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

| U Local<br>Number     | EV<br>Gateway<br>Receipt<br>Date | Report Type | Primary<br>Source<br>Qualification | Primary<br>Source<br>Country<br>for<br>Regulatory<br>Purposes | Literature Reference | Patient<br>Age<br>Group | Patient<br>Age Group<br>(as per<br>reporter) | Cov    | Parent<br>Chi <b>l</b> d<br>Report | Reaction List PT<br>(Duration – Outcome<br>- Seriousness<br>Criteria)                                     | Suspect/interacting Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route]) | Concomitant/Not<br>Administered Drug Lisi<br>(Drug Char - Indication<br>PT - Action taken -<br>[Duration - Dose -<br>Route]) |
|-----------------------|----------------------------------|-------------|------------------------------------|---|----------------------|-------------------------|--|--------|------------------------------------|---|--|--|
| I-EC-<br>013341605    | 26/08/2022                       | Spontaneous | Healthcare                         | European<br>Economic<br>Area                                  | Not available        | 12-17<br>Years          | Not<br>Specified                             | Male   | No                                 | Chills (n/a - Not<br>Recovered/Not<br>Resolved - ),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not                                    | Not reported   |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    |   | applicable - [n/a -<br>n/a - n/a])   |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Fatigue (n/a - Not<br>Recovered/Not<br>Resolved - ),  |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Headache (n/a - Not<br>Recovered/Not<br>Resolved - ),   |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Injection site<br>reaction (n/a - Not<br>Recovered/Not<br>Resolved - ),                                   |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Lymphadenopathy<br>(n/a - Not<br>Recovered/Not<br>Resolved - ),   |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Malaise (n/a - Not<br>Recovered/Not<br>Resolved - ),  |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Myalgia (n/a - Not<br>Recovered/Not<br>Resolved - ),  |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Nausea (n/a - Not<br>Recovered/Not<br>Resolved - ),   |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Pain (n/a - Not<br>Recovered/Not<br>Resolved - ),   |  |  |
| :U-EC-                | 26/09/2022                       | Spontaneous | Non                                | Europoon  | Not available        | 12-17                   | Not  | Eamala | No                                 | Pyrexia (n/a - Not<br>Recovered/Not<br>Resolved - )<br>Abdominal pain (n/a                                | COMIRNATY 30   | Not reported   |
| 0013341880            | 20/08/2022                       | Spontaneous |                                    | Economic  | NOL AVAIIADIE        | Years                   | Specified                                    | Female | INO                                | - Recovering/Resolving  | MICROGRAMS/DOSE<br>[TOZINAMERAN] (S -<br>COVID-19  | Not reported   |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Amnesia (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),                | immunisation - Not<br>applicable - [n/a -<br>1{DF} - n/a])   |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Arthralgia (n/a -<br>Recovering/Resolving<br>- ),   |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Chest pain (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),             |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Dizziness (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),              |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Headache (n/a -<br>Recovering/Resolving<br>-),  |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Hypertension (n/a -<br>Unknown - ),   |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Loss of<br>consciousness (0d -<br>Recovered/Resolved<br>-),   |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Muscle spasms (n/a - Recovering/Resolving - ),  |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Psychogenic seizure<br>(n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation), |  |  |
|                       |                                  |             |                                    |   |                      |                         |  |        |                                    | Tremor (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation)                  |  |  |
| :U-EC-<br>.0013341984 | 26/08/2022                       | Spontaneous |                                    | Economic  | Not available        | 12-17<br>Years          | Not<br>Specified                             | Female | No                                 | Myalgia (1d -<br>Recovered/Resolved<br>-)   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -             | Not reported   |

| J.11.2022             | 15.25      |              |                                   |                                     |               | RL             | ın Line L        | isting R | kepori | l.  |   |                |
|-----------------------|------------|--------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|----------|--------|---|---|----------------|
| 10013342597           |            |              | Professional                      | Economic<br>Area                    |               | Years          |                  |          |        | Recovered/Resolved - )  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -                      |                |
| EU-EC-<br>10013342664 | 26/08/2022 | Spontaneous  | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male     | No     | Fatigue (3d -<br>Recovered/Resolved<br>-),<br>Headache (2h -  | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -            | Not reported ] |
|                       |            |              |                                   |                                     |               |                |                  |          |        | Recovered/Resolved  | 1{DF} -<br>Intramuscular use])  |                |
| EU-EC-<br>10013343025 | 26/08/2022 | Spontaneous  | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male     | No     | Ventricular<br>tachycardia (n/a -<br>Unknown - Other<br>Medically Important<br>Condition)                                       | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -                    | Not reported   |
| EU-EC-                | 26/08/2022 | Spontaneous  |                                   | European                            | Not available | 12-17          | Not              | Male     | No     | Epistaxis (n/a -  | n/a - n/a])<br>COMIRNATY  | Not reported   |
| 10013343043           |            |              | Professional                      | Economic<br>Area                    |               | Years          | Specified        |          |        | Recovered/Resolved - ),  Pyrexia (n/a - Recovered/Resolved - )  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - n/a -<br>Intramuscular use])               |                |
| EU-EC-<br>10013344421 | 26/08/2022 | Spontaneous  | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No     | Headache (n/a - Not<br>Recovered/Not<br>Resolved - ),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [1d - n/a -<br>Intramuscular use])                           | Not reported   |
