Line Listing Report Time run: 30/11/2022 11:22:32

| 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- 10010654235 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Unknown - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICSR |
| | | | | | | | | | | Caused/Prolonged Hospitalisation), Pharyngitis (n/a - Unknown - Caused/Prolonged | | | |
| EU-EC- 10010654244 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Hospitalisation) Fall (n/a - Recovered/Resolved -), Presyncope (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICSR |
| | | | | | | | | | | Recovered/Resolved -), Syncope (n/a - Recovered/Resolved | n/a - n/a]) | | |
| | 15/11/2021 | | | | | 10.17 | | | | - Other Medically Important Condition) | 201172117 | | 1000 |
| EU-EC- 10010654258 | 16/11/2021 | Spontaneous | Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | <u>ICSR</u> |
| | | | | | | | | | | Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | n/a - Unknown]) | | |
| | | | | | | | | | | Pruritus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Rash (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Throat tightness (n/a | | | |
| | | | | | | | | | | Recovering/Resolving - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010654265 | 16/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Muscular weakness (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010654439 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Cough (n/a - Unknown - Caused/Prolonged Hospitalisation), | n/a - Intramuscular]) | | |
| | | | | | | | | | | Lymphadenopathy (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010654469 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest discomfort (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - | Not reported | ICSR |
| EU-EC- | 16/11/2021 | Spontaneous | Haalthaara | Non | Not | 12-17 | Not | Female | No | Chest pain (n/a - Unknown - Other Medically Important Condition) Pruritus (n/a - | Intramuscular]) COMIRNATY | Not reported | ICSR |
| 10010654478 | 25, 12, 2021 | | Professional | | available | | Specified | | | Unknown - Other | [TOZINAMERAN] | | 1/9 |

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|-----------------------|------------|--------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|--------|--|--|--------------|------|
| | | | | Economic Area | | | | | | Medically Important Condition) | (S - COVID-19 immunisation - Not applicable - [1d - n/a - | | |
| EU-EC- 10010654481 | 16/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Discomfort (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving | (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSF |
| | | | | | | | | | | -), Inflammation (n/a - Recovering/Resolving - Other Medically Important Condition), | 1,4 1,41,5 | | |
| | | | | | | | | | | Peripheral swelling (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Swelling face (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| EU-EC- | 16/11/2021 | Spontaneous | Healthcare | Non | Not | 12-17 | Not | Male | No | Vaccination site inflammation (n/a - Recovering/Resolving - Other Medically Important Condition) Dizziness (n/a - | COMIRNATY | Not reported | ICSF |
| 10010654484 | 10,11,2021 | Sportaricous | Professional | European Economic Area | available | Years | Specified | laic | | Recovering/Resolving - Caused/Prolonged Hospitalisation), Eye pain (n/a - Recovering/Resolving | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | not reported | 1051 |
| | | | | | | | | | | - Caused/Prolonged Hospitalisation), Visual impairment (n/a - Recovering/Resolving - Caused/Prolonged | and an according to | | |
| EU-EC- 10010654489 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Hospitalisation) Chest discomfort (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSF |
| | | | | | | | | | | Dyspnoea (n/a - Unknown - Other Medically Important Condition) | n/a - Intramuscular]) | | |
| EU-EC- 10010654508 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Disease recurrence (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICSF |
| EU 50 | 15/11/2021 | | | | | 10.17 | | | | Dizziness (n/a - Unknown - Other Medically Important Condition) | COMPANY | | 1000 |
| EU-EC- 10010654514 | 16/11/2021 | Spontaneous | Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported | ICSR |
| | | | | | | | | | | Unknown - Caused/Prolonged Hospitalisation), | Intramuscular]) | | |
| | | | | | | | | | | (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| EU-EC- | 16/11/2021 | Spontaneous | Healthcare | Non | Not | 12-17 | Not | Female | No | Respiratory disorder (n/a - Unknown - Caused/Prolonged Hospitalisation) Chest discomfort | COMIRNATY | Not reported | ICSR |
| 10010654522 | 10,11,2021 | Sportaricous | Professional | European Economic Area | available | Years | Specified | remaie | | (n/a - Unknown - Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - | not reported | 1001 |
| | | | | | | | | | | Hypertension (n/a - Unknown - Other Medically Important Condition), | Intramuscular]) | | |
| EU-EC- | 16/11/2021 | Spontaneous | Non | Non | Not | 12-17 | Not | Male | No | Palpitations (n/a - Unknown - Other Medically Important Condition) Abdominal pain (n/a | COMIRNATY | Not reported | ICC |
| 10010654523 | 10/11/2021 | Sportarieous | Healthcare Professional | European Economic Area | available | Years | Specified | male | INU | - Not Recovered/Not Resolved - Other | [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |

| | | | | | | | | | | Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Not | applicable - [1d - n/a - n/a]) | | |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|---|--|--------------|------|
| | | | | | | | | | | Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Sleep deficit (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| EU-EC- | 16/11/2021 | Spontaneous | Non | European | Not | 12-17 | Not | Female | No | Vomiting (1d - Recovered/Resolved - Other Medically Important Condition) Menstruation | COMIRNATY | Not reported | ICSR |
| 10010654842 | | | | Economic | available | Years | Specified | | | irregular (n/a - Not Recovered/Not Resolved -), Vaccination site pain | [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | | |
| | | | | | | | | | | (4d - Recovered/Resolved -) | | | |
| EU-EC- 10010654869 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), | n/a - Intramuscular]) | | |
| | | | | | | | | | | Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Throat irritation (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010654875 | 16/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chills (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Headache (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010654876 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Hypertension (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Nephritis (n/a - Unknown - Caused/Prolonged Hospitalisation), | n/a - Unknown]) | | |
| | | | | | | | | | | Nephrotic syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Oedema peripheral (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| T | I | I | I | I | I | I | I | l | I | I | I | I | 1 |

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| | | | | | | | | | | Systemic lupus erythematosus (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010654882 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dyspnoea (n/a - Unknown - Other Medically Important Condition), Hyperventilation (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Hypoaesthesia (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010654899 | 16/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Dermatitis acneiform (n/a - Not Recovered/Not Resolved - Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSI |
| | | | | | | | | | | Vaccination site erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Vaccination site pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Vaccination site rash (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010654901 | 16/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSF |
| | | | | | | | | | | Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010654918 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dizziness (n/a - Unknown -), Fatigue (n/a - Unknown -), Muscular weakness | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) | Not reported | ICS |
| | | | | | | | | | | (n/a - Unknown -), Syncope (n/a - Unknown - Other Medically Important Condition) | intamuscular jy | | |
| EU-EC- 10010654926 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Unknown - Other Medically Important Condition), Somnolence (n/a - Unknown - Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICSF |
| | | | | | | | | | | Medically Important Condition) | | | |
| EU-EC- 10010654945 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010654951 | 16/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Adrenal insufficiency (n/a - Unknown - Disabling), Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]), COMIRNATY | Not reported | ICSF |
| | | | | | | | | | | Cognitive disorder (n/a - Unknown - Disabling), Dizziness (n/a - Unknown -), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [85d - n/a - Intramuscular]), | | |

| | | | | | | | | | | Dysarthria (n/a - Unknown - Disabling), Feeling abnormal (n/a - Unknown -), Feeling drunk (n/a - Unknown - | [BUDESONIDE, FORMOTEROL FUMARATE DIHYDRATE, FORMOTEROL FUMARATE, BUDESONIDE] (S - n/a - n/a - [n/a - n/a - n/a]) | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|------------------|----|---|--|--------------|------|
| | | | | | | | | | | Disabling), Heart rate irregular (n/a - Unknown - | 1,42 1,421) | | |
| | | | | | | | | | | Disabling), Illness (n/a - Unknown -), | | | |
| | | | | | | | | | | Inappropriate schedule of product administration (n/a - Unknown -), | | | |
| | | | | | | | | | | Malaise (n/a - Unknown - Disabling), | | | |
| | | | | | | | | | | Motor dysfunction (n/a - Unknown - Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | | Muscular weakness (n/a - Unknown - Disabling), | | | |
| | | | | | | | | | | Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Photophobia (n/a - Unknown - Disabling), | | | |
| | | | | | | | | | | Photopsia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Presyncope (n/a - Unknown - Disabling), | | | |
| | | | | | | | | | | Skin hyperpigmentation (n/a - Unknown -), | | | |
| | | | | | | | | | | Tremor (n/a - Unknown - Disabling), | | | |
| | | | | | | | | | | Visual impairment (n/a - Unknown - Disabling) | | | |
| EU-EC- 10010655024 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Asthenia (n/a - Recovering/Resolving - Other Medically Important Condition), | (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), | .3mL - Intramuscular]) | | |
| | | | | | | | | | | Myalgia (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Respiration abnormal (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Vomiting (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010655034 | 16/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Not Specified | No | Headache (n/a - Not Recovered/Not Resolved - Other | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), | n/a - n/a]) | | |

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| | | | | | | | | | | | Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in jaw (n/a - Recovering/Resolving | | | |
| | | | | | | | | | | | - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| | EU-EC- 10010655053 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), | n/a - Unknown]) | | |
| | | | | | | | | | | | Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | | Malaise (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | | Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | | Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | | Pyrexia (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | | Rhinorrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | | Seizure (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | | Sneezing (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | | Urinary incontinence (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | | Vomiting (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| | EU-EC- 10010655054 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | | Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), | .3mL - Intramuscular]) | | |
| | <u></u> | 16/11/2001 | | | | | 10.17 | | | | Headache (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | Troop. |
| | EU-EC- 10010655276 | 16/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | remale | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) | Not reported | <u>ICSR</u> |
| | EU-EC- | 16/11/2021 | Spontaneous | Non | European | Not | 12-17 | Not | Female | No | Vaccination failure (n/a - Unknown - Other Medically Important Condition) Amenorrhoea (n/a - | COMIRNATY | Not reported | ICSR |
| | 10010655508 | 10, 11, 2021 | - Бронкан с ОИ5 | | Economic | available | Years | Specified | . Griale | .10 | Not Recovered/Not Resolved -), Chills (1d - | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | | 1COR |
| | | | | | | | | | | | Recovered/Resolved -), Pyrexia (1d - | 1{DF} - n/a]) | | |
| | | | | | l | l | | l | | | I | I | | |

| | 1.25 | | I | | | | | | s _ | Recovered/Resolved | | | |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|------------------|----------------|------------------|--------|---------|--|--|--------------|-----|
| EU-EC- 10010655513 | 16/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Intermenstrual bleeding (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICS |
| EU-EC- 10010656164 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (n/a - Unknown - Other Medically Important Condition), | 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICS |
| | | | | | | | | | | Chest pain (n/a - Unknown - Other Medically Important Condition), | n/a - Intramuscular]) | | |
| | | | | | | | | | | Palpitations (0d - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010656174 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Cold sweat (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICS |
| | | | | Alea | | | | | | Confusional state (n/a - Not Recovered/Not Resolved -), | applicable - [1d - n/a - n/a]) | | |
| | | | | | | | | | | Feeling hot (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Pallor (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Syncope (1d - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010656195 | 16/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Confusional state (n/a - Unknown - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICS |
| | | | | | | | | | | Contusion (n/a - Unknown - Other Medically Important Condition), | n/a - n/a]) | | |
| | | | | | | | | | | Disorientation (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Loss of consciousness (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Muscle spasms (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Mydriasis (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Seizure (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010656201 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal discomfort (1d - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Malaise (0d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Syncope (1d - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010656212 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Palpitations (n/a - Unknown - Other | | | |

| J.11.2022 1 | 1 | I | I | I | ı | ı | I | 1 | - | Modically Important | I | I | ı |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|------------------|----------------|------------------|--------|----------|--|--|--------------|-------------|
| | | - | | | | | | | | Medically Important Condition) | | | |
| EU-EC- 10010656226 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (2d - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) | Not reported | <u>ICSR</u> |
| | | | | | | | | | | Fatigue (2d - Recovered/Resolved - Other Medically Important Condition), | intramuscular j) | | |
| | | | | | | | | | | Palpitations (2d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Respiration abnormal (2d - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010656236 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 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 | <u>ICSR</u> |
| EU-EC- 10010656252 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), | applicable - [1d - n/a - Intramuscular]) | | |
| | | | | | | | | | | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Vaccination site pain (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010656253 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blister (3d - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Hypersensitivity (3d - Recovered/Resolved - Other Medically Important Condition), | n/a - Unknown]) | | |
| | | | | | | | | | | Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Rash (3d - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010656264 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Chest pain (n/a - Unknown - Other Medically Important Condition) | n/a - Intramuscular]) | | |
| EU-EC- 10010656625 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), | .3mL - Intramuscular]) | | |
| | | | | | | | | | | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Syncope (n/a - | | | |

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|-----------------------|------------|-------------|----------------------------|-------------------------------------|------------------|----------------|------------------|--------|-----|--|--|---------------|------|
| | | | | | | | | | | Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | | |
| EU-EC- 10010656638 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blood pressure diastolic decreased (15min - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICSI |
| | | | | | | | | | | Bradycardia (15min - Recovered/Resolved - Other Medically Important Condition), | n/a - n/a]) | | |
| | | | | | | | | | | Cold sweat (15min - Recovered/Resolved -), | | | |
| | | | | | | | | | | Depressed level of consciousness (15min - Recovered/Resolved - Other Medically | | | |
| | | | | | | | | | | Important Condition), Dizziness (15min - | | | |
| EU-EC- | 16/11/2021 | Spontaneous | Hoaltheare | Non | Not | 12-17 | Not | Male | No | Recovered/Resolved - Other Medically Important Condition) Chest discomfort | COMIRNATY | Not reported | ICS |
| 10010656640 | 10/11/2021 | Spontaneous | Professional | European Economic Area | available | Years | Specified | naic | INO | (n/a - Unknown - Caused/Prolonged Hospitalisation), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | 103 |
| | | | | | | | | | | Unknown -) | .5mL - Intramuscular]) | | |
| EU-EC- 10010656662 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSI |
| | | | | | | | | | | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation) | n/a - Intramuscular]) | | |
| EU-EC- 10010656671 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSI |
| | | | | | | | | | | Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), | n/a - Intramuscular]) | | |
| | | | | | | | | | | Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010656682 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported | ICS |
| | 16/11/2021 | C | 1.1 Ibib | N | NI-A | 12.17 | NI-4 | FI- | NI- | Chart diagrams (2 d | Intramuscular]) COMIRNATY | Not none to d | TCC |
| EU-EC- 10010656683 | 16/11/2021 | Spontaneous | Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (2d - Recovered/Resolved - Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Respiration abnormal (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010656691 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal discomfort (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported | ICSI |
| | | | | | | | | | | Diarrhoea (n/a - Unknown - Other Medically Important Condition), | Intramuscular]) | | |
| | | | | | | | | | | Discomfort (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Dyspnoea (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Erythema (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Face oedema (n/a - Unknown - Other Medically Important | | | |

| 30.11.2022 1 | 1.23 | | | | | | | Kunt | IIIe L | isting Report | | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|--------|--|--|--------------|-------------|
| | | | | | | | | | | Condition), Head discomfort (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), | | | |
| EU-EC- 10010656693 | 16/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Rash (n/a - Unknown - Other Medically Important Condition) Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Heart rate increased (n/a - Unknown - Other Medically Important Condition), | n/a - n/a]) ¯ | | |
| | | | | | | | | | | Loss of consciousness (20min - Unknown - Other Medically Important Condition), Syncope (n/a - | | | |
| | | | | | | | | | | Recovered/Resolved With Sequelae - Other Medically Important Condition) | | | |
| EU-EC- 10010656708 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest discomfort (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICSR |
| | | | | | | | | | | Chest pain (n/a - Unknown - Other Medically Important Condition), | | | |
| EU-EC- | 16/11/2021 | Spontaneous | Healthcare | Non | Not | 12-17 | Not | Female | No | Palpitations (n/a - Unknown - Other Medically Important Condition) Chest pain (n/a - | COMIRNATY | Not reported | ICSR |
| 10010656711 | 10/11/2021 | Spontaneous | Professional | | available | Years | Specified | Temaje | NO | Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported | ICSK |
| | | | | | | | | | | Unknown - Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - | Intramuscular]) | | |
| | | | | | | | | | | Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010656775 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Altered state of consciousness (n/a - Unknown - Life Threatening, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Cardio-respiratory arrest (n/a - Unknown - Life Threatening, Other Medically Important Condition), | muamusculai j) | | |
| | | | | | | | | | | Discomfort (6d - Recovered/Resolved -), | | | |
| EU EO | 16/11/2001 | | | | | 12.17 | | | | Syncope (n/a - Unknown - Life Threatening, Other Medically Important Condition) | COMPANY | | Year |
| EU-EC- 10010656891 | 16/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | <u>ICSR</u> |
| EU-EC- 10010656975 | 16/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Malaise (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Prothrombin time prolonged (n/a - Recovered/Resolved | | | |

| .11.2022 1 | 1.25 | | | | | | | Run | Line L | isting Report | | | |
|---------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|--------|---|---|--------------|-------------|
| | | | | | | | | | | - Caused/Prolonged Hospitalisation), Vaccination site haematoma (n/a - Recovered/Resolved - Caused/Prolonged | | | |
| U-EC- 0010657073 | 16/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Child | Female | No | Hospitalisation) Application site pain (n/a - Recovering/Resolving -), Headache (8h - | immunisation - Not applicable - [n/a - 1{DF} - | Not reported | ICS |
| | | | | | | | | | | Recovered/Resolved -), Insomnia (3h - Recovered/Resolved -), | Intramuscular]) | | |
| | | | | | | | | | | Lymphadenopathy (n/a - Recovering/Resolving -) | | | |
| U-EC- 0010657122 | 16/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Fatigue (9d - Not Recovered/Not Resolved -), Influenza (9d - Not | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Recovered/Not Resolved -), Malaise (9d - Not Recovered/Not | | | |
| | | | | | | | | | | Resolved -), Musculoskeletal discomfort (9d - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Myalgia (9d - Not Recovered/Not Resolved -), | | | |
| J-EC- | 16/11/2021 | Chantanaous | Haalthcara | Europoan | Not | 12-17 | Adoloscont | Malo | No | Pyrexia (9d - Not Recovered/Not Resolved -) COVID-19 (n/a - | COMIDNATY | Not reported | ICS |
| 0010657529 | 16/11/2021 | Spontaneous | Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Маје | No | Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) | Not reported | <u>1CS</u> |
| | | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | | | |
| U-EC- 0010657752 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Deep vein thrombosis (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - | Not reported | ICS |
| | | | | | | | | | | Infection (n/a - Unknown - Caused/Prolonged Hospitalisation), | Intramuscular]) | | |
| | | | | | | | | | | Osteomyelitis (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| U-EC- 0010657753 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICSI |
| | | | | | | | | | | Heart rate increased (n/a - Unknown - Other Medically Important Condition) | n/a - n/a]) | | |
| U-EC- 0010657756 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blood creatine phosphokinase increased (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported | <u>ICSI</u> |
| | | | | | | | | | | Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), | Intramuscular]) | | |
| | | | | | | | | | | Chest pain (11h - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Electrocardiogram ST segment elevation (n/a - Not Recovered/Not Resolved - Caused/Prolonged | | | |
| | | | | | | | | | | Hospitalisation), | | | |

