Vaccination site lymphadenopathy (9d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) | Not reported | ICSR |
| 10/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Seizure (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Not reported | ICSR |
| 10/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Cellulitis (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a | Not reported | ICSR |
| 09/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Pain in extremity (3d Recovered/Resolved) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| 09/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Pain in extremity (2d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| 09/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Pain in extremity (7d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| 09/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Pain in extremity (4d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - | Not reported | ICSR |
| 09/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Pain in extremity (3d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| 09/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Ecchymosis (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Petechiae (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Thrombocytopenia (4d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| 09/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Apnoea (n/a - Fatal - Results in Death, Other Medically Important Condition), Epilepsy (n/a - Fatal - Results in Death, Other Medically Important Condition), Product administered to patient of inappropriate age (n/a - Fatal - Results in Death), Renal impairment (n/a - Fatal - Results in Death), Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | 10/03/2022 10/03/2022 10/03/2022 09/03/2022 09/03/2022 09/03/2022 09/03/2022 | 10/03/2022 Spontaneous 10/03/2022 Spontaneous 10/03/2022 Spontaneous 10/03/2022 Spontaneous 09/03/2022 Spontaneous | 10/03/2022SpontaneousHealthcare Professional10/03/2022SpontaneousHealthcare Professional10/03/2022SpontaneousHealthcare Professional10/03/2022SpontaneousHealthcare Professional09/03/2022SpontaneousHealthcare Professional09/03/2022SpontaneousHealthcare Professional09/03/2022SpontaneousHealthcare Professional09/03/2022SpontaneousHealthcare Professional09/03/2022SpontaneousHealthcare Professional09/03/2022SpontaneousHealthcare Professional09/03/2022SpontaneousHealthcare Professional09/03/2022SpontaneousHealthcare Professional | 10/03/2022SpontaneousHealthcare Professional ProfessionalEuropean Economic Area10/03/2022SpontaneousHealthcare ProfessionalEuropean Economic Area10/03/2022SpontaneousHealthcare ProfessionalNon European Economic Area10/03/2022SpontaneousHealthcare European Economic Area09/03/2022SpontaneousHealthcare ProfessionalEuropean Economic Area | 10/03/2022SpontaneousHealthcare ProfessionalEuropean Economic AreaNot European European Professional10/03/2022SpontaneousHealthcare ProfessionalNon European Economic Area10/03/2022SpontaneousHealthcare ProfessionalNon European Economic Area10/03/2022SpontaneousHealthcare ProfessionalEuropean Economic Area09/03/2022SpontaneousHealthcare Economic AreaNot Economic Area09/03/2022SpontaneousHealthcare Economic AreaNot Economic Area09/03/2022SpontaneousHealthcare Economic AreaNot Economic Area09/03/2022SpontaneousHealthcare Economic AreaNot available Area09/03/2022SpontaneousHealthcare Economic AreaNot available Area | 10/03/2022 Spontaneous Professional Economic Area European Economic Economic Area Not available Sensional Economic Area 3-11 Professional Economic Area 10/03/2022 Spontaneous Professional Economic Area Non European Economic Area Not Burden available Sensional European Economic Area Not Burden available Sensional European Economic Area 10/03/2022 Spontaneous Healthcare Professional Professional Economic Area European Not European Professional Economic Area Not Area 09/03/2022 Spontaneous Healthcare Professional Professional Area European Not Area Not Area 09/03/2022 Spontaneous Healthcare Professional Area European Available Area Not Area 09/03/2022 Spontaneous Healthcare Professional Area European Available Area Not Area 09/03/2022 Spontaneous Healthcare Professional Economic Area European Available Area Not Area 09/03/2022 Spontaneous Healthcare Professional Economic Area European Available Area Not Area 09/03/2022 Spontaneous Healthcare Professional Economic Area European Available Area Not Area 09/03/2022 Spontaneous Healthcare Professional Economic Area European Available Area Not Area 09/03/2022 Spontaneous Healthcare Professional Economic Area < | 10/03/2022 Spontaneous Healthcare Professional Area Specified Specifie | 10/03/2022 Spontaneous Healthcare Professional Professional European Rotation Specified Professional Professional Reconomic Rotation Specified Re | 10/03/2022 Spontaneous Healthcare European Area Not Specified Female Not Specified Female Not Specified Female Not Specified Speci | Formation Healthcare European Not Professional Economic Area Not Professional Economic Not Professional Professional Professional Professional Professional Economic Not Professional Professio | 10/93/2022 Spontamenau Resiltone European Not Professional Professional Resiltone Recognition step plan Recognition (1998) 11/93/2022 Spontamenau Resiltone Recognition Recognition Recognition (1998) 11/93/2022 Spontamenau Resiltone Recognition Recognition Recognition (1998) 11/93/2022 Spontamenau Resiltone Recognition Recognitio | Septiment Sept |