|                       |            |              |                                   |                                     |               |                |                  |          |        | Myalgia (n/a - Not<br>Recovered/Not<br>Resolved - ),  | -   |                |
|                       |            |              |                                   |                                     |               |                |                  |          |        | Pyrexia (n/a - Not<br>Recovered/Not<br>Resolved - ),  |   |                |
|                       |            |              |                                   |                                     |               |                |                  |          |        | Vulval ulceration (n/a<br>- Not Recovered/Not<br>Resolved - )   |   |                |
| EU-EC-<br>10013344592 | 26/08/2022 | Spontaneous  | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Child            | Female   | No     | -),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [1d - n/a -<br>Intramuscular use])                           | Not reported   |
|                       |            |              |                                   |                                     |               |                |                  |          |        | Vomiting (n/a -<br>Recovering/Resolving<br>- ),   |   |                |
|                       |            |              |                                   |                                     |               |                |                  |          |        | Vulval ulceration (n/a<br>-<br>Recovering/Resolving   |   |                |
| EU-EC-<br>10013346666 | 26/08/2022 | Spontaneous  | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adult            | Male     | No     | Condition aggravated<br>(n/a - Not<br>Recovered/Not<br>Resolved -   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not  | Not reported   |
|                       |            |              |                                   |                                     |               |                |                  |          |        | Disabling), Headache (n/a - Not Recovered/Not Resolved - ),   | applicable - [1d -<br>1{DF} -<br>Intramuscular use])  |                |
|                       |            |              |                                   |                                     |               |                |                  |          |        | Hypoacusis (n/a -<br>Not Recovered/Not<br>Resolved - ),   |   |                |
|                       |            |              |                                   |                                     |               |                |                  |          |        | Tinnitus (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)                                   |   |                |
| EU-EC-<br>10013346686 | 26/08/2022 | Spontaneous  | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No     | Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Disabling, Other Medically Important Condition),                              | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>2{DF} -         | Not reported ] |
|                       |            |              |                                   |                                     |               |                |                  |          |        | Heavy menstrual<br>bleeding (n/a - Not<br>Recovered/Not<br>Resolved - Disabling,<br>Other Medically<br>Important<br>Condition), | Intramuscular use])   |                |
|                       |            |              |                                   |                                     |               |                |                  |          |        | Polymenorrhoea (n/a<br>- Not Recovered/Not<br>Resolved - Disabling,<br>Other Medically<br>Important Condition)                  |   |                |
| EU-EC-<br>10013346884 | 26/08/2022 | Spontaneous  | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No     | Menstruation delayed<br>(n/a - Not<br>Recovered/Not<br>Resolved - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[1d - 1{DF} -<br>Intramuscular use]) | Not reported ] |
| EU-EC-<br>10013346901 | 26/08/2022 | Spontaneous  | Healthcare                        | Economic                            | Not available | 12-17<br>Years | Adolescent       | Female   | No     | Dysmenorrhoea (n/a<br>- Not Recovered/Not   | COMIRNATY<br>[TOZINAMERAN] (S -   | Not reported   |
|                       |            |              | Professional                      | Area                                |               |                |                  |          |        | Resolved - ),  Oligomenorrhoea (n/a - Not Recovered/Not Resolved - )  | COVID-19<br>immunisation - n/a -<br>[1d - 1{DF} -<br>Intramuscular use])                                    |                |
| EU-EC-<br>10013346923 | 26/08/2022 | Spontaneous  | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No     | Amenorrhoea (n/a -<br>Not Recovered/Not<br>Resolved - )   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [21d - 1{DF} -                        | Not reported ] |
| E E.                  | 26/08/2022 | Spontaneous  | Healthcare                        | European                            | Not available | 12-17          | Adolescent       | Female   | No     | Vaccination site  | Intramuscular use]) COMIRNATY   | Not reported I |
| EU-EC-<br>10013346946 | 20,00,2022 | DPOMEANCOUD. | Professional                      | Economic                            |               | Years          | / tdojesecrie    | Ciriale  |        | erythema (8d -  | [TOZINAMERAN] (S -  |                |

|                       |            |             |                            |                                     |               |                |                  |        |    |   | [1d - 1{DF} -<br>Intramuscular use])  |  |          |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|---|---|--|----------|
| EU-EC-<br>10013348077 | 26/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Angioedema (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),<br>Chronic spontaneous   | COMIRNATY [TOZINAMERAN] (S - n/a - Not applicable - [n/a - n/a - n/a]), [INFLUENZA A VIRUS A/BRISBANE/10/2010               | Not reported   | <u>I</u> |
|                       |            |             |                            |                                     |               |                |                  |        |    | urticaria (n/a - Not<br>Recovered/Not<br>Resolved - )   | (H1N1) ANTIGEN (MDCK CELL DERIVED, PROPIOLACTONE INACTIVATED)] (S - n/a - Not applicable - [n/a - n/a - n/a].               |  |          |
| 10013349777           |            | Spontaneous | Professional               | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | Lymphadenopathy<br>(n/a - Unknown - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} - n/a])                    | ·  | <u>I</u> |
| EU-EC-<br>10013328147 | 25/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Disease recurrence<br>(2d -<br>Recovered/Resolved -<br>Other Medically<br>Important<br>Condition),  | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                   | [LAMOTRIGINE] (C -<br>Epilepsy - n/a - [n/a - n/a<br>- n/a]),<br>[SODIUM HYDROGEN<br>CARBONATE, POTASSIUM<br>CHLORIDE, SODIUM      |          |
|                       |            |             |                            |                                     |               |                |                  |        |    | Seizure (2d -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)  |   | CHLORIDE, MACROGOL 3350] (C - Constipation - n/a - [n/a - n/a - n/a]), [SODIUM VALPROATE] (C - Epilepsy - n/a - [n/a - n/a - n/a]) |          |