| | | | | | | | | | Caused/Prolonged Hospitalisation), | | | |
|-------------|-------------------------------|---|--|---|--------------------------------------|--|--|---|---|--|--|---|
| | | | | | | 1 | | 1 | , | | | |
| | | | | | | | | | Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| 11/2021 5 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICS |
| 11/2021 5 | | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] | Not reported | ICS |
| | | | | | | | | | Decreased appetite (n/a - Unknown -), Headache (n/a - | | | |
| | | | | | | | | | Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | Unknown -), Loss of personal | | | |
| | | | | | | | | | daily activities (n/a - Unknown -), | | | |
| | | | | | | | | | (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| 11/2021 5 | | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Optic neuritis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | IC |
| 11/2021 5 | | | l <u> </u> | Not available | l | | Male | No | Chest discomfort (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - | Not reported | IC |
| | | | | | | | | | Unknown - Other Medically Important Condition) | | | |
| 11/2021 5 | | | | Not available | 12-17 Years | Not Specified | Female | No | Facial paralysis (n/a - Unknown - Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICS |
| 11/2021 5 | | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest discomfort (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - | Not reported | ICS |
| | | | | | | | | | Chest pain (n/a - Unknown - Other Medically Important Condition) | Intramuscular]) | | |
| 11/2021 5 | | | | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (n/a - Unknown - Other Medically Important Condition) | applicable - [1d - | Not reported | IC: |
| 11/2021 5 | | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Blood lactic acid increased (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | IC |
| | | | | | | | | | Blood potassium decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), | 11/a - 11/a]) | | |
| | | | | | | | | | Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| 1: | 1/2021 \$ 1/2021 \$ 1/2021 \$ | 1/2021 Spontaneous 1/2021 Spontaneous 1/2021 Spontaneous 1/2021 Spontaneous 1/2021 Spontaneous 1/2021 Spontaneous | 1/2021 Spontaneous Healthcare Professional 1/2021 Spontaneous Healthcare Professional | 1/2021 Spontaneous Healthcare Professional European Economic Area 1/2021 Spontaneous Healthcare Professional European Economic Area 1/2021 Spontaneous Healthcare Professional European Economic Area 1/2021 Spontaneous Healthcare Non European Economic Area 1/2021 Spontaneous Healthcare Professional European Economic Area 1/2021 Spontaneous Healthcare Non European Economic Area 1/2021 Spontaneous Healthcare Non European Economic Area 1/2021 Spontaneous Healthcare Non European Economic Area 1/2021 Spontaneous Healthcare European Economic Area | Spontaneous Healthcare Non Not | 1/2021 Spontaneous Healthcare Professional European European Area 1/2021 Spontaneous Healthcare Professional European European | 1/2021 Spontaneous Healthcare Professional Realthcare Professional Spontaneous Healthcare Professional Realthcare Profes | 1/2021 Spontaneous Healthcare Non Professional European Conomic Area Not Professional European European Not Professional European Not Professional European European | 1/2021 Spontaneous Healthcare Professional Reuropean Economic Area Not Professional Reuropean Economic | 1/2021 Spontaneous Healthcare Non Professional Economic Area Non Professional Economic Ar | Formation Recommon Recommon | 1/2012 Sportsmoote Weatherner Section Section |

| 0.11.2022 1 | 1.23 | | | | | | | IXUIT | -IIIC L | isting Report | | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|---------|---|---|--|-------------|
| | | | | | | | | | | Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Myalgia (5d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Seizure (2min - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010657770 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | [THIAMAZOLE] (C - n/a - n/a - [n/a - 10mg - n/a]) | ICSR |
| EU-EC- 10010657773 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported | ICSR |
| | | | | | | | | | | Gastrooesophageal reflux disease (n/a - Recovering/Resolving - Other Medically Important Condition), | Intramuscular]) | | |
| | | | | | | | | | | Vaccination site pain (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010657774 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | n/a - Intramuscular]) | | |
| | | | | | | | | | | Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Pneumonia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Tachycardia (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010657853 | 16/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Epistaxis (n/a - Recovering/Resolving - 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), | | | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010657854 | 16/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Abdominal pain upper (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010657979 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | <u> </u> | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICSR |
| | | | | | | | | | | Heart rate increased (1d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Respiration abnormal (2d - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- | 16/11/2021 | Spontaneous | Non | European | Not | 12-17 | Not | Male | No | Chills (1d - | COMIRNATY | Not reported | <u>ICSR</u> |

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| 10010658779 | | | Healthcare Professional | | available | Years | Specified | | | Recovered/Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (1d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved Recovered/Resolved - Recovered/Resolved | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | | |
| EU-EC- 10010658780 | 16/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | -) Headache (2d - Recovered/Resolved -), Malaise (n/a - Recovering/Resolving -), Myalgia (2d - Recovered/Resolved -), Nausea (1d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10010658781 | 16/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | -) Headache (1d - Recovered/Resolved -), Myalgia (2d - Recovered/Resolved -), Nausea (3d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10010659279 | 16/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Migraine (n/a - Not Recovered/Not Resolved - Disabling), New daily persistent headache (n/a - Not Recovered/Not Resolved - Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10010659341 | 16/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10010659356 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation), Myalgia (n/a - Unknown - Caused/Prolonged Hospitalisation), Myostis (n/a - Unknown - Caused/Prolonged Hospitalisation), Somnolence (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICSR |
| EU-EC- 10010659358 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), Vertigo (n/a - Unknown - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICSR |
| | | | | | | | | | | Hospitalisation) | | | |

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| | | | | Economic Area | | | | | | Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - Caused/Prolonged | (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | | |
| EU-EC- 10010659363 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Hospitalisation) Haemorrhage (n/a - Unknown - Other Medically Important Condition), Thrombocytopenia (n/a - Unknown - Other Medically | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010659365 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Important Condition) Arrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation), Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), Headache (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) | Not reported | ICSF |
| EU-EC- | 16/11/2021 | Spontaneous | Non | European | Not | 12-17 | Not | Female | No | Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation) Herpes zoster (n/a - | COMIRNATY | [ASCORBIC ACID, MAGNESIUM | ICSR |
| 10010659387 | 20/22/2022 | GPS. Italian | Healthcare Professional | Economic Area | available | Years | Specified | , Gingle | | Recovering/Resolving -), Malaise (n/a - Unknown -), Pruritus (n/a - Unknown -), Rash (n/a - Unknown -) | | OXIDE, HEAVY, MAGNESIUM] (C-n/a-n/a-), [DOCONEXENT, ICOSAPENT, FISH OIL, ICOSAPENT ETHYL, DOCOSAHEXAENOIC ACID ETHYL ESTER, OMEGA-3-ACID ETHYL ESTERS 90, OMEGA-3-ACID ETHYL ESTERS 90, DOCOSAHEXAENOIC ACID ETHYL ESTER] (C-n/a-n/a-), [THIAMINE HYDROCHLORIDE, | |
| EU-EC- 10010659543 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blood pressure decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Hypersensitivity (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | RETINOL] (C - n/a - n/a -), [VITAMIN D] (C - n/a - n/a -) Not reported | ICSF |
| | | | | | | | | | | - Other Medically Important Condition), Oxygen saturation decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria (n/a - | | | |
| EU-EC- 10010659561 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Recovering/Resolving - Other Medically Important Condition) Abdominal pain lower (n/a - Unknown - Other Medically Important Condition), Abdominal pain upper (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSF |
| | | | | | | | | | | Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important Condition), Vomiting (n/a - Volume - Other Medically Important Condition) | | | |
| EU-EC- 10010659588 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Unknown - Other Medically Important Condition) Altered state of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation), Central nervous system lesion (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSF |

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| | | | | | | | | | | Fall (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Generalised tonic- clonic seizure (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Lip swelling (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Mechanical urticaria (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Oropharyngeal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Pyrexia (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010659595 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blister (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | <u>ICSR</u> |
| | | | | | | | | | | Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation), | .3mL - Intramuscular]) | | |
| | | | | | | | | | | Rash (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010659606 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Pneumonitis (n/a - Unknown - Other Medically Important Condition) | n/a - n/a]) | | |
| EU-EC- 10010659621 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Epilepsy (n/a - Recovering/Resolving - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - n/a]) | Not reported | <u>ICSR</u> |
| EU-EC- 10010659663 | 16/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | (n/a - Unknown -), Premenstrual syndrome (n/a - | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | ANTICONCEPTIEMIDDEL [NOT AVAILABLE] (C - n/a - Dose not changed - [n/a - n/a - n/a]) | ICSR |
| EU-EC- 10010660104 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Unknown -) Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), | immunisation - Not applicable - [n/a - n/a - | Not reported | ICSR |
| | | | | | | | | | | Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), | Intramuscular]) | | |
| | | | | | | | | | | Headache (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Palpitations (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (8d - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010660418 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Arrhythmia (n/a - Unknown - Caused/Prolonged Hospitalisation), | n/a - Intramuscular]) | | |
| | | | | | | | | | | Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010660533 | 16/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Abdominal pain (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [73d - n/a - n/a]) | Not reported | ICSR |
| | | | 1 | | | | | l | | Arthralgia (n/a - Not | l | | |

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| | | | | | | | | | | Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Diarrhoea (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Lymphadenopathy (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Oligomenorrhoea (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010660614 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010660623 | 16/11/2021 | Spontaneous | Healthcare Professional | European Economic | Not available | | Not Specified | Female | No | Chest pain (n/a - Unknown - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSF |
| | | | | Area | | | | | | Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged | immunisation - Not applicable - [1d - n/a - Intramuscular]) | | |
| EU-EC- 10010660689 | 16/11/2021 | Spontaneous | | | Not available | 12-17 Years | Adolescent | Female | No | Hospitalisation) COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported | ICSF |
| | | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | Intramuscular]) | | |
| EU-EC- 10010660801 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blood pressure decreased (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSF |
| | | | | | | | | | | Cold sweat (n/a - Recovered/Resolved -), | applicable - [n/a - n/a - Intramuscular]) | | |
| | | | | | | | | | | Fall (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Heart rate decreased (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Hypotension (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Presyncope (n/a - Recovered/Resolved -) | | | |
| EU-EC- 10010660918 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Cataract cortical (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSF |
| | | | | | | | | | | Cerebral haemorrhage (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, | | | |

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| | | | | | | | | | | | Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | | | Cerebral venous sinus thrombosis (n/a - Fatal - Results in Death, Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | | | Gait disturbance (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | | | Hemiparesis (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | | | Infarction (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | | | Intracranial pressure increased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | | | Malaise (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | | | Muscular weakness (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | | | Platelet count decreased (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | | | Thrombocytopenia (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition), | | | |
| | | | | | | | | | | | Vomiting (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition) | | | |
| | EU-EC- 10010661021 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (n/a - Unknown - Other Medically Important Condition), Palpitations (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICSR |
| | EU-EC- | 16/11/2021 | Spontaneous | Healthcaro | Non | Not | 12-17 | Not | Male | No | Unknown - Other Medically Important Condition) Discomfort (n/a - | COMIRNATY | Not reported | ICSR |
| | 10010661024 | 10/11/2021 | oponicaneous | Professional | | | | Specified | riale | 110 | Recovering/Resolving | [TOZINAMERAN] | not reported | ILOK |

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| | | | | Economic Area | | | | | | -), Dizziness (n/a - Recovering/Resolving -), | (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | | |
| | | | | | | | | | | Dyspnoea (n/a - Recovering/Resolving -), | Indumusedia: 1) | | |
| | | | | | | | | | | Hypoaesthesia (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Nausea (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Syncope (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010661026 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Blood pressure decreased (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 |
| | | | | | | | | | | Dizziness (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Feeling abnormal (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Headache (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Pallor (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010661258 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Arrhythmia (n/a - Recovering/Resolving - Other Medically Important Condition), | (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), | n/a - Intramuscular]) | | |
| | | | | | | | | | | Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010661260 | 16/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blindness transient (12750min - Recovered/Resolved - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Dizziness (12750min - Recovered/Resolved -), | | | |
| | | | | | | | | | | Hyperhidrosis (12750min - Recovered/Resolved -), | | | |
| | | | | | | | | | | Pallor (12750min - Recovered/Resolved -), | | | |
| | | | | | | | | | | Tinnitus (12750min - Recovered/Resolved -) | | | |
| EU-EC- 10010661265 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | C-reactive protein increased (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - | Not reported | ICSR |
| | | | | | | | | | | Palpitations (n/a - Unknown - Other Medically Important Condition) | Intramuscular]) | | |
| EU-EC- 10010661382 | 16/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Polymenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | <u>ICSR</u> |

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| EU-EC- 10010661442 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | 1(DF) - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICS |
| | | | | | | | | | | Dehydration (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010661443 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICS |
| | | | | | | | | | | Diarrhoea (n/a - Unknown - Other Medically Important Condition) | n/a - Intramuscular]) | | |
| EU-EC- 10010661452 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported | ICS |
| | | | | | | | | | | Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), | Intramuscular]) | | |
| | | | | | | | | | | Dizziness (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Headache (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010661453 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICS |
| | | | | | | | | | | Pain in extremity (n/a - Unknown - Caused/Prolonged Hospitalisation), | applicable - [1d - .3mL - n/a]) | | |
| | | | | | | | | | | Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Vaccination site pain (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010661531 | 16/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Cardiac disorder (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | [TOZINAMERAN] | Not reported | ICS |
| | | | | | | | | | | Chest discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | ii,a ii,ajj | | |
| | | | | | | | | | | Cough (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Cyanosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Inflammation (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Pulmonary embolism (n/a - Recovering/Resolving | | | |

| | | | | | | | | | | - Caused/Prolonged | | | |
|-----------------------|---------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|-----|--|---|--------------|--------------|
| EU-EC- 10010661867 | 16/11/2021 | Spontaneous | | Non European Economic | Not available | 12-17 Years | Not Specified | Female | No | Hospitalisation) Feeling abnormal (n/a - Unknown - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSF |
| | | | | Area | | | | | | Hospitalisation), Hypoaesthesia (n/a - Unknown - Caused/Prolonged | immunisation - Not applicable - [1d - n/a - Intramuscular]) | | |
| EU-EC- | 16/11/2021 | Spontaneous | Healthcare | Non | Not | 12-17 | Not | Male | No | Hospitalisation) Chest discomfort | COMIRNATY | Not reported | ICSI |
| 10010661875 | , , , , , , , | | | European Economic Area | available | Years | Specified | | | (n/a - Unknown - Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | | |
| | | | | | | | | | | Headache (n/a - Unknown - Other Medically Important Condition), | , | | |
| | | | | | | | | | | Heart rate irregular (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Palpitations (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010661941 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | <u>ICS</u> F |
| | | | | | | | | | | Gastrooesophageal reflux disease (n/a - Unknown - Caused/Prolonged Hospitalisation), | n/a - Intramuscular]) | | |
| | | | | | | | | | | Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010661967 | 16/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Immunisation reaction (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - | Not reported | ICSF |
| | 16/11/2021 | Spontaneous | | European | Not | 12-17 | Adolescent | Male | No | Death (n/a - Fatal - | Intramuscular]) COMIRNATY | Not reported | ICSF |
| 10010661990 | | | Professional | Economic Area | available | Years | | | | Results in Death), Pulmonary oedema (n/a - Fatal - Results in Death) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - | | |
| EU-EC- 10010662022 | 16/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Abdominal pain upper (n/a - Not Recovered/Not Resolved -), | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSF |
| | | | | | | | | | | Asthenia (n/a - Not Recovered/Not Resolved -), | applicable - [n/a - 1{DF} - Intramuscular]) | | |
| | | | | | | | | | | Headache (1d - Recovered/Resolved -), Malaise (1d - | | | |
| EU-EC- | 16/11/2021 | Spontaneous | Non | European | Not | 12-17 | Adolescent | Fomalo | No | Recovered/Resolved - Caused/Prolonged Hospitalisation) Asthenia (n/a - | COMIRNATY | Not reported | ICSF |
| 10010662184 | 10/11/2021 | Sportaneous | | Economic | available | Years | Adolescent | remaje | INO | Recovering/Resolving -), Dizziness (n/a - | | Not reported | <u>ICS</u> |
| | | | | | | | | | | Recovering/Resolving -), | | | |
| | 15/11/2021 | | | | | 10.17 | | | | Lymphadenopathy (n/a - Not Recovered/Not Resolved -) | | | 100 |
| EU-EC- 10010662209 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Back pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSF |
| | | | | | | | | | | Chest pain (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | n/a - | | |
| EII EC | 16/11/2021 | Cnorton | Non | Europa | Not | 12 17 | Adalaa | Eoma!- | No | Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIDNATY | Not reported | Too |
| EU-EC- 10010662218 | 10/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | remale | No | Menstruation delayed (n/a - Not Recovered/Not Resolved -) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | <u>ICSF</u> |

| | | | | | | | | | | | 1{DF} - Intramuscular]) | | |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|---|---|--------------|------|
| EU-EC- 10010662232 | 16/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010662315 | 16/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Headache (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010662317 | 16/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Asthenia (n/a - Recovering/Resolving -), Eye pain (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSF |
| EU-EC- 10010662896 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | -) Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation), Appendicitis (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICSR |
| EU-EC- 10010662911 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Anaphylactic shock (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICSR |
| EU-EC- 10010663196 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (n/a - Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other Medically Important | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICSR |
| EU-EC- 10010663292 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Condition) Abdominal pain upper (n/a - Recovered/Resolved Other Medically Important Condition), Back pain (n/a - Recovered/Resolved Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICSR |
| | | | | | | | | | | Diarrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), Nausea (n/a - Recovered/Resolved | | | |
| | | | | | | | | | | - Other Medically Important Condition), Pyrexia (n/a - Recovered/Resolved - Other Medically | | | |
| EU-EC- 10010663569 | 16/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Important Condition) Inappropriate schedule of product administration (n/a - Unknown -), Myocarditis (n/a - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- | 16/11/2021 | Spontaneous | Healthcare | Non | Not | 12-17 | Not | Female | No | - Caused/Prolonged Hospitalisation, Other Medically Important Condition) Dyspnoea (n/a - | COMIRNATY | Not reported | ICSR |
| 10010663570 | | | Professional | | available | Years | Specified | | | Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010663576 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blood pressure diastolic decreased (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - | Not reported | ICSR |
| | | | | | | | | | | Cough (n/a - Unknown - Caused/Prolonged | Intramuscular]) | | |

| J.11.2022 I | 1.23 | | | | | | | IXUII | LIIIE I | isting Report | | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|---------|---|---|--------------|------|
| | | | | | | | | | | Hospitalisation), White blood cell count increased (n/a - Unknown -) | | | |
| EU-EC- 10010663599 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSI |
| EU-EC- 10010663611 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Cold sweat (0d - Recovered/Resolved -), Fall (n/a - Recovered/Resolved -), Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSI |
| EU-EC- 10010663725 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European | Not available | 12-17 Years | Not Specified | Male | No | Presyncope (n/a - Recovered/Resolved -) Cardiac failure (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] | Not reported | ICS |
| 10010003723 | | | Fioressional | Economic Area | available | rears | эрестеч | | | Resolved - Caused/Prolonged Hospitalisation), Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | | |
| EU-EC- 10010663734 | 16/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Arthralgia (n/a - Recovering/Resolving -), Chills (n/a - Recovering/Resolving -), Fatique (n/a - Not | (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICSF |
| | | | | | | | | | | Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Injection site pain (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not | | | |
| | | | | | | | | | | Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010663746 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), | (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Vomiting (n/a - Recovering/Resolving - Other Medically | n/a - Intramuscular]) | | |
| EU-EC- 10010663759 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Important Condition) Dizziness (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunication - Not | Not reported | ICSF |
| | | | | | | | | | | Feeling abnormal (0d | applicable - [1d - .3mL - n/a]) | | |
| | | | | | | | | | | Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Feeling hot (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Mydriasis (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Seizure (0d - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010663776 | 16/11/2021 | Spontaneous | | European Economic | Not available | 12-17 Years | Not Specified | Male | No | Chest discomfort (n/a - | COMIRNATY [TOZINAMERAN] | Not reported | ICSR |