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| | | | | | | | | | | Death), Varicella zoster virus infection (n/a - Fatal | | | |
| EU-EC- 10011832351 | 09/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | - Results in Death) Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011834302 | 09/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Purpura (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011834849 | 09/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011834884 | 09/03/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Vaginal haemorrhage (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011834887 | 09/03/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Vaccination failure (n/a - Recovering/Resolving - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011836148 | 09/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Paraesthesia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (0d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10011836314 | 09/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011836722 | 09/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Male | No | Rash pruritic (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011836801 | 09/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Lymphadenopathy (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011837018 | 09/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Male | No | Vertigo (n/a - Recovering/Resolving -), Vomiting (n/a - Recovered/Resolved -) | COMIRNATY | Not reported | ICSR |
| EU-EC- 10011838857 | 09/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Pyrexia (n/a - Unknown -), Pyrexia (n/a - Unknown -), Superior sagittal sinus thrombosis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011839251 | 09/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Petit mal epilepsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Urinary incontinence (n/a - Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- | 09/03/2022 | Spontaneous | Healthcare | Non | Not | 3-11 | Not | Male | No | Recovered/Not Resolved -) Blood blister (n/a - | COMIRNATY | Not reported | ICSR |

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|-----------------------|------------|-------------|-----------------------------------|------------------------------|------------------|---------------|-----------|------------|-------|---|--|--------------|-------------|
| 10011839521 | | | Professional | European Economic Area | available | Years | Specified | | | Recovered/Resolved -), COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), Pain in extremity (n/a - Recovered/Resolved -), Rash pruritic (n/a - Recovered/Resolved -), Skin discolouration (n/a - Recovered/Resolved | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | | |
| EU-EC- 10011839674 | 09/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | -) Vaccination site inflammation (4d - Recovered/Resolved -), Vaccination site lymphadenopathy (4d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011839689 | 09/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Male | No | Vaccination site inflammation (4d - Recovered/Resolved -), Vaccination site lymphadenopathy (4d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011840234 | 09/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | Seizure (3min - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 10ug - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011840451 | 09/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Vomiting (1d - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011840453 | 09/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Female | No | Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011840589 | 09/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Male | No | Chest pain (5d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | <u>ICSR</u> |
| EU-EC- 10011840590 | | Spontaneous | Healthcare Professional | | Not available | 3-11 Years | Child | Female | No | Headache (30d - Recovered/Resolved -), Influenza like illness (30d - Recovered/Resolved -), Pyrexia (30d - Recovered/Resolved -), Tachycardia (30d - Recovered/Resolved -), Vomiting (30d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011840591 | 09/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Male | No | Diarrhoea (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -), Vomiting (2d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |

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| EU-EC- 10011815721 | 08/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Chills (n/a - Recovering/Resolving - Other Medically Important Condition), Hyperpyrexia (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011815895 | 08/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Axillary pain (23d - Recovered/Resolved -), Lymphadenopathy (23d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011818269 | 08/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Bell's palsy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | [CETIRIZINE, CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]) | ICSR |
| EU-EC- 10011818400 | 08/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Breast inflammation (n/a - Unknown -), Breast mass (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| EU-EC- 10011819208 | 08/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Pyrexia (3d - Recovered/Resolved -), Streptococcal bacteraemia (10d - Recovered/Resolved -), Streptococcal infection (10d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011820133 | 08/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Application site pain (n/a - Recovered/Resolved -), Fatigue (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -), Pallor (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011820486 | 08/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Abdominal pain (n/a | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011820848 | | Spontaneous | Healthcare Professional | | Not available | 3-11 Years | Child | Female | No | Abdominal pain lower (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Nausea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), Weight decreased (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011821433 | | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011821777 | | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Myocardial infarction (n/a - Unknown - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011821827 | 08/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not Recovered/Not | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | Not reported | ICSR |