| EU-EC-<br>10013328189 | 25/08/2022 | Spontaneous | Healthcare                 | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Epilepsy (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                     | Not reported   | Ī        |
|                       |            |             |                            |                                     |               |                |                  |        |    | Generalised tonic-<br>donic seizure (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),                  |   |  |          |
|                       |            |             |                            |                                     |               |                |                  |        |    | Tonic convulsion (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition)   |   |  |          |
| EU-EC-<br>10013328628 | 25/08/2022 | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No | Granuloma (n/a -<br>Not Recovered/Not<br>Resolved - )   | COMIRNATY 30 MICROGRAMS/DOSE [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported   | <u>I</u> |
| EU-EC-<br>10013329460 | 25/08/2022 | Spontaneous | Healthcare                 | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | COVID-19 (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),<br>Drug ineffective (n/a<br>- Unknown - Other<br>Medically Important<br>Condition)     | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                     | Not reported   | <u>I</u> |
| EU-EC-<br>10013329548 | 25/08/2022 | Spontaneous | Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Angina pectoris (n/a - Unknown - Other Medically Important Condition), Disturbance in attention (n/a - Recovered/Resolved - ), Loss of personal independence in | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])        | Not reported   | Ī        |
|                       |            |             |                            |                                     |               |                |                  |        |    | daily activities (n/a -<br>Unknown - ),<br>Pyrexia (n/a -<br>Recovering/Resolving - ),<br>Splenomegaly (n/a -<br>Unknown - ),                                   |   |  |          |
|                       |            |             |                            |                                     |               |                |                  |        |    | Stress (n/a -<br>Unknown - )  |   |  |          |
| EU-EC-<br>10013330028 | 25/08/2022 | Spontaneous | Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | Administration site<br>pain (3d -<br>Recovered/Resolved<br>- ),<br>Body temperature<br>increased (1d -<br>Recovered/Resolved<br>- ),                            | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])  | Not reported   | Ī        |
|                       |            |             |                            |                                     |               |                |                  |        |    | Fatigue (2d -<br>Recovered/Resolved<br>-),<br>Headache (2d -<br>Recovered/Resolved  |   |  |          |

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|---|-----------------------|--------------|----------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|-----------|------|---|--|--------------|---|
|   | EU-EC-<br>10013330423 | 25/08/2022   | Spontaneous    | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male      | No   | COVID-19 (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),                      | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- Intramuscular use])                           | Not reported | 1 |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Vaccination failure<br>(n/a - Unknown -<br>Other Medically<br>Important Condition)            |  |              |   |
|   | EU-EC-<br>10013332074 | 25/08/2022   | Spontaneous    | Healthcare                        | Non<br>European<br>Economic<br>Area | Not available |                | Not<br>Specified | Female    | No   | Headache (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),        | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])     | Not reported | 1 |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Hyperacusis (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   | - II/a])   |              |   |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Illness (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),       |  |              |   |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Nausea (1d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),           |  |              |   |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Photophobia (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   |  |              |   |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Vomiting (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)            |  |              |   |
|   | EU-EC-<br>10013333409 | 25/08/2022   | Spontaneous    |                                   | European<br>Economic                | Not available | 12-17<br>Years | Not<br>Specified | Male      | No   | Pallor (n/a -<br>Unknown - ),   | COMIRNATY<br>[TOZINAMERAN] (S -  | Not reported | I |
|   |                       |              |                |                                   | Area                                |               |                |                  |           |      | Syncope (0d -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)              | COVID-19<br>immunisation - n/a -<br>[n/a - 1{DF} - n/a])   |              |   |
|   | EU-EC-<br>10013333533 | 25/08/2022   | Spontaneous    | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male      | No   | Abdominal pain (9d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),         | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a                              | Not reported | Ī |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Dehydration (9d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),            | - Intramuscular use])  |              |   |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Glomerulonephritis<br>chronic (n/a -<br>Unknown - Other<br>Medically Important<br>Condition), |  |              |   |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Haematuria (8d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),             |  |              |   |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Headache (0d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),               |  |              |   |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Hypertension (5d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),           |  |              |   |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Nausea (2d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),                 |  |              |   |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Paraesthesia (7d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),           |  |              |   |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Proteinuria (5d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),            |  |              |   |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      | Renal disorder (n/a -<br>Unknown - ),   |  |              |   |