| Martine Mart | J.11.2022 1 | 1.20 | | | | | | | Kull | LIIIE L | isting Report | | | |
|--|-------------|------------|--------------|--------------|----------------------|-----|-------|-----|--------|---------|---|--|--------------|------|
| EMPC | | | | Professional | Area | | | | | | -), Hyperhidrosis (n/a - Recovering/Resolving | immunisation - Not applicable - [n/a - | | |
| But C | | 16/11/2021 | Spontaneous | | European Economic | | | | Female | No | Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Loss of consciousness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - | Not reported | ICSR |
| | EU EC | 16/11/2021 | Chartenasus | Lloglithopus | Non | Net | 12.17 | Not | Mala | No | Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMTONIATIV | Netroported | ICCD |
| BL-EC 16/11/2021 Spontameous New Pedestornal Composition Common New Pedestornal New Pedestornal Common New Pedestornal | | 10/11/2021 | Sportalieous | | European Economic | | | | ride | NO | Unknown - Other Medically Important Condition), Dizziness (n/a - Unknown - Other | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSN |
| | | | | | | | | | | | Condition), Headache (n/a - Unknown - Other Medically Important | | | |
| EU-EC- 16/11/2021 Spontameous Healthcare Professional Economic (Page Professional Ec | | 16/11/2021 | Spontaneous | Healthcare | European Economic | | | | Female | No | Chest pain (n/a - Recovering/Resolving - Other Medically Important | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| EU-EC- 10/11/2021 Spontaneous Healthcare Northern Month of the Professional Economic Area Windows Area Window | | | | | | | | | | | Recovering/Resolving - Other Medically Important | .,,, ., | | |
| EU-EC- 16/11/2021 Spontaneous Healthcare Non Not Recovered Resolved 1001064531 Not Not Recovered Resolved Not No | | | | | | | | | | | Unknown - Other Medically Important Condition), | | | |
| EU-EC- 10010664391 EU-EC- 10010664391 EU-EC- 10010664391 EU-EC- 10010664391 EU-EC- 10010664391 EU-EC- 10010664391 If/I1/2021 Spontaneous Healthcare Non Professional European Area Wallable European Economic Area EU-EC- 10010664391 If/I1/2021 Spontaneous Healthcare Non Not Wallable European Caused/Prolonged Healthcare Non Not Wallable European Caused/Prolonged Healthcare Non Not Wallable European Caused/Prolonged Healthcare Non Not 12-17 Not Male No Alaniee Continuous Caused/Prolonged Healthcare Non Not 12-17 Not Male No Alaniee Continuous Continuous Caused/Prolonged Healthcare Non Not reported Section Professional European Caused/Prolonged Healthcare Non Not 12-17 Not Male No Alaniee Continuous Continuous Caused/Prolonged Healthcare Non Not reported Section Professional European Caused/Prolonged Healthcare Non Not 12-17 Not Male No Alaniee Continuous Continuous Continuous Continuous Caused/Prolonged Healthcare Non Not reported Section Professional European Caused/Prolonged Healthcare Non Not reported Section Professional European Caused/Prolonged Healthcare Non Not 12-17 Not Male No Alaniee Continuous Continu | | | | | | | | | | | Unknown - Other Medically Important Condition), | | | |
| EU-EC- 10010664399 16/11/2021 Spontaneous Healthcare Non European European Frofessional Recommic Area Not Economic Not available Economic Area Not Economic Not available Economic Area Not Economic Not available Sportaneous Healthcare Not Economic Area Not Economic Are | | | | | | | | | | | Unknown - Other Medically Important Condition), Pericarditis (n/a - | | | |
| 10010664399 Frofessional European Euro | | | | | | | | | | | Medically Important Condition) | | | |
| EU-EC- 10/11/2021 Spontaneous Professional Economic Area Healthcare Professional Economic Area Nor Professional European European Economic Area Nor Recovered/Resolved -) Nor Agina pectoris (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown) Caused/Prolonged Hospitalisation), Respiration abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiration abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation) EU-EC- 16/11/2021 Spontaneous Healthcare Non Not 12-17 Not Male No Alanine Command Not reported 150 | | 16/11/2021 | Spontaneous | | European Economic | | | | Male | No | (n/a - Recovered/Resolved -), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| EU-EC- 10/11/2021 Spontaneous Healthcare Recovered/Resolved - Other Medically Important Condition), Pain (n/a - Recovered/Resolved -) Recovered/Resolved -) Angina pectoris (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiration abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation), Respiration abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | | | | | | | | | Recovered/Resolved | | | |
| EU-EC- 10010664531 Not 10010664531 EU-EC- 10010664531 EU-EC- 10010664531 EU-EC- 10010664531 Not 10010664531 EU-EC- 10010664531 Not 1001066 | | | | | | | | | | | Recovered/Resolved - Other Medically Important | | | |
| EU-EC- 1001064531 1001064531 100106645 1001066645 1001066645 1001066645 1001066645 1001066645 1001066645 1001066645 1001066645 1001066645 10010666645 1001066666666666666666666666666666666 | | | | | | | | | | | Recovered/Resolved | | | |
| EU-EC- 16/11/2021 Spontaneous Healthcare Non Not 12-17 Not Male No Alanine Chest discomfort (n/a - Unknown - Chest discomfort (n/a - Unknown - Chest pain (n/a - Unknown - | | 16/11/2021 | Spontaneous | | European Economic | | | | Female | No | Angina pectoris (n/a - Unknown - Caused/Prolonged | [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| Unknown - Caused/Prolonged Hospitalisation), Respiration abnormal (n/a - Unknown - Caused/Prolonged Hospitalisation) EU-EC- 16/11/2021 Spontaneous Healthcare Non Not 12-17 Not Male No Alanine COMIRNATY Not reported IC | | | | | | | | | | | (n/a - Unknown - Caused/Prolonged | | | |
| EU-EC- 16/11/2021 Spontaneous Healthcare Non Not 12-17 Not Male No Alanine COMIRNATY Not reported IC | | | | | | | | | | | Unknown - Caused/Prolonged Hospitalisation), | | | |
| EU-EC- 16/11/2021 Spontaneous Healthcare Non Not 12-17 Not Male No Alanine COMIRNATY Not reported IC | | | | | | | | | | | (n/a - Unknown - Caused/Prolonged | | | |
| | | 16/11/2021 | Spontaneous | | | | | | Male | No | Alanine | | Not reported | ICSR |

| 00.11.2022 | | | | | | | | | | isting report | | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|---|--|--------------|-------------|
| | | | | Economic Area | | | | | | increased (n/a - Unknown - Caused/Prolonged Hospitalisation), | (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | | |
| | | | | | | | | | | Blood pressure increased (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Blood triglycerides increased (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Blood uric acid increased (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Heart rate irregular (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Palpitations (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010664575 | 16/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Polymenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - 1{DF} - n/a]) | Not reported | <u>ICSR</u> |
| EU-EC- 10010664589 | 16/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Food aversion (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - | Not reported | ICSR |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | Unknown - [n/a - 1{DF} - n/a]) | | |
| EU-EC- | 16/11/2021 | Chantanasus | Llogithanus | F | Not | 12.17 | Adolescent | Famala | Ne | Vision blurred (n/a - Not Recovered/Not Resolved -) | COMIDNIATY | Not reported | ICCD |
| 10010664623 | 16/11/2021 | Spontaneous | Professional | European Economic Area | Not available | 12-17 Years | Adojescent | гепаје | No | Rash (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | <u>ICSR</u> |
| EU-EC- 10010664669 | | Spontaneous | Healthcare Professional | | Not available | | Adolescent | Female | No | Respiratory tract infection (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010664810 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | 71100 | | | | | | Arthralgia (n/a - Unknown - Caused/Prolonged Hospitalisation), | applicable - [1d - n/a - Unknown]) | | |
| | | | | | | | | | | Asthenia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Decreased appetite (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Headache (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Nausea (n/a - Unknown - Caused/Prolonged | | | |

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| | | | | | | | | | | Hospitalisation), | | | |
| | | | | | | | | | | Vomiting (n/a - | | | |
| | | | | | | | | | | Unknown - Caused/Prolonged | | | |
| | | | | | | | | | | Hospitalisation) | | | |
| EU-EC- 10010664945 | 16/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Amenorrhoea (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - prog withdrawn - [1d3mL - Intramuscular - | Not reported | ICSI |
| | | | | | | | | | | | More in ICSR]) | | |
| EU-EC- 10010665161 | 16/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -) | [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10010665169 | 16/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Pain in extremity (n/a - Recovering/Resolving -) | [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10010665209 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Headache (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICS |
| | | | | | | | | | | Pyrexia (9d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | n/a - Intramuscular]) | | |
| EU-EC- 10010665245 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blood creatine phosphokinase increased (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSF |
| | | | | | | | | | | Chest discomfort (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | n/a - Intramuscular]) | | |
| | | | | | | | | | | Chest pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Dyspnoea (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Heart rate decreased (n/a - Unknown -), | | | |
| | | | | | | | | | | Hyperhidrosis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Nasopharyngitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Vision blurred (n/a - Not Recovered/Not Resolved - Caused/Prolonged | | | |
| EU-EC- 10010665268 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Hospitalisation) Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSI |
| | | | | | | | | | | Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation), | applicable - [1d - n/a - Intramuscular]) | | |
| | | | | | | | | | | Syncope (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- | 16/11/2021 | Spontaneous | Healthcare Professional | Non | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] | Not reported | ICSF |

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| | | | | Economic Area | | | | | | Resolved - Other Medically Important Condition), | (S - COVID-19 immunisation - Not applicable - [1d - | | |
| | | | | | | | | | | Dizziness (n/a - Unknown - Other Medically Important Condition), | .3mL - Intramuscular]) | | |
| | | | | | | | | | | Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Thrombosis (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010665400 | 16/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest pain (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Discomfort (n/a - Unknown - Other Medically Important Condition), | n/a - Intramuscular]) | | |
| | | | | | | | | | | Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Palpitations (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Rhabdomyolysis (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | 16/11/2021 | Spontaneous | | Non | Not | | Not | Female | No | Vomiting (n/a - Unknown - Other Medically Important Condition) Dizziness (1d - | COMIRNATY | [MESTRANOL, | ICSR |
| 10010665411 | | | Professional | European Economic Area | available | Years | Specified | | | Recovered/Resolved -), Feeling abnormal (1d | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | NORETHISTERONE] (C - n/a - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Recovered/Resolved | n/a - n/a]) | | |
| | | | | | | | | | | Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Syncope (1d - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010665452 | 16/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICSR |
| EU-EC- 10010641660 | 15/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Alopecia areata (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - | TACROLIMUS [TACROLIMUS, TACROLIMUS MONOHYDRATE] (C - Eczema - n/a - [154d03% - Topical]) | ICSR |
| EU-EC- 10010641809 | 15/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Syncope (1d - Recovered/Resolved - Other Medically Important Condition) | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10010641818 | 15/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Feeling cold (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Hyperhidrosis (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |

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| EU-EC- 10010641835 | 15/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Anaphylactic reaction (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSF |
| EU-EC- 10010641876 | 15/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | [INFLUENZA VIRUS] (C - Asthma - n/a - [1d - n/a - n/a]) | ICSF |
| | | | | | | | | | | Body temperature increased (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Diarrhoea (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010641897 | 15/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | [COLCHICINE] (C - n/a - n/a - [n/a - n/a - n/a]) | ICSF |
| | | | | | | | | | | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), | n/a - n/a]) | | |
| | | | | | | | | | | Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Pericarditis (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010642740 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Urticaria (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010642767 | 15/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Heavy menstrual bleeding (n/a - Unknown -) | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - | Not reported | ICSF |
| EU-EC- 10010642806 | 15/11/2021 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Adolescent | Female | No | COVID-19 (n/a - Unknown - Other | Unknown - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] | Not reported | ICSF |
| | | | | Area | | | | | | Medically Important Condition), Vaccination failure (n/a - Unknown - Other Medically | (S - n/a - n/a - [n/a - n/a - Intramuscular]) | | |
| EU-EC- 10010643168 | 15/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Important Condition) Anaphylactic reaction (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |

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| | | | | | | | | | | Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), | n/a - Intramuscular]) | | |
| | | | | | | | | | | Flushing (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Sneezing (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Tachycardia (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Wheezing (n/a - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010643212 | 15/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Drug ineffective (n/a - Recovered/Resolved - Other Medically | | | |
| EU-EC- 10010643215 | 15/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Important Condition) Body temperature increased (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Chest pain (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Palpitations (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | | |
| EU-EC- 10010643326 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Electrocardiogram ST segment elevation (n/a - Recovered/Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | <u>ICSR</u> |
| EU-EC- 10010643358 | 15/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Fall (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | Haemorrhage (n/a - Unknown - Other Medically Important Condition), | applicable - [1d - n/a - n/a]) | | |
| | | | | | | | | | | Pallor (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Presyncope (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010643375 | 15/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Anaphylactic shock (525min - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Lip oedema (525min - Recovered/Resolved | | | |
| | | | | | | | | | | - Other Medically Important Condition), | | | |
| | | | | | | | | | | Rash pruritic (525min - Recovered/Resolved - Other Medically Important Condition), | | | |
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| | | | | | | | | | | Urticaria (525min - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010643392 | 15/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Anaphylactic reaction (2d - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Diarrhoea (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving -), Vomiting (0d - | | | |
| | | | | | | | | | | Recovered/Resolved | | | |
| EU-EC- 10010643460 | 15/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | <u>ICSR</u> |
| EU-EC- 10010643489 | 15/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (1mo - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]) | ICSR |
| EU-EC- 10010645829 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Carditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10010646525 | 15/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Anaphylactic reaction (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] | Not reported | ICSR |
| | | | | | | | | | | Cyanosis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Dysphonia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Dyspnoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Oropharyngeal discomfort (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Respiratory symptom (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Upper airway obstruction (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | | |
| EU-EC- 10010646618 | 15/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Headache (4d - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Rash (3d - Recovered/Resolved - Other Medically Important Condition), | n/a - n/a]) | | |
| EU-EC- | 15/11/2021 | Sporton | Non | Nor | Not | 12.17 | Not | Mala | No | Vomiting (1d - Recovered/Resolved - Other Medically Important Condition) | COMIDNATY | Not reported | ICCD |
| 10010646650 | 13/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Nausea (n/a - Unknown - Other Medically Important Condition), Pyrexia (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | <u>ICSR</u> |

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| | | | | | | | | | | Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010646661 | 15/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blood pressure decreased (n/a - Unknown -), Loss of | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICSR |
| | | | | | | | | | | consciousness (n/a - Recovered/Resolved - Other Medically Important Condition) | n/a - n/a]) | | |
| EU-EC- 10010646884 | 15/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Appendicitis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Inappropriate | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | [DESVENLAFAXINE, DESVENLAFAXINE SUCCINATE MONOHYDRATE] (C - n/a - n/a - [n/a - n/a - n/a]) | ICSR |
| | | | | | | | | | | schedule of product administration (n/a - Unknown -) | | | |
| EU-EC- 10010646954 | , , | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | | No | Fatigue (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10010646957 | 15/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Headache (n/a - Recovered/Resolved -), Heart rate increased | COMIRNATY [TOZINAMERAN] (S - n/a - Drug withdrawn - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved | | | |
| EU-EC- 10010647160 | 15/11/2021 | Spontaneous | Non Hea l thcare | European Economic | Not available | 12-17 Years | Adolescent | Female | No | -) Rash (2d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] | Not reported | <u>ICSR</u> |
| | | | Professional | | | | | | | -), Urticaria (2d - Recovered/Resolved | (S - Immunisation - n/a - [n/a - n/a - n/a]) | | |
| EU-EC- 10010647351 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Headache (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10010647423 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICSR |
| | | | | | | | | | | Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), | n/a - n/a]) | | |
| | | | | | | | | | | Vomiting (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010647760 | 15/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Disturbance in attention (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported | ICSR |
| | | | | | | | | | | Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | Intramuscular]) | | |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Headache (7wk - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010647986 | 15/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blister (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | FLUENZ TETRA [A/GUANGDONG- MAONAN/SWL1536/2019 (H1N1)PDM09 - LIKE STRAIN (A/HAWAII/66/2019, MEDI 326775), A/HONG | ICSR |
| | | | | | | | | | | Chills (n/a - Recovered/Resolved - Other Medically Important Condition), | n/a - n/a]) | KONG/2671/2019 (H3N2) - LIKE STRAIN (A/HONG KONG/2671/2019, MEDI 325078), B/PHUKET/3073/2013 - LIKE STRAIN (B/PHUKET/3073/2013, MEDI 306444), | |
| | | | | | | | | | | Malaise (n/a - Recovered/Resolved - Other Medically Important | | B/WASHINGTON/02/2019 - LIKE STRAIN (B/WASHINGTON/02/2019, MEDI 323797), A/TEXAS/50/2012 (H3N2)-LIKE STRAIN | |