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| | | | | | | | | | | Resolved - Other Medically Important Condition) | | | |
| EU-EC- L0011822041 | 08/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Blood pressure increased (62min - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011822052 | 08/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Pallor (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | applicable - [1d - n/a - Intramuscular]) | | |
| EU-EC- .0011822145 | 08/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10011822502 | 08/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Male | No | Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- .0011823563 | 08/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Erythema multiforme (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- | 00/02/2022 | Coordon | Nee | Nan | Nink | 2.11 | Net | Mala | NI- | Rash pruritic (n/a - Not Recovered/Not Resolved -) | COMPRIATY | [GLYCEROL] (C - | TOOD |
| 10011823887 | 06/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Abdominal discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), | immunisation - Not | Eczema - n/a - [n/a - n/a - n/a]), [LIQUID PARAFFIN] (C - Eczema - n/a - [n/a - | ICSR |
| | | | | | | | | | | Abdominal pain upper (n/a - Recovering/Resolving - Other Medically Important Condition), | | n/a - n/a]), [OAT] (C - Eczema - n/a - [n/a - n/a - n/a]), [SODIUM HYDROGEN | |
| | | | | | | | | | | Cough (n/a - Recovering/Resolving - Other Medically Important Condition), | | CARBONATE, POTASSIUM CHLORIDE, SODIUM CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - | |
| | | | | | | | | | | Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), | | [n/a - n/a - n/a]), [TETRACAINE, TETRACAINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a | |
| | | | | | | | | | | Feeling hot (n/a - Recovering/Resolving - Other Medically Important Condition), | | - n/a]) | |
| | | | | | | | | | | Headache (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Illness (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Malaise (n/a - Recovering/Resolving | | | |

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| | | | | | | | | | | | - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Rhinorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Sneezing (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Vomiting (n/a - Unknown - Other Medically Important Condition) | | | |
| | EU-EC- 10011823913 | 08/03/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | | (n/a - Unknown - Other Medically Important Condition) | 1,701) | | |
| | EU-EC- 10011823962 | 08/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Blood pressure increased (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| | EU-EC- 10011823995 | 08/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Bursitis (n/a - Recovering/Resolving - Disabling), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | | Dysstasia (n/a - Recovering/Resolving - Disabling), | applicable - [n/a - n/a - n/a]) | | |
| | | | | | | | | | | | Gait disturbance (n/a - Recovering/Resolving | | | |
| | | | | | | | | | | | - Disabling), Inflammation (n/a - Recovering/Resolving - Disabling), | | | |
| | | | | | | | | | | | Synovitis (n/a - Recovered/Resolved -) | | | |
| | EU-EC- 10011824454 | 08/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Immune thrombocytopenia (378d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d1mL - Intramuscular]), | Not reported | ICSR |
| | | | | | | | | | | | | GARDASIL 9 SUSPENSION FOR INJECTION IN A PRE FILLED SYRINGE. HUMAN PAPILLOMAVIRUS 9 VALENT VACCINE (RECOMBINANT, ADSORBED) [HUMAN PAPILLOMAVIRUS TYPE 31 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS- LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN | | |
| | | | | | | | | | | | | PAPILLOMAVIRUS TYPE 33 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS- LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 45 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS- LIKE PARTICLES PRODUCED IN YEAST | | |

| | | | | | | | | | | | CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 52 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS- LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 58 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS- LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 11 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS- LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 11 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS- LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 16 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS- LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS- LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS- LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS- LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS- LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, HUMAN PAPILLOMAVIRUS TYPE 18 L1 PROTEIN - ADSORBED - IN THE FORM OF VIRUS- LIKE PARTICLES PRODUCED IN YEAST CELLS (SACCHAROMYCES CEREVISIAE CANADE 3C-5 (STRAIN 1895)) BY RDNA, AMORPHOUS ALUMINIUM AMORPHOUS ALUMINIUM AMORPHOUS ALUMINIUM AMORPHOUS ALUMINIUM AMORPHOUS ALUMINIUM ANDRED - Intramuscular]) | | |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|------------------|---------------|------------------|--------|----|--|--|--|------|
| EU-EC- 10011824730 | 08/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Tachycardia (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011825017 | 08/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Condition aggravated (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Seizure (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [1d - n/a - Intramuscular]) | LARONIDASE [LARONIDASE] (C - n/a - n/a - [n/a - 14.5mg - Intravenous (not otherwise specified)]), [OXCARBAZEPINE] (C - n/a - n/a - [n/a - 15mL - n/a]), [PARACETAMOL] (C - n/a - n/a - n/a - [n/a - n/a - n/a]), [VALPROATE SEMISODIUM] (C - n/a - n/a - [n/a - 750mg - n/a]) | ICSR |