|   | EU-EC-                | 25/08/2022   | Spontaneous    | Non                               | European                            | Not available | 12-17          | Adolescent       | Female    | No   | Vomiting (9d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation)                | COMIRNATY  | Not reported | I |
|   | 10013334087           | _5, 50, 2022 | - Sportaine0u3 | Healthcare<br>Professional        | Economic                            |               | Years          | . WOLCOURT       | . Gridic  |      | reactivation (25d -<br>Recovered/Resolved - )   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} -<br>Intramuscular use]) | sc.roportou  |   |
|   | EU-EC-<br>10013334091 | 25/08/2022   | Spontaneous    | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male      | No   | Tinnitus (n/a - Not<br>Recovered/Not<br>Resolved - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -                      | Not reported | Ι |
|   |                       |              |                |                                   |                                     |               |                |                  |           |      |   | 1{DF} -<br>Intramuscular use])   |              |   |
|   | EU-EC-<br>10013337485 | 25/08/2022   | Spontaneous    | Healthcare<br>Professional        | European<br>Economic                | Not available | 12-17<br>Years | Adolescent       | Female    | No   | Abdominal pain (n/a<br>- Unknown - ),   | COMIRNATY<br>[TOZINAMERAN] (S -  | Not reported | Ī |
|   |                       | -            |                |                                   |                                     | -             |                | . '              |           |      |   |  |              |   |

|                       | 15.25      |             |                            |                                     |   |                | n Line L         |                  | 000.1 |  |  |              |          |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|---|----------------|------------------|------------------|-------|--|--|--------------|----------|
|                       |            |             |                            | Area                                |   |                |                  |                  |       | Headache (n/a -<br>Unknown - ),  | COVID-19<br>immunisation - Not<br>applicable - [1d -   |              |          |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Malaise (n/a -<br>Unknown - ),   | 1{DF} - n/a])  |              |          |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Pyrexia (n/a -<br>Unknown - )  |  |              |          |
| EU-EC-<br>10013337506 | 25/08/2022 | Spontaneous | Healthcare<br>Professional |                                     | Not available   | 12-17<br>Years | Adolescent       | Male             | No    | Pyrexia (n/a -<br>Unknown - ),<br>Vomiting (n/a -<br>Unknown - )   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])                | Not reported | Ī        |
| EU-EC-<br>10013316250 | 24/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Eldokla, A Postural orthostatic tachycardia syndrome after mRNA COVID-19 vaccine. Clinical autonomic research, 2022;1-5. doi:10.1007/s10286-022-00880-3 Eldokla, A Postural orthostatic tachycardia syndrome after mRNA COVID-19 vaccine. Clinical autonomic research. 2022;32(4):307-311. doi:10.1007/s10286-022-00880-3 | 12-17<br>Years | Not<br>Specified | Female           | No    | Postural orthostatic<br>tachycardia<br>syndrome (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)              | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])               | Not reported | 10       |
| EU-EC-<br>10013316620 | 24/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Gokay, S Urticaria as a rare side<br>effect of polyethylene Glycol-3350 in<br>a child: case report. Acta Clin Croat.<br>2018;57:187-189.<br>doi:10.20471/acc.2018.57.01.26  | 12-17<br>Years | Not<br>Specified | Not<br>Specified | No    | Urticaria (n/a -<br>Unknown - Other<br>Medically Important<br>Condition)   | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])               | Not reported | <u>I</u> |
| EU-EC-<br>10013316979 | 24/08/2022 | Spontaneous | Healthcare<br>Professional | European<br>Economic<br>Area        | Not available   | 12-17<br>Years | Adolescent       | Female           | No    | Administration site<br>erythema (1d -<br>Recovered/Resolved<br>-),<br>Administration site<br>oedema (2d -<br>Recovered/Resolved<br>-), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported | 10       |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Administration site<br>pain (4d -<br>Recovered/Resolved<br>-),   |  |              |          |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Diarrhoea (0d -<br>Recovered/Resolved<br>-),   |  |              |          |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Headache (2d -<br>Recovered/Resolved<br>-),  |  |              |          |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Lymphadenitis (n/a -<br>Recovered/Resolved<br>- ),   |  |              |          |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Lymphadenopathy<br>(n/a -<br>Recovered/Resolved<br>-)  |  |              |          |
| EU-EC-<br>10013317049 | 24/08/2022 | Spontaneous |                            | European<br>Economic<br>Area        | Not available   |                | Not<br>Specified | Female           | No    | Chills (n/a -<br>Recovered/Resolved<br>- ),<br>Malaise (n/a - Not  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -                 | Not reported | Ī        |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Recovered/Not<br>Resolved - ),<br>Pyrexia (n/a -   | 1{DF} - n/a])  |              |          |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Recovered/Resolved<br>- ),<br>Syncope (n/a - Not   |  |              |          |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Recovered/Not<br>Resolved - ),<br>Syncope (n/a -   |  |              |          |
| EU-EC-                | 24/08/2022 | Spontaneous | Healthcare                 | European                            | Not available   | 12-17          | Not              | Male             | No    | Recovered/Resolved<br>- )<br>Nausea (n/a -   | COMIRNATY  | Not reported | 1        |
| 10013317113           |            |             | Professional               |                                     |   | Years          | Specified        |                  |       | Unknown - ),<br>Rash macular (n/a -<br>Unknown - ),  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - n/a -                                   | ·            |          |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Vaccination site<br>oedema (n/a -<br>Unknown - ),  | Intramuscular use])  |              |          |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Vaccination site pain<br>(n/a - Unknown - ),   |  |              |          |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Vaccination site<br>reaction (n/a -<br>Unknown - )   |  |              |          |
| EU-EC-<br>10013317949 | 24/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available   |                | Not<br>Specified | Female           | No    | Axillary pain (n/a -<br>Recovered/Resolved<br>With Sequelae -<br>Other Medically<br>Important<br>Condition),                           | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a]) | Not reported | <u>I</u> |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Fatigue (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),  |  |              |          |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Migraine (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important  |  |              |          |