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|-----------------------|------------|-------------|-----------------------------------|------------------------------|------------------|----------------|------------|--------|----|--|--|---|------|
| | | | | | | | | | | Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), Photosensitivity reaction (n/a - Unknown - Other Medically Important Condition), Pruritus (n/a - Recovered/Resolved - Other Medically Important Condition), Pyrexia (1d - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | | (A/TEXAS/50/2012, MEDI 237514), B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228030), B/MASSACHUSETTS/2/2012 (YAMAGATA LINEAGE)-LIKE STRAIN (B/SASACHUSETTS/2/2012, MEDI 237751), A/CALIFORNIA/7/2009 (HIN1)PDM09-LIKE STRAIN (A/CALIFORNIA/7/2009, MEDI 228029), B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE STRAIN (B/BRISBANE/60/2008, MEDI 228029), B/BRISBANE/60/2008, MEDI 228030), A/CALIFORNIA/7/2009 (HIN1)PDM09-LIKE STRAIN (A/BOLIVIA/559/2013, MEDI 255962), B/PHUKET/3073/2013 (YAMAGATA LINEAGE)-LIKE STRAIN (B/PHUKET/3073/2013, MEDI 254977), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (A/NEW CALEDONIA/71/2014, MEDI 254977), A/HONG KONG/4801/2014 (H3N2)-LIKE STRAIN (B/PHUKET/3073/2013) (YAMAGATA LINEAGE)-LIKE STRAIN (B/PHUKET/3073/2013, MEDI 254977), A/MICHIGAN/45/2015 (H1N1)PDM09 - LIKE STRAIN (A/SLOVENIA/2903/2015, MEDI 279432), A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (A/SINGAPORE/INFIMH-16-0019/2016 (H3N2)-LIKE STRAIN (B/COLORADO/06/2017-LIKE STRAIN (B/COLORADO/06/2017-LIKE) STRAIN (B/COLORADO/06/2017-LIKE) STRAIN (B/COLORADO/06/2017-LIKE) | |
| EU-EC- 10010648275 | 15/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Presyncope (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - | - n/a - [1d - n/a - n/a]) Not reported | ICSR |
| EU-EC- 10010648286 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d3mL - | Not reported | ICSR |
| EU-EC- 10010648300 | 15/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -) | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - | Not reported | ICSR |
| EU-EC- 10010648308 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Asthenia (n/a - Not Recovered/Not Resolved -), Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Orthostatic hypotension (n/a - Not Recovered/Not Not Recovered/Not Not Recovered/Not Not Recovered/Not Not Recovered/Not Not Not Recovered/Not Not Not Recovered/Not Recovered/Recove | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010648375 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Resolved -) Lip oedema (1h - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010648393 | 15/11/2021 | Spontaneous | Non Healthcare Professional | | Not available | 12-17 Years | Adolescent | Female | No | Menstruation delayed (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010648413 | | Spontaneous | Professional | Area | Not available | 12-17 Years | Adolescent | | No | Disease recurrence (n/a - Recovering/Resolving Caused/Prolonged Hospitalisation), Tonic clonic movements (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [31d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010648581 | 15/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Facial paralysis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d3mL - Intramuscular]) | Not reported | ICSR |
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| EU-EC- 10010648625 | 15/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Heavy menstrual bleeding (n/a - Recovering/Resolving -), Menstruation delayed (n/a - Recovering/Resolving -) | immunisation - Not applicable - [n/a - | Not reported | ICSR |
| 10010648697 | | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Menstrual disorder (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - prog withdrawn - [1d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010648739 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Haemoptysis (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010648756 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Mastitis (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010648865 | 15/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Immunisation reaction (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | [CRATAEGI FOLIUM CUM FLORE, PASSIFLORA EXTRACT, VALERIANA OFFICINALIS EXTRACT, BALLOTA NIGRA, CRATAEGUS, BALLOTA NIGRA, PASSIFLORA INCARNATA L. HERBA, VALERIANA OFFICINALIS L., DRY EXTRACT FROM HAWTHORN LEAF AND FLOWER (5-7:1); EXTRACTION SOLVENT: WATER, DRY EXTRACT OF VALERIAN ROOT (1-5:1), EXTRACTION SOLVENT: ETHANOL 60% V/V, DRY EXTRACT OF PASSION FLOWER (1-4:1), EXTRACTION SOLVENT: ETHANOL 60% V/V, DRY EXTRACT OF BLACK HOREHOUND (DER 2-4:1), EXTRACTION SOLVENT: ETHANOL 60% V/V, DRY EXTRACT OF BLACK HOREHOUND (DER 2-4:1), EXTRACTION SOLVENT: WATER] (C - n/a - n/a - n/a) | ICSR |
| EU-EC- 10010648871 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Malaise (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| 10010649144 | | Spontaneous | Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blood creatine phosphokinase MB increased (n/a - Unknown - Life Threatening), Blood creatine phosphokinase increased (n/a - Unknown - Life Threatening), Brain natriuretic peptide increased (n/a - Unknown - Life Threatening), Cardiac arrest (n/a - Unknown - Life Threatening), Troponin increased (n/a - Unknown - Life Threatening), Ventricular fibrillation (n/a - Unknown - Life Threatening), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10010649234 | 5/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Decreased appetite (n/a - Not Recovered/Not Resolved - Disabling), Parosmia (n/a - Not Recovered/Not Resolved - Disabling), Taste disorder (n/a - Not Recovered/Not Resolved - Disabling), Weight decreased (n/a - Not Recovered/Not Resolved - Disabling) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10010649912 | 15/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Fall (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |

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| | | | | | | | | | | Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), | applicable - [n/a - n/a - Intramuscular]) | | |
| | | | | | | | | | | Musculoskeletal stiffness (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Pallor (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Presyncope (n/a - Recovering/Resolving -) | | | |
| EU-EC- 10010649973 | 15/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Menstruation delayed (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]), [NOT AVAILABLE] | Not reported | ICSR |
| | | | | | | | | | | | (S - Hypersensitivity - Dose not changed - [n/a - 1{DF} - n/a]) | | |
| EU-EC- 10010650054 | 15/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Cardiac arrest (n/a - Fatal - Results in Death), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | <u>ICSR</u> |
| | | | | | | | | | | in Death), | applicable - [1d - n/a - Unknown]) | | |
| | | | | | | | | | | Nervous system disorder (n/a - Fatal - Results in Death), | | | |
| | | | | | | | | | | Respiratory arrest (n/a - Fatal - Results in Death), | | | |
| | | | | | | | | | | Respiratory failure (n/a - Fatal - Results in Death), | | | |
| | | | | | | | | | | Sudden death (n/a - Fatal - Results in Death), | | | |
| | | | | | | | | | | Syncope (n/a - Fatal - Results in Death) | | | |
| EU-EC- 10010651339 | 15/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Condition), Pain (n/a - Unknown -), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Pyrexia (n/a - Unknown -) | | | |
| EU-EC- 10010651365 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Vaccination failure (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010651624 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Asthenia (n/a - Unknown - Other Medically Important Condition), Pyrexia (3d - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Syncope (3d - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010651893 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Herpes simplex meningoencephalitis (n/a - Recovered/Resolved With Sequelae - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010651919 | 15/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Cough (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Vulval ulceration | COMIRNATY | | _ |

| | | | | | | | | | | | applicable - [1d - | | |
|---------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|-----|--|---|---|-----------|
| J-EC- 0010652101 | 15/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Vaccination failure | n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) | Not reported | IC |
| 1.50 | 111110001 | | | | | 10.17 | | | | (n/a - Unknown - Other Medically Important Condition) | CONTRACT | | 100 |
| J-EC- 0010640630 | 14/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Malaise (2d - Recovered/Resolved -), Oropharyngeal pain (8d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | <u>IC</u> |
| | | | | | | | | | | Pyrexia (3d - Recovered/Resolved | | | |
| U-EC- 0010640720 | 14/11/2021 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Intermenstrual bleeding (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | <u>IC</u> |
| U-EC- 0010640854 | 14/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Resolved -) Hyperventilation (n/a - Recovering/Resolving -) | [TOZINAMERAN] | Not reported | IC |
| U-EC- 0010640884 | 14/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Asthenia (20min - Recovered/Resolved -), Dizziness (20min - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported | IC |
| | | | | | | | | | | Recovered/Resolved -), Pallor (20min - Recovered/Resolved | | | |
| U-EC- 0010640891 | 14/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | Yes | Pyrexia (12h - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - | Not reported | IC |
| U-EC- 0010640930 | 14/11/2021 | Spontaneous | | | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -) | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | IC |
| J-EC- 0010640942 | 14/11/2021 | Spontaneous | Non Hea l thcare | European Economic | Not available | 12-17 Years | Not Specified | Male | No | Fatigue (n/a - Not Recovered/Not | 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] | NOT AVAILABLE (C - n/a - n/a - [n/a - n/a - n/a]), | IC |
| J0100+03+2 | | | Professional | | available | rears | эрестеч | | | Resolved -), Injection site inflammation (n/a - Not Recovered/Not Resolved -), | (S - COVID-19 | [COLECALCIFEROL] (C - n/a - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Injection site pain (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Injection site swelling (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved -), | | | |
| J-EC- | 14/11/2021 | Spontaneous | Haalthaara | Non | Not | 12-17 | Not | Male | No | Myalgia (n/a - Not Recovered/Not Resolved -) Eczema (n/a - | COMIRNATY | Not reported | IC |
| 0010640965 | 14/11/2021 | Spontaneous | Professional | Non European Economic Area | available | Years | Specified | Male | NO | Recovering/Resolving -), Pruritus (n/a - Recovering/Resolving | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | 10 |
| | | | | | | | | | | -), Type I hypersensitivity (n/a | .,, ., ., ., | | |
| | | | | | | | | | | - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Urticaria (n/a - Recovering/Resolving -) | | | |
| U-EC- 0010640968 | 14/11/2021 | Spontaneous | Healthcare Professional | Non European | Not available | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] | Not reported | IC |

| J.11.2022 1 | | | | Economic Area | | | | | | - Other Medically Important Condition) | n/a - | | |
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| EU-EC- 10010640983 | 14/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blood pressure decreased (n/a - Recovering/Resolving - Other Medically Important Condition), Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | Not reported | ICS |
| | | | | | | | | | | Feeling abnormal (n/a - Recovered/Resolved - Other Medically Important Condition), Hypotension (n/a - Recovering/Resolving | | | |
| | | | | | | | | | | Nausea (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010641045 | 14/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICS |
| EU-EC- 10010641061 | 14/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICS |
| EU-EC- 10010641071 | 14/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Resolved -) Chest discomfort (n/a - Not Recovered/Not Resolved -), Chills (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICS |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved -), Headache (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Injection site pain (n/a - Recovering/Resolving -), Injection site pruritus (n/a - Recovering/Resolving | | | |
| | | | | | | | | | | -), Malaise (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - | | | |
| | | | | | | | | | | Recovering/Resolving -), Nausea (n/a - Recovering/Resolving | | | |
| EU-EC- 10010641173 | 14/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Lip swelling (n/a - Unknown - Other Medically Important Condition), | [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Pharyngeal swelling (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Swollen tongue (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| 5U 50 | 14/11/000 | Const. | Nece | | Not | 10.45 | Note | | | Throat tightness (n/a - Unknown - Other Medically Important Condition) | COMPLET | | |
| EU-EC- 10010641177 | 14/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chills (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | <u>ICS</u> |

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| | | | | | | | | | | Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), | immunisation - Not applicable - [n/a - 1{DF} - n/a]) | | |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Headache (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Malaise (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Myalgia (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Nausea (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Recovering/Resolving -) | | | |
| EU-EC- 10010637976 | 13/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Erythema (0d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | Injury (0d - Recovered/Resolved -), | applicable - [n/a - 1{DF} - Intramuscular]) | | |
| | | | | | | | | | | Urticaria (0d - Recovered/Resolved -) | | | |
| EU-EC- 10010637980 | 13/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Rash erythematous (0d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICSR |
| | | | | | | | | | | Urticaria (0d - Recovered/Resolved -) | 1{DF} - Intramuscular]) | | |
| EU-EC- 10010638099 | 13/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Herpes simplex (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a | Not reported | ICSR |
| | | | | | | | | | | Injury (n/a - Recovered/Resolved -) | - [n/a3mL - n/a]) | | |
| EU-EC- 10010638320 | 13/11/2021 | Spontaneous | Healthcare Professional | | | 12-17 Years | | Male | No | Bradycardia (n/a - Recovering/Resolving - Other Medically | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010638381 | 13/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - | Not reported | ICSR |
| | | | | | | | | | | Loss of consciousness (n/a - Recovering/Resolving - Caused/Prolonged | Intramuscular]) | | |
| | | | | | | | | | | Hospitalisation), Myalgia (n/a - Recovering/Resolving - Caused/Prolonged | | | |
| | | | | | | | | | | Hospitalisation), Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010638777 | 13/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Menstruation irregular (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICSR |
| EU-EC- 10010638817 | 13/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Epistaxis (n/a - Not Recovered/Not Resolved -), | 1{DF} - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | Haematoma (n/a - Not Recovered/Not Resolved -), | applicable - [n/a - 1{DF} - n/a]) | | |
| | | | | | | | | | | Headache (1d - Recovered/Resolved -), | | | |
| | | | | | | | | | | | | | |

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|-----------------------|------------|-------------|-----------------------------------|------------------------------|------------------|----------------|------------------|--------|-----|---|---|--------------|-------------|
| | | | | | | | | | | Injection site erythema (3d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Injection site inflammation (3d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Injection site swelling (3d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Injection site warmth (3d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Myalgia (1d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Nausea (1d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Pyrexia (1d - Recovered/Resolved -) | | | |
| EU-EC- 10010638861 | 13/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dysmenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | <u>ICSR</u> |
| EU-EC- 10010638866 | 13/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Tinnitus (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10010638885 | 13/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Child | Female | No | Drug ineffective (7d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [27d3mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010638964 | 13/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10010639287 | 13/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | Yes | Influenza like illness (1d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010639860 | 13/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Skin exfoliation (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] | Not reported | ICSR |
| EU-EC- 10010639985 | 13/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain upper (2d - Recovered/Resolved -), Headache (2d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Malaise (2d - Recovered/Resolved -), Nausea (2d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Polymenorrhoea (n/a - Unknown -), | | | |
| EU-EC- | 13/11/2021 | Spontaneous | Non | European | Not | 12-17 | Adolescent | Malo | No | Pyrexia (2d - Recovered/Resolved -) | COMIRNATY | Not reported | ICSP |
| 10010640004 | 11/2021 | aportaneous | Healthcare Professional | European Economic Area | available | Years | AUDESCENT | nale | INU | Lymphadenopathy (n/a - Not Recovered/Not Resolved -) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010640074 | 13/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Heavy menstrual bleeding (n/a - Unknown -), Nausea (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10010640109 | 13/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Pyrexia (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |

| | | | | | | | | | | | applicable - [n/a - 1{DF} - | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|--|--|--------------|------|
| EU-EC- 10010640146 | 13/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Fatigue (1d - Recovered/Resolved -), Menstrual disorder (n/a - Not Recovered/Not | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10010640212 | 13/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Resolved -) Chills (1d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (1d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Malaise (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -), Rash (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010625665 | 12/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Tremor (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010626457 | 12/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Loss of consciousness (0d - Recovered/Resolved - Other Medically Important Condition), Nausea (0d - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Recovered/Resolved -), Seizure (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Tremor (0d - Recovered/Resolved -) | | | |
| EU-EC- 10010626616 | 12/11/2021 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Not Specified | Male | No | Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), Vomiting (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10010626718 | 12/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Recovering/Resolving -) Immune thrombocytopenia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010626737 | 12/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Syncope (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Vomiting (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010627828 | 12/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chills (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved -), Syncope (n/a - Unknown -) | | | |
| EU-EC- 10010627882 | 12/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Arthralgia (n/a - Recovering/Resolving -), Body temperature | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |

| | | | | | | | | | | increased (n/a - Recovering/Resolving | applicable - [n/a - | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|---|---|--------------|-------------|
| | | | | | | | | | | recovering/Resolving -), Chills (72h - | ן זעטו <u>ז -</u> וו/מ]) | | |
| | | | | | | | | | | Recovered/Resolved -), | | | |
| | | | | | | | | | | Fatigue (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Headache (3d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Injection site inflammation (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Injection site pain (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Injection site swelling (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Injection site warmth (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Lymphadenopathy (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Malaise (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Myalgia (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Nausea (3d - Recovered/Resolved -) | | | |
| EU-EC- 10010628445 | 12/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Asthma (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Malaise (n/a - Unknown - Other Medically Important Condition), | n/a - n/a]) | | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Seizure (1d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010628475 | 12/11/2021 | Spontaneous | Healthcare Professional | Non European Economic | Not available | 12-17 Years | Not Specified | Male | No | Dizziness (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |
| | | | | Area | | | | | | Syncope (n/a - | immunisation - Not applicable - [n/a - n/a - n/a]) | | |
| EU-EC- 10010628499 | 12/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Dysmenorrhoea (5d - Recovered/Resolved -), | [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |
| | | | | | | | | | | Heavy menstrual bleeding (5d - Recovered/Resolved | immunisation - Not applicable - [n/a - 1{DF} - n/a]) | | |
| EU-EC- 10010628529 | 12/11/2021 | Spontaneous | Healthcare Professional | Non European Economic | Not available | 12-17 Years | Not Specified | Female | No | Altered state of consciousness (n/a - Unknown - | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | <u>ICSR</u> |
| | | | | Area | | | | | | Caused/Prolonged Hospitalisation), | immunisation - Not applicable - [n/a - n/a - n/a]) | | |
| | | | | | | | | | | Anaphylactic reaction (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Dyspnoea (n/a - Unknown - Caused/Prolonged | | | |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|---------|---|--|--|------|
| | | | | | | | | | | Hospitalisation), Oropharyngeal discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010629224 | 12/11/2021 | Spontaneous | Non Healthcare Professional | European Economic | Not available | 12-17 Years | Adolescent | Female | No | Arthralgia (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | ANTICONCEPTIEPIL [NOT AVAILABLE] (C - n/a - n/a - [n/a - n/a - n/a]) | ICSR |
| | | | FIORESSIONAL | Alea | | | | | | Chills (n/a - Not Recovered/Not Resolved -), | immunisation - Not applicable - [n/a - 1{DF} - n/a]) | 11/4 - 11/4]) | |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Injection site pain (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Myalgia (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Weight decreased (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010629230 | 12/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adult | Female | No | Flushing (30min - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |
| | | | | | | | | | | Presyncope (30min - Recovered/Resolved -), | immunisation - Not applicable - [n/a - 1{DF} - n/a]) | | |
| | | | | | | | | | | Throat tightness (30min - Recovered/Resolved | | | |
| EU-EC- 10010629456 | 12/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | -) Fatigue (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Hallucination (2d - Recovered/Resolved - Other Medically Important Condition), | n/a - n/a]) | | |
| | | | | | | | | | | Headache (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Myalgia (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010629457 | 12/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Pleurisy (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10010629465 | 12/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Anaphylactic reaction (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | Anaphylactic shock (n/a - Unknown - Caused/Prolonged Hospitalisation), | applicable - [n/a - n/a - n/a]) | | |
| | | | | | | | | | | Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010629479 | 12/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Anaphylactic reaction (2225min - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Loss of consciousness (2257min - | | | |

| | 0 | I | I | I | ı | ı | ı | | . | Pecovered/Pecolved | I | I | ı |
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| | | | | | | | | | | Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010629529 | 12/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Fall (n/a - Unknown -), Head injury (n/a - Unknown -), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICS |
| | | | | | | | | | | Pyrexia (n/a - Unknown -), | n/a - n/a]) | | |
| | | | | | | | | | | Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Tremor (n/a - Unknown -), | | | |
| | | | | | | | | | | Vomiting (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010629939 | 12/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Nephrotic syndrome (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - | Not reported | ICS |
| EU-EC- 10010630898 | 12/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Fatigue (n/a - Not Recovered/Not Resolved -), | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICS |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved -), | immunisation - Not applicable - [n/a - 1{DF} - n/a]) | | |
| | | | | | | | | | | Myalgia (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010631618 | 12/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain upper (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - | Not reported | ICS |
| | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | Intramuscular]) | | |
| EU-EC- 10010631844 | 12/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Cardiomyopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICS |
| | | | | | | | | | | Diarrhoea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Vaccination site erythema (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Vaccination site pain (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010631953 | 12/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Alanine aminotransferase decreased (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICS |
| | | | | | | | | | | Albumin globulin ratio increased (n/a - Unknown -), | n/a - Intramuscular]) | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | Bilirubin conjugated increased (n/a - Unknown -), | | | |

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| | | | | | | | | | | Blood bilirubin increased (n/a - Unknown -), | | | |
| | | | | | | | | | | Blood glucose increased (n/a - Unknown -), | | | |
| | | | | | | | | | | Blood potassium decreased (n/a - Unknown -), | | | |
| | | | | | | | | | | Blood pressure decreased (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Blood sodium decreased (n/a - Unknown -), | | | |
| | | | | | | | | | | Depressed level of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Headache (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Heart rate decreased (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Mean platelet volume decreased (n/a - Unknown -), | | | |
| | | | | | | | | | | Nausea (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Protein total decreased (n/a - Unknown -), | | | |
| | | | | | | | | | | Shock (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010631959 | 12/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (6d - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Chills (n/a - Unknown -), | .,, .,, | | |
| | | | | | | | | | | Decreased appetite (6d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Erythema (8d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Kawasaki's disease (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pruritus (8d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (8d - Recovered/Resolved - Other Medically Important Condition), | | | |
| EU-EC- | 12/11/2021 | Spontaneous | Healthcaro | Non | Not | 12-17 | Not | Male | No | Rash (n/a - Unknown -) Blood pressure | COMIRNATY | Not reported | ICSR |
| 10010631962 | 12/11/2021 | aporica reous | Professional | | | Years | Specified | inale | INU | decreased (n/a - Recovered/Resolved - Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | постеропец | ICSK |