| | | | | I | | I | I | | | Other Medically | | | |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|------------------|---------------|------------------|--------|----|---|---|--------------|------|
| EU-EC- | 08/03/2022 | Spontaneous | | European | Not | 3-11 | Not | Female | No | Important Condition) Malaise (2d - | COMIRNATY | Not reported | ICSR |
| 10011825157 | | | Professional | Economic Area | available | Years | Specified | | | Recovered/Resolved -), Nausea (2d - Recovered/Resolved -), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | | |
| | | | | | | | | | | Pyrexia (2d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Urticaria (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10011803034 | 07/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Conjunctivitis (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Resolved -), Erythema (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Kawasaki's disease (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pruritus (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Rash (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Vomiting (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10011803044 | 07/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011803482 | 07/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Chest discomfort (n/a - Recovering/Resolving -), | 1,123) | | |
| | | | | | | | | | | Drug ineffective (n/a | | | |
| | | | | | | | | | | Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Myalgia (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Oropharyngeal pain (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Rhinorrhoea (n/a - Recovering/Resolving -) | | | |
| EU-EC- 10011804691 | 07/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Female | No | Herpes zoster (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011805110 | 07/03/2022 | Spontaneous | Healthcare | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Chest discomfort (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|---------------|------------------|------------------|--------|--|---|--------------|------|
| EU-EC- 10011806534 | 07/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Facial paresis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Lymphopenia (n/a - Unknown - Caused/Prolonged Hospitalisation), Neutrophilia (n/a - Unknown - Caused/Prolonged Hospitalisation), Paralytic lagophthalmos (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), Red blood cell sedimentation rate increased (n/a - Unknown - Caused/Prolonged Hospitalisation), Tetany (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 10ug - n/a]) | Not reported | ICSR |
| EU-EC- 10011808219 | 07/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | - Caused/Prolonged Hospitalisation) Diarrhoea (11d - Recovered/Resolved -), Neck pain (14d - Recovered/Resolved -), Vomiting (3d - Recovered/Resolved -) | COMIRNATY 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a2mL - n/a]) | Not reported | ICSF |
| EU-EC- 10011808842 | 07/03/2022 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Not Specified | No | COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), Drug ineffective (n/a - Recovering/Resolving - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011810933 | 07/03/2022 | Spontaneous | Healthcare | European Economic Area | Not available | 3-11 Years | Child | Female | No | Tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Vomiting (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSF |
| EU-EC- 10011811563 | 07/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011811893 | 07/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Lymphadenopathy (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011811899 | 07/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Asthmatic crisis (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011813393 | 07/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Henoch-Schonlein purpura (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), IgA nephropathy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .2mL - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011813398 | 07/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Inflammation (n/a - Unknown -), Pruritus (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - .2mL - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10011813401 | 07/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Fatigue (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug | Not reported | ICSR |

| | l | I | l | I | I | I | I | | | lg report | withdrawn - [1d - | I | ı |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|---------------|------------------|------------------|----|--|---|--------------|------|
| | | | | | | | | | | | .2mL - Intramuscular]) | | |
| EU-EC- 10011814000 | 07/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Pollakiuria (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011814038 | 07/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Not Specified | No | Cough (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011799550 | 05/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Gait disturbance (n/a - Not Recovered/Not Resolved -), Limb discomfort (n/a - Not Recovered/Not Resolved -), Pain in extremity (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - | Not reported | ICSR |
| EU-EC- 10011799985 | 05/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Headache (5d - Recovered/Resolved -), Vomiting (5d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011800059 | | Spontaneous | Healthcare Professional | | Not available | 3-11 Years | Not Specified | Female | No | Transient ischaemic attack (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011800077 | 05/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Headache (3d - Recovered/Resolved -), Pain in extremity (3d - Recovered/Resolved -), Paraesthesia (3d - Recovered/Resolved -), Vomiting (3d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 10ug - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011789738 | 04/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Multisystem inflammatory syndrome in children (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011789753 | 04/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Arthralgia (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 -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), Seizure (n/a - Not Recovered/Not Resolved -), Seizure (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination site reaction (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |

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|-----------------------|---------------|-------------------------|-----------------------------------|-------------------------------------|------------------|---------------|------------------|------------|---------|--|--|--------------|------|
| | | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Arthralgia (n/a - Not Recovered/Not Resolved -), Diarrhoea (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Lethargy (n/a - Not Recovered/Not Resolved -), Lethargy (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSI |
| EU-EC- 10011790934 | 04/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Resolved -) Myalgia (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10011791033 | 04/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Recovered/Not Resolved -), Immune thrombocytopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Myalgia (n/a - Not Recovered/Not Resolved -), Petechiae (n/a - Not Recovered/Not Resolved -), Skin disorder (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICS |
| 10011791557 | | Spontaneous Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Application site pain (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), Vomiting (n/a - Recovered/Resolved -) Vomiting (n/a - Vomiting (n/ | COMIRNATY [TOZINAMERAN] (S - n/a | Not reported | ICS |
| 10011791562 | 0 17 037 2022 | Sportericous | Healthcare Professional | Economic | available | Years | Cilia | ridic | | Unknown -) | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | not reported | 100 |
| EU-EC- 10011791943 | 04/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Confusional state (n/a - Recovered/Resolved -), Diarrhoea (n/a - Recovered/Resolved -), Headache (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSI |
| EU-EC- 10011793177 | | Spontaneous | Healthcare Professional | Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Headache (n/a - Recovering/Resolving -), Myalgia (n/a - Recovering/Resolving -), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSF |

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| | | | | | | | | | | Tremor (n/a - Recovering/Resolving | | | |
| EU-EC- 10011793220 | 04/03/2022 | Spontaneous | Healthcare Professional | Non European | Not available | 3-11 Years | Not Specified | Female | No | Abdominal pain (n/a | COMIRNATY [TOZINAMERAN] (S - | Not reported | ICSR |
| | | | | Economic Area | | | | | | Recovered/Resolved -), Delirium (n/a - Recovered/Resolved - Other Medically Important | COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | | |
| | | | | | | | | | | Condition), Diarrhoea (n/a - | | | |
| | | | | | | | | | | Recovered/Resolved -), Fatigue (n/a - | | | |
| | | | | | | | | | | Recovered/Resolved -), Headache (n/a - | | | |
| | | | | | | | | | | Recovered/Resolved -), | | | |
| | | | | | | | | | | Myalgia (n/a - Recovered/Resolved -), | | | |
| EU-EC- | 04/03/2022 | Spontaneous | Healthcare | Non | Not | 3-11 | Not | Male | No | Pyrexia (n/a - Recovered/Resolved -) Abdominal pain (n/a | COMIRNATY | Not reported | ICSR |
| 10011793263 | 0 170372022 | Sportaneous | Professional | | available | Years | Specified | ridic | | Recovered/Resolved | [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICOK |
| | | | | | | | | | | Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), | applicable - [1d - n/a - n/a]) | | |
| | | | | | | | | | | Vomiting (n/a - Recovered/Resolved -) | | | |
| EU-EC- 10011793269 | 04/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Conjunctival hyperaemia (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Not reported | ICSR |
| | | | | | | | | | | Coronary artery aneurysm (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | - n/a]) | | |
| | | | | | | | | | | Diarrhoea (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Electrocardiogram abnormal (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Rash (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Tachycardia (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10011793287 | 04/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Arrhythmia (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Chest pain (n/a - Recovered/Resolved -), | - | | |
| | | | | | | | | | | Vomiting (n/a - Recovered/Resolved -) | | | |
| EU-EC- 10011794055 | 04/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Abdominal pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Not reported | ICSR |
| | | | | | | | | | | Anaphylactic reaction (1d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Other Medically | - Intramuscular]) | | |