|                       |            |             |                            |                                     |   |                |                  |                  |       | Condition),<br>Nausea (n/a -   |  |              |          |

| - | ).11.2022             | 10.20       |             |                                   |                                     |               | 110            | n Line Li        | July IV | ероп |  |   |              |            |
|---|-----------------------|-------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|---------|------|--|---|--------------|------------|
|   |                       |             |             |                                   |                                     |               |                |                  |         |      | Important<br>Condition),<br>Pain in extremity<br>(n/a -<br>Recovered/Resolved  |   |              |            |
|   |                       |             |             |                                   |                                     |               |                |                  |         |      | With Sequelae -<br>Other Medically<br>Important<br>Condition),<br>Somnolence (n/a -  |   |              |            |
|   |                       |             |             |                                   |                                     |               |                |                  |         |      | Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),  |   |              |            |
|   | EU-EC-                | 24/08/2022  | Spontaneous | Non                               | Non                                 | Not available | 12-17          | Not              | Female  | No   | Somnolence (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)<br>Asthma (n/a -                      | TOZINAMERAN   | Not reported | <u>I</u>   |
|   | 10013318218           | 2 1700/2022 | Sportaneous | Healthcare<br>Professional        | European                            |               | Years          | Specified        | remaie  |      | Recovering/Resolving - Other Medically Important Condition),  Dyspnoea (n/a -  |   | net reported |            |
|   |                       |             |             |                                   |                                     |               |                |                  |         |      | Unknown - Other Medically Important Condition), Wheezing (n/a - Unknown - Other  |   |              |            |
|   | EU 50                 | 24/00/2022  | <u></u>     | New                               | None                                | N. A Hald     | 12.17          | No.              | F1-     | NI-  | Medically Important<br>Condition)  | TRUMP OFFI  | Notaronada   |            |
|   | EU-EC-<br>10013318274 | 24/08/2022  | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female  | No   | No adverse event<br>(2d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),                           | IBUPROFEN<br>[IBUPROFEN,<br>IBUPROFEN<br>SODIUM] (S - Pain -<br>Unknown - [n/a - n/a<br>- n/a]),          | Not reported | <u>I</u> ! |
|   |                       |             |             |                                   |                                     |               |                |                  |         |      | - Other Medically  | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a             |              |            |
|   | EU-EC-                | 24/08/2022  | Spontaneous | Non                               | Non                                 | Not available | 12-17          | Not              | Female  | No   | Fatigue (3d -  | - n/a]),<br>[PARACETAMOL] (S -<br>Pain - Unknown -<br>[n/a - n/a - n/a])<br>IBUPROFEN                     | Not reported | <u>I</u>   |
|   | 10013318303           | 24,00,2022  | эропапеоиз  | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | Years          | Specified        | remale  | INO  | Recovered/Resolved - Other Medically Important Condition),   | [IBUPROFEN,<br>IBUPROFEN<br>SODIUM] (S - Pain -<br>Unknown - [n/a - n/a<br>- n/a]),                       | Not reported |            |
|   |                       |             |             |                                   |                                     |               |                |                  |         |      | Gait disturbance (3d -<br>Recovered/Resolved - Other Medically<br>Important<br>Condition),                                 | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a]), |              |            |
|   |                       |             |             |                                   |                                     |               |                |                  |         |      | Headache (2d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),                                      | [PARACETAMOL] (S -<br>Pain - Unknown -<br>[n/a - n/a - n/a])  |              |            |
|   |                       |             |             |                                   |                                     |               |                |                  |         |      | Malaise (3d -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)   |   |              |            |
|   | EU-EC-<br>10013318604 | 24/08/2022  | Spontaneous | Non<br>Healthcare<br>Professional | Economic                            | Not available | 12-17<br>Years | Not<br>Specified | Male    | No   | Asthenia (n/a - Not<br>Recovered/Not<br>Resolved - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>Immunisation - n/a -<br>[n/a - n/a - n/a])                             | Not reported | <u>I</u>   |
|   |                       |             |             |                                   |                                     |               |                |                  |         |      | Dizziness (n/a - Not<br>Recovered/Not<br>Resolved - ),   |   |              |            |
|   | EU-EC-                | 24/08/2022  | Spontaneous | Non                               | European                            | Not available | 12-17          | Adolescent       | Malo    | No   | Nausea (n/a - Not<br>Recovered/Not<br>Resolved - )<br>Chest pain (3d -   | COMIRNATY   | Not reported | <u>I</u>   |
|   | 10013318710           | 24/00/2022  | эропшнеоиз  | Healthcare<br>Professional        | Economic                            | not available | Years          | Adojescent       | riale   |      | Recovering/Resolving   | [TOZINAMERAN] (S -<br>Immunisation - n/a -<br>[n/a - n/a - n/a])  | Not reported | Ē          |
|   |                       |             |             |                                   |                                     |               |                |                  |         |      | Dyspnoea (3d -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),  |   |              |            |
|   |                       |             |             |                                   |                                     |               |                |                  |         |      | Pericardial effusion<br>(3d -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),                           |   |              |            |