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| | | | | | | | | | Dysphoria (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | Feeling hot (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | Hyperhidrosis (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition) | | | |
| 12/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Presyncope (0d - Recovered/Resolved - Other Medically | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICS |
| 12/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Recovered/Not Resolved -), | [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICS |
| | | | | | | | | | Not Recovered/Not Resolved - Other Medically Important Condition) | n/a - n/a]) | | |
| 12/11/2021 | Spontaneous | Healthcare | Economic | | 12-17 Years | Adult | Not Specified | No | COVID-19 (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) | COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a]) | <u>ICS</u> |
| | | | | | | | | | Vaccination failure (n/a - Recovered/Resolved - Other Medically | | | |
| 12/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Important Condition) Herpes zoster (n/a - Recovering/Resolving - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICS |
| | | | | | | | | | Pain in extremity (1wk - Recovered/Resolved | n/a - Intramuscular]) | | |
| 12/11/2021 | Spontaneous | Healthcare | | Not available | 12-17 Years | Not Specified | Not Specified | No | Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other | | Not reported | ICS |
| | | | | | | | | | Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | Recovered/Resolved - Other Medically Important Condition) | | | |
| 12/11/2021 | Spontaneous | Healthcare | Economic | | 12-17 Years | Adult | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | [TOZINAMERAN] (S - Immunisation - n/a - [n/a - | COMIRNATY [TOZINAMERAN] (C - Immunisation - n/a - [n/a - 1{DF} - n/a]) | ICS |
| | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | _(=-,) .,,=_j) | | |
| 12/11/2021 | Spontaneous | Healthcare | Economic | | 12-17 Years | Adolescent | Female | No | Recovered/Not Resolved - Other | (S - n/a - n/a - [1d - n/a - | Not reported | ICS |
| | | | | | | | | | Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important | | | |
| | | | | | | | | | Condition), | | | |
| 1 1 | 2/11/2021 2/11/2021 2/11/2021 | 2/11/2021 Spontaneous 2/11/2021 Spontaneous 2/11/2021 Spontaneous 2/11/2021 Spontaneous 2/11/2021 Spontaneous | 2/11/2021 Spontaneous Healthcare Professional 2/11/2021 Spontaneous Non Healthcare Professional | Professional European Economic Area 2/11/2021 Spontaneous Healthcare Professional European Economic Area 2/11/2021 Spontaneous Non Healthcare Professional Economic Area | Professional European Economic Area Non Professional European Economic Area Non Professional European Economic Area | Professional Economic Area Non Economic Area Non Professional Economic Area Non Healthcare Professional Economic Area Non | Professional European Reconomic Area 2/11/2021 Spontaneous Healthcare Professional European Reconomic Area 2/11/2021 Spontaneous Non Healthcare Professional Healthcare Professional Reconomic Area Non European Reconomic Area Not Wears Specified | Professional European Endemonic Area Specified Spe | Professional European Carcamic Area available Years Specified Spec | Professional Forontics Professional European Pro | Recovered Recolored Condition Recovered Recolored Recovered Recolore | 2/11/7021 Sportenessa Main Ma |

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| | | | | | | | | | | Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Rhinitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Urticaria chronic (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010632681 | 12/11/2021 | Spontaneous | Non Healthcare Professional | | Not available | 12-17 Years | Adult | Female | No | Feeling cold (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved -), | immunisation - Not applicable - [n/a - 1{DF} - n/a]) | | |
| | | | | | | | | | | Myalgia (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010632971 | 12/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Cardiac failure (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| FUEC | 12/11/2021 | Constitution | New | New | Nec | 12.17 | Net | Family | No | Myocarditis (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | COMPNATY | | Icco |
| EU-EC- 10010632995 | 12/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Dizziness postural (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Dysstasia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Gait disturbance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Gait inability (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Somnolence (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010632996 | 12/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Urticaria (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10010633006 | 12/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Decreased appetite (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Gastric disorder (n/a - Not Recovered/Not Resolved - | | | |

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| | | | | | | | | | | Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | General physical health deterioration (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010633414 | 12/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Arthralgia (n/a - Recovering/Resolving -), | (S - COVID-19 | Not reported | <u>ICSR</u> |
| | | | | | | | | | | Chills (n/a - Not Recovered/Not Resolved -), | immunisation - Not applicable - [n/a - 1{DF} - n/a]) | | |
| | | | | | | | | | | Dizziness (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Dyspnoea (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Injected limb mobility decreased (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Myalgia (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Nausea (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010633556 | 12/11/2021 | Spontaneous | Non Healthcare Professional | | Not available | 12-17 Years | Adolescent | Female | No | Dizziness (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | <u>ICSR</u> |
| | | | | | | | | | | Gait disturbance (n/a | n/a - | | |
| | | | | | | | | | | Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Muscular weakness (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Tremor (n/a - Recovered/Resolved | | | |
| | | | | | | | | | | -), Vision blurred (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010633601 | 12/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Appendicitis (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - | Not reported | <u>ICSR</u> |
| | | | | | | | | | | Peritonitis (10d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | Drug withdrawn - [1d - 1{DF} - Intramuscular]) | | |
| EU-EC- 10010633781 | 12/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Menstrual disorder (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010633867 | 12/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Immunisation reaction (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - 1{DF} - | Not reported | ICSR |
| | | | | | | | | | | | Întramuscular]) | | |

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| EU-EC- 10010633909 | 12/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Menometrorrhagia (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010634296 | 12/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Rash erythematous (5d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010634321 | 12/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Dysmenorrhoea (n/a - Recovered/Resolved -), Heavy menstrual bleeding (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010634364 | 12/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Menstruation delayed (n/a - Not Recovered/Not Resolved -), Presyncope (1d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010634379 | 12/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | -) Chest pain (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010634391 | 12/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Herpes zoster (n/a - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010634516 | 12/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Dysarthria (n/a - Recovering/Resolving - Other Medically Important Condition), Headache (n/a - Recovering/Resolving - Other Medically Important Condition), Migraine (n/a - Recovering/Resolving - Other Medically Important Condition), Muscular weakness (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Nausea (n/a - Recovering/Resolving - Other Medically Important Condition), Values (n/a - Recovering/Resolving - Other Medically Important Condition), | | [CETIRIZINE DIHYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]) | ICSR |
| 511 50 | 12/11/2021 | | | | | 10.17 | | | | Visual impairment (n/a - Unknown - Other Medically Important Condition) | | | 1000 |
| EU-EC- 10010635592 | 12/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Asthma exercise induced (n/a - Not Recovered/Not Resolved -), Fatigue (2d - Recovered/Resolved -), Headache (1d - Recovered/Resolved -), Injection site pain (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), Pyrexia (1d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10010635615 | 12/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Fatigue (2d - Recovered/Resolved -), Malaise (2d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSR |

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| | | | | | | | | | | Pruritus (n/a - Recovering/Resolving -) | | | |
| EU-EC- 10010635627 | 12/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Headache (n/a - Not Recovered/Not Resolved -), Injection site inflammation (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSF |
| | | | | | | | | | | -), Injection site pain (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Injection site swelling (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Palpitations (n/a - Recovering/Resolving -) | | | |
| EU-EC- 10010635876 | 12/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Blood pressure decreased (26min - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | Not reported | <u>ICSF</u> |
| | | | | | | | | | | Cold sweat (n/a - Recovered/Resolved - Other Medically Important Condition), | intamuscular j | | |
| | | | | | | | | | | Depressed level of consciousness (19min - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Fall (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Gaze palsy (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Heart rate decreased (1min - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pallor (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Presyncope (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (n/a - Unknown -), | | | |
| | | | | | | | | | | Vision blurred (n/a - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010636771 | 12/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dyspnoea (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 |
| | | | | | | | | | | Dyspnoea (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010637055 | 12/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Dyspnoea (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition), | [TOZINAMERAN] (S - n/a - Unknown - [n/a - n/a - n/a]) | Not reported | ICSI |

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| | | | | | | | | | | Lip swelling (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition), | | | |
| | | | | | | | | | | Oropharyngeal pain (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition), | | | |
| | | | | | | | | | | Swollen tongue (n/a | | | |
| | | | | | | | | | | Recovering/Resolving - Life Threatening, Other Medically Important Condition), | | | |
| | | | | | | | | | | Wheezing (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition), | | | |
| | | | | | | | | | | Withdrawal syndrome (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition) | | | |
| EU-EC- 10010637369 | 12/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010613468 | 11/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010613819 | 11/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Agitation (n/a - Recovered/Resolved -), Feeling hot (n/a - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | [ASCORBIC ACID, DRIED FERROUS SULFATE, SODIUM ASCORBATE, FERROUS SULFATE] (C - n/a - n/a - [n/a - n/a - n/a]) | ICSR |
| | | | | | | | | | | Recovered/Resolved -), Insomnia (n/a - Recovered/Resolved -), | 1{DF} - Intramuscular]) | | |
| | | | | | | | | | | Pain in extremity (n/a - Recovered/Resolved -) | | | |
| EU-EC- 10010614060 | 11/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Asthenia (0d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a | Not reported | ICSR |
| | | | | | | | | | | Chills (0d - Recovered/Resolved -), | - [n/a3mL - Intramuscular]) | | |
| | | | | | | | | | | Hyperhidrosis (0d - Recovered/Resolved -), | | | |
| 511.50 | | | | | | 10.17 | | | | Vision blurred (0d - Recovered/Resolved -) | 20147011477 | | 1000 |
| EU-EC- 10010614354 | 11/11/2021 | Spontaneous | Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Dyskinesia (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Hyperventilation (n/a - Recovering/Resolving | , - ·/··// | | |
| | | | | | | | | | | - Other Medically Important Condition), | | | |
| | | | | | | 42 :- | | | | Somatic symptom disorder (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010614365 | 11/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Feeling cold (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important | applicable - [1d - n/a - n/a]) | | |

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| | | | | | | | | | | Condition), Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Nasopharyngitis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Swelling (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Syncope (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition) | | | |
| EU-EC- 10010614739 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 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 - [1d - n/a - n/a]) | Not reported | <u>ICSR</u> |
| | | | | | | | | | | Hypopnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Productive cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010614755 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Confusional state (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Syncope (1d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | 10.1- | | | | Tremor (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | 1.000 |
| EU-EC- 10010614799 | 11/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Abdominal pain upper (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | | |
| EU-EC- 10010614875 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICSR |
| | | | | | | | | | | Dizziness postural (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | n/a - n/a]) | | |
| | | | | | | | | | | Pallor (n/a - Not Recovered/Not | | | |

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| | | | | | | | | | | | Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Sudden onset of sleep (n/a - Unknown - Other Medically Important Condition) | | | |
| | EU-EC- 10010615158 | 11/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - | Not reported | <u>ICSR</u> |
| | | | | | | | | | | | Hypomenorrhoea (n/a - Not Recovered/Not Resolved -), | Intramuscular]) | | |
| | | | | | | | | | | | Menstrual disorder (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | | Menstruation irregular (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | | Syncope (0d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Vaccination site pain (1d - Recovered/Resolved -) | | | |
| | EU-EC- 10010615281 | 11/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chills (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | MELATONIN [MELATONIN] (C - Poor quality sleep - n/a - [n/a - n/a - n/a]), [METHYLPHENIDATE | ICSR |
| | | | | | | | | | | | Fatigue (n/a - Unknown - Other Medically Important Condition), | n/a - n/a]) | HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | | | Feeling cold (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Feeling hot (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Insomnia (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Nausea (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Pyrexia (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| | EU-EC- 10010615289 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chills (n/a - Unknown - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | <u>ICSR</u> |
| | | | | | | | | | | | Dizziness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | n/a - n/a]) | | |
| | | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved - Other | | | |

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| | | | | | | | | | | Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010615292 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10010615299 | 11/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation) | [TOZINAMERAN] [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010615302 | 11/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Arachnoid cyst (n/a - Unknown - Caused/Prolonged Hospitalisation), Benign enlargement of the subarachnoid spaces (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - .3mL - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Kyphoscoliosis (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Seizure (4530min - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | | |
| EU-EC- 10010616178 | 11/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Body temperature increased (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | [EPINEPHRINE] (N - n/a - n/a - [n/a - n/a - n/a]) | ICSR |
| | | | | | | | | | | Chest pain (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Feeling abnormal (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Hypoaesthesia (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Injection site hypoaesthesia (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Palpitations (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Tachycardia (n/a - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010616218 | 11/11/2021 | Spontaneous | Healthcare Professional | Non European Economic | Not available | 12-17 Years | Not Specified | Female | No | Blood pressure increased (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |
| | | | | Area | | | | | | Diplopia (n/a - Unknown -), | immunisation - Not applicable - [1d - n/a - n/a]) | | |
| | | | | | | | | | | Feeling abnormal (n/a - Unknown -), | | | |
| | | | | | | | | | | Syncope (1d - | | | |

| | | | | | | | | | | Recovered/Resolved - Other Medically | | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|------------------|----|---|--|--------------|------|
| EU-EC- 10010616232 | 11/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Important Condition) Anaphylactic shock (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular]) | Not reported | ICSF |
| | | | | | | | | | | Dizziness (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition), | | | |
| | | | | | | | | | | Eye swelling (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition), | | | |
| | | | | | | | | | | Loss of consciousness (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition), | | | |
| | | | | | | | | | | Oxygen saturation decreased (n/a - Recovered/Resolved - Life Threatening, Other Medically Important Condition) | | | |
| EU-EC- 10010616266 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Not Specified | No | 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 |
| | | | | | | | | | | Vomiting (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010616270 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Anaphylactic shock (1d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Chest discomfort | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | (n/a - Unknown - Caused/Prolonged Hospitalisation), Dyspnoea (n/a - Unknown - Caused/Prolonged | | | |
| | | | | | | | | | | Hospitalisation), Rash (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Swelling face (n/a - Unknown - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010616272 | 11/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Throat tightness (n/a - Recovering/Resolving -), Troponin increased | | | |
| | | | | | | | | | | (n/a - Recovering/Resolving -) | | | |
| EU-EC- 10010616306 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Headache (2d - Recovered/Resolved - Other Medically Important Condition), Influenza like illness | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSF |
| | | | | | | | | | | (2d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010616378 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European | Not available | 12-17 Years | Not Specified | Male | No | Angina pectoris (n/a - Not Recovered/Not Resolved - Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSF |

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| | | | | Economic Area | | | | | | Medically Important Condition), | immunisation - Not applicable - [1d - n/a - n/a]) | | |
| | | | | | | | | | | Chest pain (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Musculoskeletal disorder (n/a - Unknown -) | | | |
| EU-EC- 10010616379 | | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | COVID-19 (n/a - Recovering/Resolving - Other Medically Important Condition), | (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), | n/a - n/a]) | | |
| | | | | | | | | | | Dyspnoea (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Fatigue (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Palpitations (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (n/a - Unknown - Other Medically Important Condition) | | | 1000 |
| EU-EC- 1001061639 | | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICSR |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | n/a - n/a]) | | |
| | | | | | | | | | | Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Nausea (n/a - Recovered/Resolved With Sequelae - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Restlessness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010616398 | | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Arthralgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not apple a plant plant | Not reported | ICSR |
| | | | | | | | | | | Diarrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | n/a - n/a]) | | |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved - Other | | | |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|---------|--------|--|---|--|------|
| | | | | | | | | | | Medically Important Condition), | | | |
| | | | | | | | | | | Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010616537 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Menarche (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10010616654 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Child | Female | No | COVID-19 immunisation (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]), | INTUNIV [GUANFACINE] (C - Tourette's disorder - n/a - [n/a - n/a - Oral]), MELATONIN [MELATONIN] (C - | ICSR |
| | | | | | | | | | | Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), | MODERNA (CX- 024414)] (S - n/a - | n/a - n/a - [n/a - n/a - Oral]), [FLUTICASONE PROPIONATE] (C - Asthma - n/a - [n/a - n/a - n/a]), | |
| | | | | | | | | | | Fatigue (n/a - Unknown - Caused/Prolonged Hospitalisation), | n/a - [1d - n/a - Intramuscular]) | [IACTULOSE, LACTULOSE, LIQUID] (C - Constipation - n/a - [n/a - n/a - n/a]), [METHYLPHENIDATE | |
| | | | | | | | | | | Hypoaesthesia (n/a - Unknown - Caused/Prolonged Hospitalisation), | | IME INTERPEDIATE HYDROCHLORIDE] (C - Attention deficit hyperactivity disorder - n/a - [n/a - n/a - Oral]), [RISPERIDONE] (C - Tourette's | |
| | | | | | | | | | | Livedo reticularis (n/a - Unknown - Caused/Prolonged Hospitalisation), | | disorder - n/a - [n/a - n/a - Oral]), [SALBUTAMOL, SALBUTAMOL SULFATE] (C - Asthma - n/a - | |
| | | | | | | | | | | Muscular weakness (n/a - Unknown - Caused/Prolonged Hospitalisation), | | [n/a - n/a - Respiratory (inhalation)]) | |
| | | | | | | | | | | Slow speech (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| Ell EC | 11/11/2021 | Constant | Non | 5 | Net | 12.17 | Adolescent | NA-I- | NI- | Vision blurred (n/a - Unknown - Caused/Prolonged Hospitalisation) | COMPNATY | Network | ICCD |
| EU-EC- 10010616902 | | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | | | No | Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition) | (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10010616983 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| EU FC | 11/11/2021 | Sporton | Non | Non | Not | 12.17 | Not | Mala | No | Hyperventilation (n/a - Unknown - Other Medically Important Condition) | - | Not reported | ICCD |
| EU-EC- 10010616985 | 11/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Anaphylactic reaction (n/a - Unknown - Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported | ICSR |
| EU FC | 11/11/2021 | Charter | Non | Nor | Not | 12.47 | Not | Eores!- | Ne | Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition) | Intramuscular]) | Not reported | ICCD |
| EU-EC- 10010617057 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dysmenorrhoea (n/a - Unknown - Other Medically Important Condition), Menstrual disorder | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | (n/a - | n/a - n/a]) | | |

| 7.11.2022 1 | | ı | ı | ı | ı | ı | ı | | | isting report | I | 1 | 1 |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|---|---|--------------|-------------|
| | | | | | | | | | | Recovering/Resolving - Other Medically | | | |
| EU-EC- 10010617064 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Important Condition) Syncope (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSF |
| | | | | | | | | | | Visual impairment (n/a - Recovering/Resolving -) | | | |
| EU-EC- 10010617474 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Feeling abnormal (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Syncope (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010617485 | 11/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICSF |
| | | | | | | | | | | Pericarditis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | n/a - Intramuscular]) | | |
| EU-EC- 10010617531 | 11/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Angioedema (1d - Recovered/Resolved - Life Threatening), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | Angioedema (n/a - Unknown - Life Threatening, Other Medically Important Condition), | applicable - [1d - n/a - n/a]) | | |
| | | | | | | | | | | Clonic convulsion (n/a - Unknown - Life Threatening), | | | |
| | | | | | | | | | | Dyspnoea (n/a - Unknown - Life Threatening), | | | |
| | | | | | | | | | | Hot flush (n/a - Unknown - Life Threatening), | | | |
| | | | | | | | | | | Hypokinesia (n/a - Unknown - Life Threatening), | | | |
| | | | | | | | | | | Malaise (n/a - Unknown - Life Threatening), | | | |
| | | | | | | | | | | Rash (1d - Recovered/Resolved - Life Threatening), | | | |
| | | | | | | | | | | Tonic convulsion (n/a - Unknown - Life Threatening), | | | |
| | | | | | | | | | | Tremor (n/a - Unknown - Life Threatening) | | | |
| EU-EC- 10010617559 | | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Menstruation delayed (n/a - Not Recovered/Not Resolved -) | CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- 10010617648 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Urticaria (155h - Recovered/Resolved - Life Threatening, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | <u>ICSR</u> |
| EU-EC- 10010617658 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Hypersensitivity (n/a - Recovering/Resolving - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] | Not reported | ICSR |
| | | | | | | | | | | Pain (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pruritus (n/a - Recovering/Resolving - Other Medically Important | | | |