| | | | | | | | | | | Important | | | |
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| | | | | | | | | | | Condition), Blood pressure decreased (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Disorientation (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Dizziness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Fear (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Nausea (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Restlessness (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Somnolence (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| EU-EC- | 04/03/2022 | Spontaneous | Hoalthcaro | Non | Not | 3-11 | Not | Female | No | Tachycardia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) Abdominal pain (n/a | COMIRNATY | Not reported | ICSR |
| 10011795063 | 04/03/2022 | Sportaneous | Professional | European Economic | available | Years | Specified | remale | INO | - Recovered/Resolved | [TOZINAMERAN] (S - COVID-19 | Not reported | <u>ICSR</u> |
| | | | | Area | | | | | | Diarrhoea (n/a - Recovered/Resolved -), | immunisation - Not applicable - [1d - n/a - n/a]) | | |
| | | | | | | | | | | Rectal haemorrhage (n/a - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10011795453 | 04/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Malaise (n/a - Recovered/Resolved -), Vomiting (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| EU-EC- | 04/03/2022 | Spontaneous | Non | Non | Not | 3-11 | Not | Female | No | -) Dysmenorrhoea (n/a | Intramuscular]) | Not reported | ICSR |
| 10011796305 | 0 1, 00, 2022 | Sportanicous | Healthcare | European Economic Area | available | Years | Specified | , sinais | | - Not Recovered/Not Resolved - Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | | 10011 |
| EU-EC- 10011796308 | 04/03/2022 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Myelitis transverse (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011797176 | 04/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Diarrhoea (n/a - Recovered/Resolved -), Dizziness (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Not reported | ICSR |
| | | | | | | | | | | Recovered/Resolved | - n/a]) | | |
| | | | | | | | | | | Pain in extremity (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Vomiting (n/a - Recovered/Resolved -) | | | |
| EU-EC- 10011797432 | 04/03/2022 | Spontaneous | | Non European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Delirium (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |

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|-----------------------|------------|-------------|-----------------------------------|------------------------------|------------------|---------------|------------------|-------------|----------|--|--|--------------|------|
| | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving -), | applicable - [1d - n/a - n/a]) | | |
| | | | | | | | | | | Urticaria (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Vomiting (n/a - Recovering/Resolving | | | |
| EU-EC- 10011798165 | 04/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Lymphadenopathy (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (5 - COVID-19 immunisation - Not applicable - [1d - .2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011798876 | 04/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Female | No | Cough (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011774258 | 03/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Pharyngeal erythema (5d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Pyrexia (5d - Recovered/Resolved -) | | | |
| EU-EC- 10011774267 | 03/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Dermatitis (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011774486 | 03/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Vasculitis (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011774490 | 03/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Headache (8d - Recovered/Resolved -), Insomnia (8d - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - | Not reported | ICSR |
| | | | | | | | | | | Recovered/Resolved -), Pyrexia (8d - Recovered/Resolved | Intramuscular]) | | |
| | | | | | | | | | | -), Tinnitus (8d - Recovered/Resolved | | | |
| EU-EC- 10011774498 | 03/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | Chest pain (3d - Recovered/Resolved -), Palpitations (3d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10011774500 | 03/03/2022 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Male | No | Pyrexia (5d - Recovered/Resolved -), Urticaria (5d - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a2mL - | Not reported | ICSR |
| EU-EC- | 03/03/2022 | Spontaneous | | European | Not | 3-11 | Not | Female | No | Recovered/Resolved -) Lymphadenitis (n/a - | Intramuscular]) COMIRNATY | Not reported | ICSR |
| 10011774763 | | | Healthcare Professional | Economic Area | available | Years | Specified | | | Recovering/Resolving -) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | | |
| EU-EC- 10011779807 | 03/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Child | Male | No | Fatigue (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Headache (n/a - Recovered/Resolved -) | | | |
| EU-EC- 10011782310 | 03/03/2022 | Spontaneous | | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011782408 | 03/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Not Specified | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10011782890 | 03/03/2022 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 3-11 Years | Child | Male | No | Pruritus (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | Rash morbilliform | applicable - [1d - | | |

| | | | | | | | (n/a - Recovering/Resolving -) | 1{DF} - Intramuscular]) | |
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