|   |                       |             |             |                                   |                                     |               |                |                  |         |      | Pericarditis (3d -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation)                                       |   |              |            |
|   | EU-EC-<br>10013319942 | 24/08/2022  | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male    | No   | Infection (n/a - Fatal<br>- Results in Death,<br>Caused/Prolonged<br>Hospitalisation),                                     | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -                               | Not reported | Ī          |
|   |                       |             |             |                                   |                                     |               |                |                  |         |      | Myocarditis (n/a -<br>Fatal - Results in<br>Death,<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important | n/a - n/a])   |              |            |

| 0.11.2022             | 15.25      |             |                            |                                     |               | Ru             | in Line L        | isting R | сероги |   |   |              |          |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|----------|--------|---|---|--------------|----------|
|                       |            |             |                            |                                     |               |                |                  |          |        | Condition), Pulmonary oedema (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)              |   |              |          |
| EU-EC-<br>10013320260 | 24/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female   | No     | Syncope (Od -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)  | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                  | Not reported | <u>I</u> |
| EU-EC-<br>10013320279 | 24/08/2022 | Spontaneous | Healthcare                 | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female   | No     | Fatigue (3d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),<br>Headache (1d -<br>Recovered/Resolved<br>- Other Medically | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                  | Not reported | <u>I</u> |
|                       |            |             |                            |                                     |               |                |                  |          |        | Important Condition), Menstruation delayed (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),                              |   |              |          |
|                       |            |             |                            |                                     |               |                |                  |          |        | Somnolence (2d -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)   |   |              |          |
| EU-EC-<br>10013321322 | 24/08/2022 | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female   | No     | Dacryoadenitis<br>acquired (n/a -<br>Unknown - Life<br>Threatening,<br>Caused/Prolonged<br>Hospitalisation),                                      | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])      | Not reported | <u>I</u> |
|                       |            |             |                            |                                     |               |                |                  |          |        | Eye swelling (n/a -<br>Not Recovered/Not<br>Resolved - Life<br>Threatening,<br>Caused/Prolonged<br>Hospitalisation),                              |   |              |          |
|                       |            |             |                            |                                     |               |                |                  |          |        | Headache (n/a - Not<br>Recovered/Not<br>Resolved - Life<br>Threatening,<br>Caused/Prolonged<br>Hospitalisation),                                  |   |              |          |
|                       |            |             |                            |                                     |               |                |                  |          |        | Inappropriate schedule of product administration (n/a - Unknown - ),  |   |              |          |
|                       |            |             |                            |                                     |               |                |                  |          |        | Myopia (n/a -<br>Unknown - Life<br>Threatening,<br>Caused/Prolonged<br>Hospitalisation),  |   |              |          |
|                       |            |             |                            |                                     |               |                |                  |          |        | Ocular hyperaemia<br>(n/a - Not<br>Recovered/Not<br>Resolved - Life<br>Threatening,<br>Caused/Prolonged<br>Hospitalisation)                       |   |              |          |
| EU-EC-<br>10013321354 | 24/08/2022 | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female   | No     | Eye swelling (n/a -<br>Not Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a                               | Not reported | <u>I</u> |
|                       |            |             |                            |                                     |               |                |                  |          |        | Headache (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),   | - Intramuscular use])   |              |          |
|                       |            |             |                            |                                     |               |                |                  |          |        | Ocular hyperaemia<br>(n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),   |   |              |          |
|                       |            |             |                            |                                     |               |                |                  |          |        | Paraesthesia (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation)   |   |              |          |
| EU-EC-<br>10013321587 | 24/08/2022 | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No     | Conduction disorder<br>(n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important Condition)          | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[1d3mL -<br>Intramuscular use]),<br>[FLUOXETINE    | Not reported | 1        |
|                       |            |             |                            |                                     |               |                |                  |          |        |   | HYDROCHLORIDE] (S - Depression - Drug withdrawn - [n/a - 20mg - Oral use])  |              |          |
| EU-EC-<br>10013321617 | 24/08/2022 | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male     | No     | Dyspnoea (n/a - Not<br>Recovered/Not<br>Resolved -<br>Disabling),<br>Tachycardia (n/a -   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} -<br>Intramuscular use]) | Not reported | <u>I</u> |

|                       |             |             |                            |                                     |               |                |                  |        |    | Not Recovered/Not<br>Resolved - Disabling)  |   |   |
|-----------------------|-------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|---|---|---|