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| EU-EC- 10010617779 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Child | Female | No | Condition), Rash (n/a - Recovering/Resolving - Other Medically Important Condition), Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition) Dizziness (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Myalgia (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Nausea (n/a - Not Recovered/Not Resolved -), Pyrexia (n/a - Not Recovered/Not Resolved -), | COMIRNATY CONCENTRATE FOR DISPERSION FOR INJECTION COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) [TOZINAMERAN] (S - COVID-19 immunisation - Unknown - [n/a - n/a - n/a]) | [PROPRANOLOL HYDROCHLORIDE] (C - Migraine prophylaxis - Unknown - [n/a - 20mg - n/a]), [SERTRALINE, SERTRALINE HYDROCHLORIDE] (C - Anxiety, Depression - Unknown - [n/a - 50mg - n/a]) | ICSR |
| | | | | | | | | | | Sensitive skin (n/a - Not Recovered/Not | | | |
| EU-EC- 10010617892 | 11/11/2021 | Spontaneous | Non Healthcare Professional | | Not available | 12-17 Years | Not Specified | Female | No | Resolved -) Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | [ETHINYLESTRADIOL, LEVONORGESTREL] (C - Endometriosis - n/a - [n/a - 1{DF} - n/a]) | ICSR |
| | | | | | | | | | | Menstrual disorder (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Not Recovered/Not | | | |
| EU-EC- 10010618286 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Resolved -) Headache (n/a - Recovered/Resolved -), Injection site erythema (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Injection site swelling (n/a - Recovered/Resolved -), Nausea (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Vaccination site reaction (n/a - | | | |
| EU-EC- 10010618684 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Recovered/Resolved -) Application site pain (n/a - Unknown - Other Medically Important Condition), Application site | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | swelling (n/a - Unknown -), Cardiovascular disorder (n/a - Recovered/Resolved - Other Medically Important | | | |
| | | | | | | | | | | Condition), Confusional state (n/a - Recovered/Resolved -), | | | |
| | | | | | | | | | | Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), Fatigue (n/a - | | | |
| EU-EC- 10010618909 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Unknown -) Menstrual disorder (5d - Unknown -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |
| | | | | | | | | | | Menstruation irregular (5d - Unknown -) | immunisation - Not applicable - [n/a - n/a - n/a]) | | |

| EU-EC- 10010618929 | 11/11/2021 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Adolescent | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
|-----------------------|------------|------------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|---|---|------------------------------------|----------|
| | | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010619044 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Influenza (n/a - Recovering/Resolving - Other Medically Important Condition), | (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Influenza like illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | n/a - n/a]) | | |
| | | | | | | | | | | Limb discomfort (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Mobility decreased (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010619125 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Discomfort (n/a - Recovering/Resolving - Other Medically Important Condition), | (S - COVID-19 immunisation - Not applicable - [1d - | Contraception - n/a - [n/a - n/a - | ICSR |
| | | | | | | | | | | Dysphagia (n/a - Recovering/Resolving - Other Medically Important Condition), | n/a - Intramuscular]) | n/a]) | |
| | | | | | | | | | | Rash (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Swollen tongue (n/a | | | |
| | | | | | | | | | | - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Throat tightness (n/a | | | |
| | | | | | | | | | | Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Urticaria (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010619264 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dysmenorrhoea (n/a - Recovering/Resolving - Other Medically Important Condition) | immunisation - Not | Not reported | ICSR |
| EU-EC- 10010619325 | 11/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Dizziness (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Vomiting (n/a - Unknown - Other Medically Important Condition) | .3mL - Intramuscular]) | | |
| EU-EC- 10010619326 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Conjunctivitis (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 |
| | | | | | | | | | | Insomnia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | 1,4 1,41,5 | | |
| | | | | | | | | | | Myalgia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Nasal congestion (n/a - Not Recovered/Not Resolved - Other | | | |
| ns://dan.ei | ma auran | ∣ a.eu/analyi | l tice/saw.dl | 2 G o | I | 1 | I | I | 1 | I | I | I | 58/8 |

| EU-EC- 10010619502 Il/11/2021 Spontaneous Non Healthcare Professional Real Real Real Real Real Real Real Re | |
|--|--|
| EU-EC- 10010619502 EU-EC- 10010619502 EU-FC- | |
| Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) EU-EC-10010619502 11/11/2021 Spontaneous Non Healthcare Professional Professional Real Not Recovered/Not Resolved - Other Medically Important Condition) Non Healthcare Professional Resolved - Not Recovered/Not Resolved - Other Medically Important Condition) Not reported Not Recovered/Not Resolved - Other Medically Important Condition) | |
| EU-EC- 10010619502 | |
| Healthcare Professional Resolved -), (S - COVID-19 immunisation - Not members of members of the professional Resolved -), (S - COVID-19 immunisation - Not applicable - [n/a - (n/a - Not n/a - n/a]) | |
| | ICSF |
| Resolved -) | |
| EU-EC- 101010619541 Spontaneous Realthcare Professional Spontaneous Area Non Healthcare Professional Spontaneous Area Specified Specifie | ICSF |
| Anosmia (n/a - immunisation - n/a Unknown -), - [n/a - 1{DF} - Intramuscular]) | |
| Arthralgia (n/a - Unknown - Life Threatening), | |
| Back pain (n/a - Unknown - Life Threatening), | |
| Myalgia (n/a - Unknown - Life Threatening), | |
| Skin irritation (n/a - Unknown - Life Threatening), | |
| Somnolence (n/a - Unknown - Life Threatening) | |
| EU-EC- 10010619932 Spontaneous Healthcare Professional Reconomic Area Specified Resolved - Caused/Prolonged Hospitalisation) Healthcare Professional Economic Area Not reported Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) n/a - [n/a - n/a | ICSF |
| EU-EC- 101010620010 Spontaneous Healthcare Professional European Economic Spontaneous Healthcare Professional Economic Healthcare Professional Economic European available Specified Speci | ICSF |
| Area Condition), immunisation - Not applicable - [1d - | |
| EU-EC- 11/11/2021 Spontaneous Non Not 12-17 Not Female No Blister (n/a - Not Recovered/Not Recovered/Not Resolved - Other (S - COVID-19 n/a - n/a]), | ACICLOVIR ICSF |
| Area Medically Important immunisation - Not Condition) Condition Conditi | AMINE MALEATE] (C n/a - n/a - n/a]) |
| EU-EC- 10010620096 11/11/2021 Spontaneous Spontaneou | ICSF |
| n/a - n/a]) Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), | |
| Dyspnoea (n/a - Recovering/Resolving - Other Medically Important Condition), | |
| Headache (n/a - Recovering/Resolving - Other Medically Important Condition), | |
| Heart rate increased (1d - Recovered/Resolved - Other Medically Important Condition), | |
| Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition), | |

| 0.11.2022 1 | | | | | | | | Kuii | | Vision blurred (n/a - Recovering/Resolving - Other Medically | | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|---|---|--------------|------|
| EU-EC- 10010620293 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Important Condition) Dysmenorrhoea (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - | Not reported | ICSF |
| EU-EC- 10010620334 | 11/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Drug hypersensitivity (n/a - Recovered/Resolved - Other Medically Important Condition), | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Urticaria (n/a - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010620335 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Bronchospasm (n/a - Fatal - Results in Death), Death (n/a - Fatal - Results in Death), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Dyspnoea (n/a - Unknown - Caused/Prolonged Hospitalisation), | 11/a - 11/a]) | | |
| | | | | | | | | | | Loss of consciousness (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| EU-EC- 10010620344 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Vaccination site pain (n/a - Unknown -) Chest pain (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 |
| | | | | | | | | | | Dyspnoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | | |
| EU-EC- 10010620376 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Palpitations (n/a - Unknown -) Muscular weakness (n/a - Not Recovered/Not Resolved - Disabling), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Vaccination site movement impairment (n/a - Not Recovered/Not Resolved - Disabling) | | | |
| EU-EC- 10010620425 | 11/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Lymphadenopathy (n/a - Recovering/Resolving -), Pyrexia (n/a - Recovering/Resolving | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010620446 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Lymphadenopathy (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10010620545 | 11/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Parotid gland enlargement (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 - n/a - [n/a3mL - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Rash (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010620558 | 11/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Discomfort (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Palpitations (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | n/a - Intramuscular]) | | |
| EU-EC- 10010620657 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Menstrual disorder (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Oligomenorrhoea (n/a - Not | | | |

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|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|---|--|--------------|------|
| | | | | | | | | | | Recovered/Not Resolved -) | | | |
| EU-EC- 10010620692 | 11/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Presyncope (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10010620934 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved -), Polymenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | ICSF |
| EU-EC- 10010621167 | 11/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Syncope (n/a - Recovered/Resolved - Other Medically Important Condition) | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) | Not reported | ICS |
| EU-EC- 10010621638 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Arthralgia (n/a - Not Recovered/Not Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Nausea (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICSF |
| EU-EC- 10010621903 | 11/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Not Recovered/Not Resolved - Other | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSF |
| EU-EC- 10010621984 | | Spontaneous | Professional | Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Arthralgia (n/a - Unknown - Other Medically Important Condition), Dyspnoea (n/a - Unknown - Other Medically Important Condition), Epistaxis (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Headache (n/a - Unknown - Other Medically Important Condition), Myalgia (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Nausea (n/a - Unknown - Other Medically Important Condition), Medically Important Condition) Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10010621988 | | Spontaneous | Professional | Economic Area | Not available | 12-17 Years | Not Specified | Male | No | | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010622326 | 11/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Loss of consciousness (n/a - Recovered/Resolved - Other Medically Important Condition), Pallor (n/a - Recovered/Resolved - Other Medically Important Condition), Syncope (1d - Recovered/Resolved - Recovered/Resolved) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSE |

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|-----------------------|------------|--------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|------|--|---|--|------|
| EU-EC- | 11/11/2021 | Spontaneous | Healthcare | Non | Not | 12-17 | Not | Male | No | Important Condition) Dysphoria (n/a - | COMIRNATY | Not reported | ICSI |
| 10010622338 | 11,11,2021 | Sportaricous | Professional | European Economic Area | available | Years | Specified | ridic | | Unknown -), Erythema (n/a - Recovering/Resolving -), | [TOZINAMERAN] (S - COVID-19 immunisation - Not | | 100 |
| | | | | | | | | | | Seizure (n/a - Recovering/Resolving - Other Medically Important Condition), | Intramuscular]) | | |
| | | | | | | | | | | Swelling (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Urticaria (n/a - Recovered/Resolved -) | | | |
| EU-EC- 10010622347 | 11/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Facial paralysis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | | Not reported | ICS |
| | | | | | | | | | | Guillain-Barre syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010622361 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Facial paralysis (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), | [TOZINAMERAN] (S - Immunisation - n/a - [n/a - | Not reported | ICS |
| | | | | | | | | | | Guillain-Barre syndrome (15d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | 2{DF} - n/a]) | | |
| EU-EC- 10010622927 | 11/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chills (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICS |
| | | | | | | | | | | Dizziness (n/a - Recovering/Resolving -), | applicable - [n/a - | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Malaise (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010623985 | 11/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Headache (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | [MELATONIN] (C - Insomnia - n/a - [2329d - n/a - Oral]), [METHYLPHENIDATE HYDROCHLORIDE] (C - Disturbance in attention - n/a - | ICSI |
| EU-EC- 10010624070 | 11/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Headache (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Unknown]) | [n/a - n/a - Oral]) Not reported | ICSI |
| EU-EC- 10010624236 | 11/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Headache (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | [FLUTICASONE PROPIONATE] (C - Asthma - n/a - [n/a - n/a - Respiratory (inhalation)]), [IBUPROFEN, IBUPROFEN BP, IBUPROFEN LYSINE, IBUPROFEN, | |
| | | | | | | | | | | | Intramuscular]) | CODEINE PHOSPHATE HEMIHYDRATE] (C - Headache - n/a - [n/a - n/a - Oral]), | |
| | | | | | | | | | | | | [PRANLUKAST] (C - Asthma - n/a - [n/a - n/a - Oral]), [SALMETEROL, SALMETEROL XINAFOATE] (C - Asthma - n/a - | |
| EU-EC- | 11/11/2021 | Spontaneous | | European | Not | 12-17 | Adolescent | Male | No | Contusion (n/a - | COMIRNATY | [n/a - n/a - Respiratory (inhalation)]) Not reported | ICSI |
| 10010624248 | | | Professional | Economic Area | available | Years | | | | Unknown - Caused/Prolonged Hospitalisation), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | | |
| | | | | | | | | | | Haematoma (n/a - Unknown - Caused/Prolonged Hospitalisation), | 1{DF} - n/a]) | | |
| | | | | | | | | | | Malaise (n/a - Recovered/Resolved - Caused/Prolonged | | | |

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|-----------------------|------------|---------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|---------|---------|--|--|--------------|-----|
| | | | | | | | | | | Hospitalisation), Pruritus (n/a - Unknown - Caused/Prolonged | | | |
| EU-EC- 10010624374 | 11/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Hospitalisation) COVID-19 immunisation (n/a - Unknown -), Myocarditis (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]), INTUNIV [GUANFACINE] (S - Attention deficit hyperactivity disorder - Unknown - [n/a - | Not reported | ICS |
| EU-EC- 10010624560 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Pyrexia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | n/a - Unknown]) COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10010624562 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Dizziness (53d - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10010624626 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Dyspnoea (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Rash (0d - Recovered/Resolved - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10010624644 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Hospitalisation) Pyrexia (16d - Recovered/Resolved - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a] | Not reported | ICS |
| EU-EC- 10010624702 | 11/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Chronic kidney disease (n/a - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10010601416 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Bell's palsy (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10010602141 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Electrocardiogram abnormal (n/a - Not Recovered/Not Resolved -), Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10010602179 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (n/a - Unknown - Caused/Prolonged Hospitalisation), Chest pain (n/a - Unknown - Caused/Prolonged Hospitalisation), Palpitations (n/a - Unknown - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Unknown]) | Not reported | ICS |
| EU-EC- 10010602205 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Hospitalisation) Dizziness (n/a - Unknown -), Presyncope (1d - Recovered/Resolved -), Syncope (n/a - Unknown - Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICS |
| EU-EC- | 10/11/2021 | Spontaneous | Healthcare | Non | Not | 12-17 | Not | Female | No | Medically Important Condition) Fatigue (n/a - Not | COMIRNATY | Not reported | ICS |
| 10010602269 | 20/11/2021 | Sportrailetus | Professional | European Economic Area | available | Years | Specified | , endle | NO | raugue (r)/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -), Loss of consciousness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved -), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | not reported | |

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|-----------------------|------------|-------------|-----------------------------------|------------------------------|------------------|----------------|------------------|--------|--------|--|--|--|------|
| | | | | | | | | | | Sensory loss (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Slow response to stimuli (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010602776 | 10/11/2021 | Spontaneous | Healthcare | European Economic | Not available | 12-17 Years | Adolescent | Female | No | Alopecia (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] | Not reported | ICSR |
| | | | Professional | | | | | | | COVID-19 immunisation (n/a - Unknown -) | (S - n/a - n/a - [1d - n/a - n/a]) | | |
| EU-EC- 10010602792 | 10/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Cough (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Rhinitis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010602797 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Rash (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Vaccination site rash (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010603076 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Dysmenorrhoea (n/a - Not Recovered/Not Resolved -), Heavy menstrual | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | bleeding (n/a - Not Recovered/Not Resolved -), | ini amusculai j | | |
| | | | | | | | | | | Menometrorrhagia (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Menstrual disorder (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Menstruation irregular (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010603331 | 10/11/2021 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Amenorrhoea (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | ARANESP 20 MICROGRAMS SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE. [DARBEPOETIN ALFA] (C - Renal transplant - n/a - [n/a - n/a - n/a]), | ICSR |
| | | | | | | | | | | | | CELLCEPT 500 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION [MYCOPHENOLATE MOFETIL] (C - Renal transplant - n/a - [n/a - 150mg - n/a]), | |
| | | | | | | | | | | | | MODIGRAF 1 MG GRANULES FOR ORAL SUSPENSION [TACROLIMUS, TACROLIMUS MONOHYDRATE] (C - Renal transplant - n/a - [n/a - 3mg - n/a]), | |
| | | | | | | | | | | | | [COLECALCIFEROL] (C - Renal transplant - n/a - [n/a - n/a - n/a]), | |
| | | | | | | | | | | | | [ESOMEPRAZOLE, ESOMEPRAZOLE MAGNESIUM] (C - Renal transplant - n/a - [n/a - 10mg - n/a]), | |
| | | | | | | | | | | | | [FERROUS (II) GLYCINE SULFATE COMPLEX, FERROUS ION, FERROUS (II) GLYCINE SULFATE COMPLEX] (C - Renal transplant - n/a - n/a - n/a - n/a]), | |
| | | | | | | | | | | | | [NATRIUMHYDROGENKARBONAT] (C - Renal transplant - n/a - [n/a - 500mg - n/a]), | |
| | | | | | | | | | | | | [PREDNISOLON] (C - Renal | |

| | | | | | | | | | | | | transplant - n/a - [n/a - n/a - n/a]) | |
|----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|--|--|---|----------|
| U-EC- .0010603622 | 10/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Hyperaesthesia (n/a - Unknown - Other Medically Important Condition), Pain in extremity (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Peripheral swelling (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| U-EC- 0010603623 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | | [TOZINAMERAN] | Not reported | IC |
| | | | | | | | | | | Dizziness (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Flushing (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Sneezing (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Tachycardia (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Wheezing (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | | | |
| U-EC- 0010603630 | 10/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | Ī |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| U.50 | 10/41/2021 | | lu bi | | | 12.17 | | | | Vomiting (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMPANY | | |
| U-EC- 0010603654 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Anaphylactic reaction (1d - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | <u>I</u> |
| | | | | | | | | | | Eye pruritus (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation), | | | |
| | | | | | | | | | | Hypersensitivity (n/a - Unknown - Life Threatening, Caused/Prolonged Hospitalisation), | | | |
| U-EC- | 10/11/2021 | Spontaneous | Non | Non | Not | 12-17 | Not | Female | No | Malaise (n/a - Recovered/Resolved - Life Threatening, Caused/Prolonged Hospitalisation) | COMIRNATY | IBUPROFEN [IBUPROFEN, | I |
| 0010603663 | ,,, | | Healthcare Professional | European | available | Years | Specified | | | bleeding (n/a - Recovering/Resolving | [TOZINAMERAN] | IBUPROFEN SODIUM] (C - Pain - n/a - [n/a - n/a - n/a]), | |

| | | | | Economic Area | | | | | | - Caused/Prolonged Hospitalisation, Other Medically Important Condition) | immunisation - Not applicable - [n/a - n/a - n/a]) | [DESOGESTREL, ETHINYLESTRADIOL] (C - Contraception - n/a - [n/a - n/a - n/a]) | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|---|---|--|------|
| EU-EC- 10010603676 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 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 - Intramuscular]) | Not reported | ICS |
| EU-EC- 10010603681 | 10/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chills (n/a - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Disorientation (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Dizziness (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Headache (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (n/a - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010603693 | 10/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Heavy menstrual bleeding (n/a - Recovering/Resolving - Other Medically Important Condition) | | [DESOGESTREL] (C - n/a - n/a - n/a - n/a - n/a - n/a - n/a), [PROPRANOLOL, PROPRANOLOL HYDROCHLORIDE] (C - n/a - n/a - n/a - n/a - n/a) | ICS |
| EU-EC- 10010603732 | 10/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Illness (1d - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY | Not reported | ICSI |
| | | | | | | | | | | Vomiting (n/a - Unknown - Other Medically Important Condition) | , , , <u>,</u> | | |
| EU-EC- 10010603772 | 10/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chest discomfort (n/a - Unknown - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Chest pain (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Dyspnoea (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Fatigue (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010603783 | 10/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Abdominal pain upper (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | [INFLUENZA VIRUS] (C - Immunisation - n/a - [n/a - n/a - n/a]) | ICSI |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010603833 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Abdominal pain (n/a - Recovering/Resolving - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - .3mL - | Not reported | ICS |
| | | | | | | | | | | Diarrhoea (n/a - Recovering/Resolving | Intramuscular]) | | |