| EU-EC-<br>10013321813 | 24/08/2022  | Spontaneous | Healthcare<br>Professional |                                     | Not available | 12-17<br>Years | Adolescent       | Female | No | Erythema (n/a - Not<br>Recovered/Not<br>Resolved - ),<br>Pyrexia (n/a - Not<br>Recovered/Not  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d -<br>1{DF} -                        | Not reported  |
| EU-EC-<br>10013321836 | 24/08/2022  | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | Resolved - ) Amenorrhoea (n/a - Not Recovered/Not Resolved - )  | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use])          | Not reported  |
| EU-EC-<br>10013321900 | 24/08/2022  | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | Dizziness (n/a - Not<br>Recovered/Not<br>Resolved - ),<br>Influenza like illness<br>(n/a - Not<br>Recovered/Not<br>Resolved - ),<br>Nausea (n/a - Not | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d -<br>1{DF} -<br>Intramuscular use]) | Not reported  |
|                       |             |             |                            |                                     |               |                |                  |        |    | Recovered/Not<br>Resolved - )   |   |   |
| EU-EC-<br>10013321913 | 24/08/2022  | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | Ear infection (8d -<br>Not Recovered/Not<br>Resolved - ),<br>Influenza like illness<br>(n/a - Not<br>Recovered/Not<br>Resolved - ),                   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d -<br>1{DF} -<br>Intramuscular use]) | Not reported  |
|                       |             |             |                            |                                     |               |                |                  |        |    | Lacrimation<br>increased (8d - Not<br>Recovered/Not<br>Resolved - ),  |   |   |
|                       |             |             |                            |                                     |               |                |                  |        |    | Menstrual disorder<br>(n/a - Not<br>Recovered/Not<br>Resolved - ),  |   |   |
| EU-EC-                | 24/08/2022  | Spontaneous | Healthcare                 | European                            | Not available | 12-17          | Adolescent       | Female | No | Tonsillitis (8d - Not<br>Recovered/Not<br>Resolved - )<br>Menstrual disorder  | COMIRNATY   | Not reported  |
| 10013321924           | 2 1700/2022 | эропшисоиз  | Professional               |                                     | not available | Years          | Adolescent       | Temale | No | (n/a - Not<br>Recovered/Not<br>Resolved - )   | [TOZINAMERAN] (S -<br>n/a - Drug withdrawn<br>- [1d - 1{DF} -<br>Intramuscular use])                                      | Not reported  |
| EU-EC-<br>10013322816 | 24/08/2022  | Spontaneous | Healthcare                 | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Myalgia (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),<br>Pyrexia (n/a - Not                                   | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                  | Not reported  |
|                       |             |             |                            |                                     |               |                |                  |        |    | Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),<br>Suspected COVID-19   |   |   |
| EU-EC-                | 24/09/2022  | Capatanagua | Non                        | Non                                 | Not available | 12.17          | Not              | Mala   | No | (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)  | COMPONATO   | FACCODRIC ACIDI (C  |
| 10013322841           | 24/08/2022  | Spontaneous | Healthcare                 | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Antinuclear antibody<br>positive (n/a -<br>Unknown - ),<br>Asthenia (n/a - Not  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -  | [ASCORBIC ACID] (C - n/a - n/a - [n/a - n/a - n/a - n/a]), [CALCIUM                         |
|                       |             |             |                            |                                     |               |                |                  |        |    | Recovered/Not<br>Resolved - ),<br>Autoimmune  | n/a - n/a])   | PANTOTHENATE] (C - n/a<br>- n/a - [n/a - n/a - n/a]),<br>[CYANOCOBALAMIN] (C -              |
|                       |             |             |                            |                                     |               |                |                  |        |    | disorder (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),  |   | n/a - n/a - [n/a - n/a -<br>n/a]),<br>[CYPROHEPTADINE] (C -<br>n/a - n/a - [n/a - n/a -     |
|                       |             |             |                            |                                     |               |                |                  |        |    | Balance disorder (n/a<br>- Unknown -<br>Caused/Prolonged<br>Hospitalisation),   |   | n/a = 1/a = [1/a = 1/a = 1/a = n/a]),<br>[FLUNARIZINE] (C = n/a = n/a = [n/a = n/a = n/a]), |
|                       |             |             |                            |                                     |               |                |                  |        |    | Bedridden (n/a -<br>Unknown - ),  |   | [INOSITOL] (C - n/a - n/a<br>- [n/a - n/a - n/a]),  |
|                       |             |             |                            |                                     |               |                |                  |        |    | Blood alkaline<br>phosphatase<br>decreased (n/a -<br>Unknown - ),   |   | [LYSINE<br>HYDROCHLORIDE] (C -<br>n/a - n/a - [n/a - n/a -<br>n/a]),                        |
|                       |             |             |                            |                                     |               |                |                  |        |    | Blood copper<br>decreased (n/a -<br>Unknown - ),  |   | [NICOTINAMIDE] (C - n/a<br>- n/a - [n/a - n/a - n/a]),<br>[PYRIDOXINE                       |
|                       |             |             |                            |                                     |               |                |                  |        |    | Blood creatinine<br>decreased (n/a -<br>Unknown - ),  |   | HYDROCHLORIDE] (C -<br>n/a - n/a - [n/a - n/a -<br>n/a]),                                   |
|                       |             |             |                            |                                     |               |                |                  |        |    | Blood urea<br>decreased (n/a -<br>Unknown - ),  |   | [RIBOFLAVIN] (C - n/a - n/a - [n/a - n/a - n/a]), [THIAMINE                                 |
|                       |             |             |                            |                                     |               |                |                  |        |    | Bradycardia (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),   |   | HYDROCHLORIDE] (C -<br>n/a - n/a - [n/a - n/a -<br>n/a])                                    |
|                       |             |             |                            |                                     |               |                |                  |        |    | CSF glucose<br>increased (n/a -<br>Unknown - Other  |   |   |

| 30.11.2022 15.25 Run Line Listing Report   |                 |
|--|-----------------|
| Medically Important Condition),  |                 |
| CSF protein decreased (n/a - Unknown - ),  |                 |
| Drooling (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation),  |                 |
| Dyskinesia (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation),  |                 |