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|--|----------|-----------|-------------|------------|----------------------|--|----------|---------|--|--|--------------|------|
| Control Cont | | | | | | | | | Important | | | |
| BU-55 | | | | | | | | | Recovering/Resolving - Other Medically Important | | | |
| Sci-SC 10/11/2021 Southerece Healthcare Healthc | | | | | | | | | Recovering/Resolving - Other Medically Important | | | |
| Professional Exception Professional Except | | | | | | | | | (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| | | | Spontaneous | | European Economic | | Male | No | phosphokinase increased (n/a - Unknown -), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| ELF-C: 10011693342 Sportaneous Intentions (No. 1) Reference (No. 1 | | | | | | | | | (n/a - Unknown - Other Medically Important | | | |
| Cli-EC 10/11/2021 Sportaneous Politicare Month Recovering Recovering Preserving Condition Politicare Politicare Condition Politicare Politicare Condition Politicare Politicare Condition Politicare Politicare Politicare Condition Politicare Pol | | | | | | | | | (n/a - Unknown - Other Medically Important | | | |
| E31-EC- 1011603842 10111/2021 Sportaneous Healthcare Professional Engagement Area Specified Male No. Professional Engagement Area Specified Male No. Professional Engagement Area Specified No. Professional Engagement No. N | | | | | | | | | (n/a - Unknown - Other Medically Important | | | |
| Professional European Campan European Campan | | | | | | | | | Unknown - Other Medically Important | | | |
| EU-EC- 10/11/20/21 Spontaneous Healthcare European Professional European 10/11/20/21 Spontaneous Healthcare European Professional Professiona | | | Spontaneous | | European Economic | | Male | No | Recovering/Resolving | [TOZINAMERAN] (S - COVID-19 | Not reported | ICSR |
| Healthcare European Professional European Profes | | | | | , , , , | | | | Recovering/Resolving - Other Medically | applicable - [n/a - | | |
| Headache (r/n) = Not Recovered Not Resolved - Other Medically Important Condition), Private (r/n) = Not Recovered Not Resolved - Other Medically Important Condition), Private (r/n) = Not Recovered Not Resolved - Other Medically Important Condition), Private (r/n) = Not Recovered Not Resolved - Other Medically Important Condition), Private (r/n) = Not Recovered Not Resolved - Other Medically Important Condition), Private (r/n) = Not Recovered Not Resolved - Other Medically Important Condition), Private (r/n) = Not Private P | | | Spontaneous | Healthcare | European Economic | | Male | No | Recovered/Not Resolved - Other Medically Important | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| EU-EC- 10010603857 IO/11/2021 Spontaneous Healthcare Professional Professional Area Professional Professional Leconomic Area Professional Leconomic Area Professional Leconomic Area Professional Leconomic Area Leconom | | | | | | | | | Recovered/Not Resolved - Other Medically Important | 11/a - 11/a]) | | |
| EU-EC- 10/11/2021 Spontaneous Healthcare Professional Resolution From Medically Important Condition). EU-EC- 10010603857 Professional Resolution Site pain (n/a - Recovering/Resolving - Other Medically Important Condition). EU-EC- 10010603857 Resolution Resolution Resolution Resolution Resolution Resolution Resolution Resolution (n/a - Recovering/Resolution). EU-EC- 10010603857 Resolution Resolution Resolution Resolution Resolution (n/a - Recovered/Resolution). Arial septial defect (n/a - Recovered/Resolution). Heart disease congenital (n/a - Recovered/Resolution). Resolution Resolution Resolution Resolution Resolution Resolution Resolution Resolution (n/a - Recovered/Resolution). Heart disease congenital (n/a - Recovered/Resolution). Recovered/Resolution Resolution Resoluti | | | | | | | | | (n/a - Not Recovered/Not Resolved - Other Medically Important | | | |
| EU-EC- 10010603857 10/11/2021 Spontaneous Healthcare Professional European Area European Area European Area Specified Specifi | | | | | | | | | Recovered/Not Resolved - Other Medically Important | | | |
| EU-EC-10010603857 10/11/2021 | | | | | | | | | (n/a - Recovering/Resolving - Other Medically | | | |
| congenital (n/a - Recovered/Resolved - Other Medically Important Condition), Hypotension (n/a - Recovered/Resolved - Other Medically Important Condition), Lung disorder (n/a - Recovered/Resolved | | | Spontaneous | | Economic | | Female | No | Atrial septal defect (n/a - Recovered/Resolved - Other Medically Important | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| Recovered/Resolved - Other Medically Important Condition), Lung disorder (n/a - Recovered/Resolved | | | | | | | | | congenital (n/a - Recovered/Resolved - Other Medically Important | | | |
| Recovered/Resolved | | | | | | | | | Recovered/Resolved - Other Medically Important | | | |
| - Other Medically Important | | 1 | | | | | l | | | | | ' |

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| | | | | | | | | | | Condition), Mitral valve atresia (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Myopericarditis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Pulmonary hypoplasia (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Thrombocytopenia (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Transposition of the great vessels (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Ventricular septal defect (n/a - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010603868 | 10/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Myocarditis (n/a - Not Recovered/Not Resolved - Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Nasal congestion (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Nasopharyngitis (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Oropharyngeal pain (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Troponin I increased (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010603979 | 10/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| | | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | 1, | | |
| EU-EC- 10010604201 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | COVID-19 immunisation (n/a - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [1d - n/a - n/a]), | Not reported | ICSR |
| | | | | | | | | | | Lymphadenopathy (n/a - Recovering/Resolving -), Pyrexia (n/a - | SPIKEVAX [COVID- 19 MRNA VACCINE MODERNA (CX- 024414)] (S - n/a - n/a - [1d - n/a - n/a]) | | |
| EU-EC- 10010604267 | 10/11/2021 | Spontaneous | Non Healthcare | European Economic | Not available | 12-17 Years | Adolescent | Female | No | Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] | Not reported | ICSR |
| | 10/41/5 | | Professional | Area | | | | | | Recovering/Resolving | (S - n/a - n/a - [1d - n/a - Intramuscular]) | <u></u> | 105- |
| EU-EC- 10010604395 | 10/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | - Other Medically Important Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Eye swelling (n/a - Unknown - Other Medically Important | | | |

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|-----------------------|------------|-------------|----------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|---|--|--------------|-------------|
| | | | | | | | | | | Condition), Ocular hyperaemia (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pharyngeal swelling (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Rash (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Swelling face (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010604398 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Electrocardiogram abnormal (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICSR |
| | | | | | | | | | | Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | n/a - n/a]) | | |
| EU-EC- 10010604449 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Abdominal pain (n/a - Unknown - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICSR |
| | | | | | | | | | | Diarrhoea (n/a - Unknown - Caused/Prolonged Hospitalisation), | n/a - Intramuscular]) | | |
| | | | | | | | | | | Dizziness (n/a - Unknown - Caused/Prolonged Hospitalisation), | | | |
| EU-EC- | 10/11/2021 | Spontaneous | Non | European | Not | 12-17 | Adolescent | Mala | No | Nausea (n/a - Unknown - Caused/Prolonged Hospitalisation) Facial paralysis (n/a - | COMIRNATY | Not separted | ICCD |
| 10010604887 | | Spontaneous | Healthcare Professional | Economic Area | available | Years | | | | Not Recovered/Not Resolved - Other Medically Important Condition) | [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) | Not reported | ICSR |
| EU-EC- 10010604893 | 10/11/2021 | Spontaneous | Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Asthenia (0d - Recovered/Resolved -), Chest pain (n/a - | COMIRNATY COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED) | Not reported | ICSR |
| | | | | | | | | | | Recovered/Resolved -), Fatigue (0d - Recovered/Resolved | CONCENTRATE FOR DISPERSION FOR INJECTION [TOZINAMERAN] (S - Immunisation | | |
| | | | | | | | | | | -), Pain in extremity (n/a - Recovered/Resolved -), | - Not applicable - [n/a3mL - Intramuscular]) | | |
| | | | | | | | | | | Pyrexia (0d - Recovered/Resolved -) | | | |
| EU-EC- 10010604908 | 10/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Dizziness (n/a - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- | 10/11/2021 | Spontaneous | Non | Europoan | Not | 12 17 | Not | Fomalo | No | Syncope (n/a - Recovered/Resolved -) Epistaxis (4d - | COMIDNATY | Not reported | ICCD |
| 10010604958 | 10/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Recovered/Resolved Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | <u>ICSR</u> |
| | | | | | | | | | | Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition), | n/a - n/a]) | | |
| | | | | | | | | | | Hypersomnia (36h - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (24h - | | | |

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| | | | | | | | | | | Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Vomiting (24h - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010605010 | 10/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Brugada syndrome (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Myocarditis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation) | | | |
| EU-EC- 10010605308 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Arthralgia (1d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - | [FLUDROCORTISONE ACETATE] (C - Hypotension - n/a - [n/a - n/a - n/a]), | <u>ICSR</u> |
| | | | | | | | | | | Arthralgia (3d - Recovered/Resolved -), | Intramuscular]) | [METHOTREXATE] (C - Rheumatoid arthritis - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Heavy menstrual bleeding (1mo - Recovered/Resolved -), | | | |
| | | | | | | | | | | Myalgia (1d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Myalgia (3d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Pyrexia (3d - Recovered/Resolved -) | | | |
| EU-EC- 10010605316 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Arthralgia (n/a - Not Recovered/Not Resolved - Disabling), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]), | Not reported | ICSR |
| | | | | | | | | | | Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Disabling), | VAXZEVRIA [COVID-19 VACCINE ASTRAZENECA | | |
| | | | | | | | | | | Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - Disabling), | (CHADOX1 NCOV- 19)] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | | |
| | | | | | | | | | | Myalgia (n/a - Not Recovered/Not Resolved - Disabling) | | | |
| EU-EC- 10010605547 | 10/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Chills (1d - Recovered/Resolved -), Myalgia (1d - | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | <u>ICSR</u> |
| | | | | | | | | | | Recovered/Resolved | n/a - n/a]) | | |
| EU-EC- | 10/11/2021 | Spontaneous | Haaltheara | European | Not | 12-17 | Not | Male | No | Pyrexia (1d - Recovered/Resolved -) Rash (n/a - Not | COMIRNATY | Not reported | ICSR |
| 10010605639 | 10/11/2021 | Spontaneous | Professional | Economic Area | available | Years | Specified | Male | INO | Recovered/Not Resolved -) | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSK |
| EU-EC- 10010606390 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Balance disorder (0d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - | Not reported | ICSR |
| | | | | | | | | | | Dyspnoea (0d - Recovered/Resolved -), | n/a]) | | |
| | | | | | | | | | | Fatigue (0d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Muscle spasms (0d - Recovered/Resolved -), | | | |
| | | | | | | | | | | Muscle twitching (0d - Recovered/Resolved | | | |
| | | | | | | | | | | Paraesthesia (0d - Recovered/Resolved | | | |
| EU-EC- 10010606585 | 10/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - | Not reported | ICSR |

| | | | | | | | | | | Vaccination failure (n/a - Unknown - Other Medically Important Condition) | [n/a - n/a - Intramuscular]) | | |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|--|--|--|------|
| EU-EC- 10010607043 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Abdominal discomfort (4d - Recovered/Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | [CETIRIZINE DIHYDROCHLORIDE] (C - Multiple allergies - n/a - [n/a - n/a - n/a]) | ICSI |
| | | | | | | | | | | Abdominal pain upper (17h - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Asthenia (5d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Bedridden (17h - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Bedridden (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Erythema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Feeling hot (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Flushing (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Headache (2d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Hypoaesthesia (2d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Influenza like illness (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Oropharyngeal pain (2d - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Rash papular (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Sinus congestion (1wk - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Sneezing (n/a - Recovered/Resolved - Other Medically | | | |
| EU-EC- 10010607441 | 10/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Important Condition) Myocarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICS |
| | | | | | | | | | | Troponin abnormal (n/a - Not Recovered/Not Resolved -) | 1//0 1//0]) | | |
| EU-EC- 10010607447 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European | Not available | 12-17 Years | Not Specified | Female | No | Chills (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICSF |

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| | | | | Economic Area | | | | | | Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | immunisation - Not applicable - [1d - n/a - n/a]) | | |
| | | | | | | | | | | Throat tightness (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010607468 | 10/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Diarrhoea (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSI |
| | | | | Al Cu | | | | | | Myalgia (n/a - Not Recovered/Not Resolved -), | applicable - [n/a - n/a - n/a]) | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Pericarditis (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010607592 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Abdominal pain upper (n/a - Unknown - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICS |
| EU-EC- 10010607601 | 10/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | Not reported | ICS |
| | | | | | | | | | | Myocarditis (3d - Recovered/Resolved - Other Medically Important Condition), | n/a - n/a]) | | |
| | | | | | | | | | | Palpitations (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pericarditis (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Tachycardia (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010607614 | 10/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Chest pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 | Not reported | ICS |
| | | | | | | | | | | Suspected COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | , . | | |
| EU-EC- 10010607624 | 10/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Aphasia (1h - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | [INFLUENZA VIRUS] (C - Immunisation - n/a - [1d - n/a - n/a]) | ICS |
| | | | | | | | | | | Confusional state (0d - Recovered/Resolved | | | |
| | | | | | | | | | | - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Gait disturbance (0d | | | |
| | | | | | | | | | | Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Headache (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | | | |
| | | | | | | | | | | Pain (0d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically | | | |

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|---------------------|------------|-------------|----------------------------|------------------|------------------|----------------|------------------|-----------|--------|--|--|--------------|-----|
| | | | | | | | | | | Important Condition), | | | |
| | | | | | | | | | | Peripheral coldness | | | |
| | | | | | | | | | | (0d - Recovered/Resolved | | | |
| | | | | | | | | | | - Caused/Prolonged Hospitalisation, | | | |
| | | | | | | | | | | Other Medically Important | | | |
| | | | | | | | | | | Condition), | | | |
| | | | | | | | | | | Product use issue (n/a - Unknown -) | | | |
| U-EC- 0010607625 | 10/11/2021 | Spontaneous | Non Healthcare | Non European | Not available | 12-17 Years | Not Specified | Male | No | Dizziness postural (n/a - Not | COMIRNATY [TOZINAMERAN] | Not reported | 10 |
| 3010007023 | | | | Economic Area | available | rears | Specifica | | | Recovered/Not Resolved - Other | (S - COVID-19 immunisation - Not | | |
| | | | | 71100 | | | | | | | applicable - [n/a - n/a - n/a]) | | |
| | | | | | | | | | | Fatigue (n/a - Not | .,, ., .,, .,, | | |
| | | | | | | | | | | Recovered/Not Resolved - Other | | | |
| | | | | | | | | | | Medically Important Condition), | | | |
| | | | | | | | | | | Headache (n/a - Not | | | |
| | | | | | | | | | | Recovered/Not Resolved - Other | | | |
| | | | | | | | | | | Medically Important Condition), | | | |
| | | | | | | | | | | Influenza like illness | | | |
| | | | | | | | | | | (n/a - Not Recovered/Not | | | |
| | | | | | | | | | | Resolved - Other Medically Important | | | |
| -EC- | 10/11/2021 | Spontaneous | Non | Non | Not | 12-17 | Not | Not | No | Condition) Abdominal pain | COMIRNATY | Not reported | |
| 010607637 | , _, _, | | Healthcare Professional | | available | Years | Specified | Specified | | upper (n/a - Not Recovered/Not | [TOZINAMERAN] (S - COVID-19 | | |
| | | | | Area | | | | | | Resolved - Other Medically Important | immunisation - Not applicable - [1d - | | |
| | | | | | | | | | | Condition), | n/a - n/a]) | | |
| | | | | | | | | | | Diarrhoea (1d - Recovered/Resolved | | | |
| | | | | | | | | | | - Other Medically Important | | | |
| | | | | | | | | | | Condition), | | | |
| | | | | | | | | | | Pain in extremity (n/a - Unknown - | | | |
| | | | | | | | | | | Other Medically Important Condition) | | | |
| -EC- 010607644 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European | Not available | 12-17 Years | Not Specified | Male | No | Bone pain (n/a - Not Recovered/Not | [TOZINAMERAN] | Not reported | 1 |
| / | | | | Economic Area | | | | | | Resolved - Other Medically Important | (S - COVID-19 immunisation - Not | | |
| | | | | | | | | | | Condition), | applicable - [n/a - n/a - | | |
| | | | | | | | | | | Chest discomfort (n/a - Not | Intramuscular]) | | |
| | | | | | | | | | | Recovered/Not Resolved - Other | | | |
| | | | | | | | | | | Medically Important Condition), | | | |
| | | | | | | | | | | Chest pain (n/a - Not | | | |
| | | | | | | | | | | Recovered/Not Resolved - Other | | | |
| | | | | | | | | | | Medically Important Condition), | | | |
| | | | | | | | | | | Dyskinesia (n/a - Not | | | |
| | | | | | | | | | | Recovered/Not Resolved - Other | | | |
| | Į. | | 1 | | | | | | | | | I | - 1 |
| | | | | | | | | | | Medically Important Condition), | | | |
| | | | | | | | | | | Medically Important | | | |
| | | | | | | | | | | Medically Important Condition), | | | |
| | | | | | | | | | | Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important | | | |
| | | | | | | | | | | Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not | | | |
| | | | | | | | | | | Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Medically Important Condition), Feeling abnormal (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Feeling cold (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Gait disturbance (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Hypoaesthesia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |

| EU-EC- 10010607652 | 10/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Muscular weakness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) Eye pain (n/a - Not Recovered/Not Resolved - Disabling), Pain in extremity (n/a - Not Recovered/Not Resolved - Disabling), Pain in extremity (n/a - Not Recovered/Not Resolved - Disabling), Poor quality sleep (n/a - Not Recovered/Not Resolved - Recovered/Not Recovered/Not Recovered/Not Recovered/Not | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported | ICSR |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|--|--|--|-------------|
| EU-EC- 10010607684 | 10/11/2021 | Spontaneous | Non Healthcare | Non European | Not available | 12-17 Years | Not Specified | Female | No | Resolved - Disabling) Epilepsy (n/a - Not Recovered/Not | TOZINAMERAN [TOZINAMERAN] | [TOPIRAMATE] (C - Epilepsy - n/a - [n/a - n/a - n/a]) | <u>ICSR</u> |
| | | | Professional | Economic Area | | | | | | Resolved - Other Medically Important Condition) | (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | | |
| EU-EC- 10010607685 | 10/11/2021 | Spontaneous | | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - | Not reported | ICSR |
| | | | | | | | | | | Oropharyngeal pain (n/a - Unknown -), Pyrexia (n/a - | Intramuscular]) | | |
| | | | | | | | | | | Unknown -), Vaccination failure (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010607717 | 10/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisablion - Not applicable - [1d - | [ETHINYLESTRADIOL, LEVONORGESTREL] (C - Heavy menstrual bleeding - n/a - [n/a - n/a - n/a]) | ICSR |
| | | | | | | | | | | Feeling cold (n/a - Unknown - Other Medically Important Condition), | n/a - n/a]) | | |
| | | | | | | | | | | Headache (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Malaise (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Vomiting (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010607728 | 10/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Vaccination site pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | [ETHINYLESTRADIOL, LEVONORGESTREL] (C - Heavy menstrual bleeding - n/a - [n/a - n/a - n/a]) | ICSR |
| EU-EC- 10010607757 | 10/11/2021 | Spontaneous | Healthcare | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Hypokinesia (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | Inflammation (1d - Recovered/Resolved - Other Medically Important Condition), | applicable - [1d - n/a - n/a]) | | |
| | | | | | | | | | | Peripheral swelling (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | Rash macular (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010607758 | 10/11/2021 | Spontaneous | Non Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Feeling cold (n/a - Unknown - Other Medically Important Condition), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICSR |
| | | | | | | | | | | Feeling hot (n/a - Unknown - Other | applicable - [1d - n/a - n/a]) | | |

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|----|-----------------------|------------|-------------|------------------------------|---|------------------|----------------|------------------|---------|----------|--|---|--|-------------|
| | | | | | | | | | | | Medically Important Condition), | | | |
| | | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Influenza like illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Pain (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Pain in extremity (n/a - Unknown - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Tongue biting (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Vaccination site mass (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | | Vaccination site pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| | EU-EC- 10010607769 | 10/11/2021 | Spontaneous | Non Healthcare | Non European | Not available | 12-17 Years | Not Specified | Male | No | Death (n/a - Fatal - | TOZINAMERAN [TOZINAMERAN] | Not reported | <u>ICSR</u> |
| | | | | Professional | | aranazio | | | | | | (S - COVID-19 immunisation - Not applicable - [n/a - | | |
| | EU-EC- 10010607836 | 10/11/2021 | Spontaneous | Professional Non | Economic Area Non European | Not available | 12-17 Years | Not Specified | Female | No | Other Medically Important Condition) Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important | (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | [PARACETAMOL, PARACETAMOL PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - | ICSR |
| | EU-EC- 10010607836 | 10/11/2021 | Spontaneous | Professional Non Healthcare | Economic Area Non European Economic | Not | 12-17 | Not | Female | No | Other Medically Important Condition) Fatigue (n/a - Not Recovered/Not Resolved - Other | (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | PH. EUR.] (C - n/a - n/a - [n/a - | ICSR |
| | EU-EC- 10010607836 | 10/11/2021 | Spontaneous | Professional Non Healthcare | Economic Area Non European Economic | Not | 12-17 | Not | Female | | Other Medically Important Condition) Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important | (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - | ICSR |
| | EU-EC- 10010607836 | 10/11/2021 | Spontaneous | Professional Non Healthcare | Economic Area Non European Economic | Not | 12-17 | Not | Female | | Other Medically Important Condition) Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza like illness (n/a - Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not Resolved - Other Medically Important | (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - | ICSR |
| | EU-EC- 10010607836 | 10/11/2021 | Spontaneous | Professional Non Healthcare | Economic Area Non European Economic | Not | 12-17 | Not | Female | | Other Medically Important Condition) Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza like illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), | (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - | ICSR |
| | EU-EC- 10010607836 | 10/11/2021 | Spontaneous | Professional Non Healthcare | Economic Area Non European Economic | Not | 12-17 | Not | Female | | Other Medically Important Condition) Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza like illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - | ICSR |
| | EU-EC- 10010607836 | 10/11/2021 | Spontaneous | Professional Non Healthcare | Economic Area Non European Economic | Not | 12-17 | Not | Female | | Other Medically Important Condition) Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza like illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - | ICSR |
| | EU-EC- 10010607836 | 10/11/2021 | Spontaneous | Professional Non Healthcare | Economic Area Non European Economic | Not | 12-17 | Not | Female | | Other Medically Important Condition) Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Influenza like illness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Malaise (n/a - Unknown - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - | PH. EUR.] (C - n/a - n/a - [n/a - n/a - n/a]), [PARACETAMOL] (C - n/a - n/a - | ICSR |

| | 1.25 | | | | | | | | | isting Report | | | |
|-----------------------|------------|--------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|----|--|--|---|------|
| | | | | | | | | | | Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010608198 | 10/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Child | Male | No | Urticaria (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010608275 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Herpes zoster (5d - Not Recovered/Not Resolved -), Rash (5d - Not | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Recovered/Not Resolved -) | 1.4.23 | | |
| EU-EC- 10010608393 | 10/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Herpes zoster (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010608544 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Syncope (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICSF |
| EU-EC- 10010608629 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Eye pain (n/a - Not Recovered/Not Resolved -), Feeling hot (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | MELATONIN [MELATONIN] (C - n/a - n/a - [n/a - n/a - n/a]) | ICSR |
| | | | | | | | | | | Foreign body sensation in eyes (n/a - Unknown -), | | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Tinnitus (0d - Recovered/Resolved | | | |
| EU-EC- 10010608640 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Heavy menstrual bleeding (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] (S - Immunisation | [COD-LIVER OIL] (C - n/a - n/a -), [DESLORATADINE] (C - Mite | ICSF |
| | | | | | | | | | | Malaise (n/a - Unknown -), | - n/a - [n/a - n/a - Intramuscular]) | allergy, Seasonal allergy - n/a -), | |
| | | | | | | | | | | Menstrual disorder (n/a - Unknown -), | | [VITAMIN D] (C - n/a - n/a - [n/a - n/a - n/a]) | |
| | | | | | | | | | | Pain (n/a - Unknown -), | | | |
| EU EC | 10/11/2021 | Chantanasiis | Non | Funencen | Not | 12 17 | Not | Comple | No | Polymenorrhoea (n/a - Unknown -) | COMIDNIATY | Not veneuted | TCCF |
| EU-EC- 10010608653 | 10/11/2021 | Spontaneous | Healthcare | European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Menstrual disorder (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICSR |
| EU-EC- 10010608922 | 10/11/2021 | Spontaneous | | European | Not | 12-17 | Not | Male | No | Polymenorrhoea (n/a - Unknown -) Asthenia (n/a - Unknown -), | COMIRNATY [TOZINAMERAN] | Not reported | ICSF |
| 10010606922 | | | Healthcare Professional | Economic Area | available | Years | Specified | | | Decreased appetite (n/a - Unknown -), | (S - COVID-19 immunisation - Not applicable - [n/a - | | |
| | | | | | | | | | | Fatigue (n/a - Unknown -), | 1{DF} - Intramuscular]) | | |
| | | | | | | | | | | Headache (n/a - Unknown -), | | | |
| | | | | | | | | | | Myalgia (2d - Recovering/Resolving -), | | | |
| | | | | | | | | | | Pyrexia (1d - Recovering/Resolving -), | | | |
| | | | | | | | | | | Vomiting (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010609894 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Rash (1d - Recovered/Resolved -), | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| | | | | | | | | | | Urticaria (1d - Recovered/Resolved | ,, a ., a ₁ , | | |
| EU-EC- 10010609969 | 10/11/2021 | Spontaneous | Healthcare | European Economic | Not available | 12-17 Years | Adolescent | Female | No | Anaphylactic reaction (n/a - Unknown - | [TOZINAMERAN] | Not reported | ICSF |
| | | | | Area | | | | | | Life Threatening, Caused/Prolonged Hospitalisation) | (S - Immunisation - n/a - [n/a - 1{DF} - n/a]) | | |
| EU-EC- | 10/11/2021 | Spontaneous | Healthcare | Non | Not | 12-17 | Not | Female | No | Chills (n/a - | COMIRNATY | Not reported | ICSF |

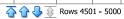
| J.11.2022 I | 1.25 | ı | I | I | I | ı | I | Kuii i | | - Unknown -), | applicable - [n/a - | I | ı |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|------------------|----------------|------------------|--------|------|--|---|--------------|------|
| | | | | | | | | | | Loss of | n/a - n/a]) | | |
| | | | | | | | | | | consciousness (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010610051 | 10/11/2021 | Spontaneous | | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Anaphylactic reaction (n/a - Recovering/Resolving - Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - | Not reported | ICS |
| | | | | | | | | | | Anaphylactic shock (n/a - Recovered/Resolved - Other Medically Important Condition), | Intramuscular]) | | |
| | | | | | | | | | | Blood pressure decreased (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Cold sweat (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Dyskinesia (n/a - Unknown -), | | | |
| | | | | | | | | | | Dysstasia (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Headache (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Heart rate decreased (n/a - Recovering/Resolving -), | | | |
| | | | | | | | | | | Shock (n/a - Recovering/Resolving - Other Medically Important Condition), | | | |
| | | | | | | | | | | Visual impairment (n/a - Recovering/Resolving -) | | | |
| EU-EC- 10010610109 | 10/11/2021 | Spontaneous | Healthcare Professional | European Economic | Not available | 12-17 Years | Adolescent | Male | No | Immune thrombocytopenia | COMIRNATY [TOZINAMERAN] | Not reported | ICS |
| | | | | Area | | | | | | (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation) | (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | | |
| EU-EC- 10010610289 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Amenorrhoea (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - | Not reported | ICS |
| EU-EC- 10010610308 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Immunisation reaction (5d - Recovered/Resolved -) | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - | Not reported | ICS |
| EU-EC- | 10/11/2021 | Spontaneous | Non | European | Not | 12-17 | Adolescent | Male | No | Headache (n/a - | Intramuscular]) COMIRNATY | Not reported | ICSI |
| 10010610309 | 10/11/2021 | эропшисов | Healthcare Professional | Economic | available | Years | Adolescenc | Tale | | Recovering/Resolving | [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) | not reported | 100 |
| EU-EC- 10010610417 | 10/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Herpes zoster (n/a - Recovering/Resolving -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - | Not reported | ICSI |
| EU-EC- 10010610421 | 10/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Dizziness (5d - Recovered/Resolved -), | Intramuscular]) COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | ICS |
| | | | | | | | | | | Hypersensitivity (5d - Recovered/Resolved -), | immunisation - Unknown - [1d - 1{DF} - Intramuscular]) | | |
| | | | | | | | | | | Oedema mucosal (5d | | | |
| | | | | | | | | | | Recovering/Resolving -), Urticaria (5d - | | | |
| EU EC | 10/4: " | | | _ | | 40.1- | | | | Recovered/Resolved | COMPRESSE | | |
| EU-EC- 10010610424 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Fatigue (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | ICS |
| | | | | | | | | | | Tremor (n/a - Not Recovered/Not Resolved -) | applicable - [1d - 1{DF} - Intramuscular]) | | |

| J.11.2022 I | | | | | | | | | | isting Report | | | |
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| EU-EC- 10010610468 | 10/11/2021 | Spontaneous | Non Healthcare Professional | | Not available | 12-17 Years | Adolescent | Female | No | Diarrhoea (8d - Recovered/Resolved -), Menstruation delayed (9d - Recovered/Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not reported | ICSF |
| EU-EC- 10010610487 | 10/11/2021 | Spontaneous | Non Healthcare Professional | Economic | Not available | 12-17 Years | Adolescent | Male | No | Influenza like illness (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular]) | Not reported | ICS |
| EU-EC- 10010610491 | 10/11/2021 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Adolescent | Female | No | Amenorrhoea (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [22d - 2{DF} - Intramuscular]) | Not reported | ICS |
| EU-EC- 10010610512 | 10/11/2021 | Spontaneous | Non Healthcare Professional | Economic | Not available | 12-17 Years | Adolescent | Female | No | Gastrointestinal disorder (n/a - Not Recovered/Not Resolved -), Headache (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICS |
| EU-EC- 10010610606 | 10/11/2021 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Adolescent | Female | No | Accidental overdose (n/a - Recovered/Resolved -), Incorrect dose administered (n/a - Recovered/Resolved -), Pyrexia (n/a - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - 5{DF} - Intramuscular]) | Not reported | ICS |
| EU-EC- | 10/11/2021 | Spontaneous | Healthcare | European | Not | 12-17 | Adolescent | Female | No | -) Rash (n/a - | COMIRNATY | Not reported | ICS |
| 10010610827 | 10/11/2021 | Spontaneous | Professional | | available | Years | Adolescent | remale | No | Recovered/Resolved | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular]) | Not reported | 100 |
| EU-EC- 10010610882 | 10/11/2021 | Spontaneous | Non Healthcare Professional | Economic | Not available | 12-17 Years | Adolescent | Female | No | Influenza like illness (n/a - Not Recovered/Not Resolved -), Malaise (n/a - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICS |
| EU-EC- 10010610894 | 10/11/2021 | Spontaneous | Non Healthcare Professional | Economic | Not available | 12-17 Years | Adolescent | Female | No | -) Menstruation irregular (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICS |
| EU-EC- 10010610902 | 10/11/2021 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Adolescent | Male | No | Headache (n/a - Not Recovered/Not Resolved -), Hypertension (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular]) | Not reported | ICS |
| EU-EC- 10010611046 | 10/11/2021 | Spontaneous | Non Healthcare Professional | Economic | Not available | 12-17 Years | Not Specified | Male | No | Chills (2d - Recovered/Resolved -), Fatigue (n/a - Recovering/Resolving -), Headache (n/a - Recovering/Resolving -), Malaise (n/a - Recovering/Resolving -), Myalgia (2d - Recovered/Resolved -), Pyrexia (n/a - Recovering/Resolving - Recovering/Resolving -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - | Not reported | ICS |
| EU-EC- 10010611493 | 10/11/2021 | Spontaneous | Healthcare Professional | | Not available | 12-17 Years | Adolescent | Male | No | -) Circulatory collapse (n/a - Recovered/Resolved - Life Threatening), Loss of consciousness (n/a - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - Intramuscular]) | Not reported | ICS |
| EU-EC- 10010611627 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | - Life Threatening) Myocarditis (n/a - Recovering/Resolving - Other Medically Important Condition), Troponin increased | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | ICS |

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| | | | | | | | | | | (n/a - Recovering/Resolving - Other Medically Important Condition) | | | |
| EU-EC- 10010611974 | 10/11/2021 | Spontaneous | Healthcare Professional | Non European Economic Area | Not available | 12-17 Years | Not Specified | Female | No | Decreased appetite (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 |
| | | | | | | | | | | Headache (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Malaise (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Pyrexia (n/a - Unknown - Other Medically Important Condition) | | | |
| EU-EC- 10010611998 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Female | No | Chest pain (2d - Recovered/Resolved -), Dyspnoea (2d - Recovered/Resolved | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - n/a - n/a]) | Not reported | ICSR |
| EU-EC- | 10/11/2021 | Spontaneous | Healthcare | Non | Not | 12-17 | Not | Female | No | -) Muscle contractions | TOZINAMERAN | Not reported | ICSR |
| 10010612195 | | | Professional | European Economic Area | available | Years | Specified | | | involuntary (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular - | | |
| | | | | | | | | | | Pain (n/a - Not Recovered/Not Resolved -), | More in ICSR]) | | |
| | | | | | | | | | | Vaccination site pain (n/a - Not Recovered/Not Resolved -) | | | |
| EU-EC- 10010612207 | 10/11/2021 | Spontaneous | Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Arthralgia (n/a - Not Recovered/Not Resolved -), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not | Not reported | <u>ICSR</u> |
| | | | | | | | | | | Asthenia (n/a - Not Recovered/Not Resolved -), | applicable - [1d - n/a - Intramuscular]) | | |
| | | | | | | | | | | Fatigue (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Headache (n/a - Not Recovered/Not Resolved -), | | | |
| | | | | | | | | | | Leukopenia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010612259 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Autoimmune haemolytic anaemia (n/a - Not Recovered/Not Resolved - | COMIRNATY [TOZINAMERAN] (S - Immunisation - n/a - [n/a - 2{DF} - n/a]) | Not reported | ICSR |
| EU-EC- | 10/11/2021 | Spontaneous | Non | European | Not | 12-17 | Not | Male | No | Caused/Prolonged Hospitalisation) Chills (n/a - | [TOZINAMERAN] | Not reported | ICSR |
| 10010612696 | 10/11/2021 | Sportaneous | Healthcare Professional | Economic | available | Years | Specified | Маје | INO | Recovered/Resolved - Other Medically Important Condition), | (S - n/a - Unknown - [n/a - n/a - n/a]) | Not reported | <u>ICSK</u> |
| | | | | | | | | | | Headache (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Nausea (n/a - Recovered/Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Vomiting (1d - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010612810 | 10/11/2021 | Spontaneous | Non Healthcare Professional | European Economic Area | Not available | 12-17 Years | Not Specified | Male | No | Neck pain (n/a - Not Recovered/Not Resolved -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | BETMIGA 50 MG PROLONGED- RELEASE TABLETS [MIRABEGRON] (C - n/a - n/a - [n/a - n/a - n/a]), [METHYLPHENIDATE | ICSR |
| | | | | | | | | | | | | HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]) | |
| EU-EC- 10010612841 | 10/11/2021 | Spontaneous | Non Healthcare Professional | | Not available | 12-17 Years | Not Specified | Male | No | Chills (n/a - Not Recovered/Not Resolved - Other | COMIRNATY [TOZINAMERAN] (S - COVID-19 | Not reported | <u>ICSR</u> |

Run Line Listing Report

| | | | | Economic Area | | | | | | Medically Important Condition), | immunisation - Not applicable - [1d - n/a - n/a]) | | |
|-----------------------|------------|-------------|--------------|------------------------------|------------------|----------------|------------|------|----|---|--|--------------|------|
| | | | | | | | | | | Cluster headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | 1,7 1,7 1,7 1,7 1,7 1,7 1,7 1,7 1,7 1,7 | | |
| | | | | | | | | | | Nausea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | | | |
| | | | | | | | | | | Primary headache associated with sexual activity (3d - Recovered/Resolved - Other Medically Important Condition) | | | |
| EU-EC- 10010612883 | 10/11/2021 | Spontaneous | Professional | European Economic Area | Not available | 12-17 Years | Adolescent | Male | No | Vaccination site inflammation (n/a - Unknown -) | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Unknown]) | Not reported | ICSR |



Return - Refresh - Print - Export