| Fatigue (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),   |                 |
| Fear of disease (n/a<br>- Unknown - ),   |                 |
| Gait disturbance (n/a<br>- Unknown -<br>Caused/Prolonged<br>Hospitalisation),  |                 |
| Headache (n/a - Recovered/Resolved - Other Medically Important Condition),   |                 |
| Hypotension (n/a -<br>Unknown - ),   |                 |
| Left ventricular dysfunction (n/a – Unknown – ),   |                 |
| Loss of personal independence in daily activities (n/a - Unknown - ),  |                 |
| Lymphadenopathy<br>(n/a - Unknown - ),   |                 |
| Mean cell haemoglobin concentration increased (n/a - Unknown - ),  |                 |
| Migraine (n/a - Not<br>Recovered/Not<br>Resolved - ),  |                 |
| Muscular weakness<br>(n/a - Unknown - ),   |                 |
| Myocarditis (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),  |                 |
| Pain (n/a - Unknown),  |                 |
| Pharyngitis (n/a -<br>Unknown - ),   |                 |
| Pyrexia (n/a -<br>Unknown - ),   |                 |
| Scoliosis (n/a -<br>Unknown - ),   |                 |
| Sinus tachycardia<br>(n/a - Unknown - ),   |                 |
| Supraventricular extrasystoles (n/a - Unknown - ),   |                 |
| Tachycardia (n/a -<br>Unknown - ),   |                 |
| Tremor (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),  |                 |
| Urine output increased (n/a -  |                 |
| EU-EC- 10013323782 Spontaneous Non Healthcare Professional Real Professional Real Recovered Resolved Recovered Resolved Recovered Resolved Recovered Recover | rted <u>I</u> ! |
| Dizziness (2d - Recovered/Resolved - Other Medically Important Condition),   |                 |
| Dysphagia (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),  |                 |

| _ |                       |            |             |                                   |                                     |               |                |                  | 5      | •  |  |  |  |          |
|---|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|--|--|--|----------|
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Ear pain (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),               |  |  |          |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Fatigue (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),                      |  |  |          |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Headache (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),                     |  |  |          |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Lymphadenopathy<br>(n/a -<br>Recovering/Resolving -<br>Other Medically<br>Important<br>Condition),           |  |  |          |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Nausea (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),                         |  |  |          |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Pain in jaw (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),            |  |  |          |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Pharyngeal swelling<br>(n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition), |  |  |          |
|   | FU 50                 | 24/00/2022 |             |                                   |                                     |               | 12.17          |                  |        |    | Pyrexia (2d -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)                             | COMPANY  |  | Ļ        |
|   | EU-EC-<br>10013324925 | 24/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No |  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use]) | Not reported   | <u>I</u> |
|   | EU-EC-<br>10013305117 | 23/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No |  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular                     | [METHYLPHENIDATE<br>HYDROCHLORIDE] (C -<br>Attention deficit<br>hyperactivity disorder -<br>n/a - [n/a - n/a - Oral<br>use]) | <u>I</u> |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    |  | use])  | y  |          |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Drug ineffective (n/a  |  |  |          |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Recovered/Resolved Other Medically Important Condition),   |  |  |          |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Lethargy (7d -<br>Recovered/Resolved<br>- ),   |  |  |          |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Malaise (n/a -<br>Recovered/Resolved<br>- ),   |  |  |          |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Nausea (n/a -<br>Recovered/Resolved<br>- ),  |  |  |          |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Pyrexia (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),                        |  |  |          |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Vomiting (n/a -<br>Recovered/Resolved<br>- )   |  |  |          |
|   | EU-EC-<br>10013306108 | 23/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No | pain (1d -   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not  | Not reported   | ľ        |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Fatigue (1d -  | applicable - [n/a -<br>1{DF} -<br>Intramuscular use])  |  |          |
|   | EU-EC-<br>10013306472 | 23/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available |                | Not<br>Specified | Female | No | Nausea (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important                                | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])             | Not reported   | <u>I</u> |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Syncope (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important Condition)                          | · <del>-</del> ,   |  | L        |
|   | EU-EC-<br>10013306476 | 23/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Abdominal pain<br>upper (n/a -<br>Unknown - Other<br>Medically Important                                     | COVID-19<br>immunisation - Not<br>applicable - [1d - n/a   | [IBUPROFEN,<br>IBUPROFEN SODIUM] (C<br>- Pain - n/a - [2d - n/a -  | <u>I</u> |
|   |                       |            |             |                                   |                                     |               |                |                  |        |    | Dizziness (n/a -<br>Unknown - Other  | - n/a])  |  |          |

| ٥١ | J.11.2022             | 13.23      |             |                                   |                                     |               | Κt             | in Line Li       | Sung R | eport |  |  |              |            |
|----|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|-------|--|--|--------------|------------|
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | Medically Important<br>Condition),<br>Illness (n/a -<br>Unknown - Other<br>Medically Important   |  |              |            |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | Condition),  Syncope (n/a - Recovering/Resolving - Other Medically Important   |  |              |            |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | Condition), Tremor (n/a - Unknown - Other Medically Important Condition)   |  |              |            |
|    | EU-EC-<br>10013306846 | 23/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female | No    | Influenza like illness<br>(n/a - Unknown - ),<br>Sleep disorder (n/a -<br>Unknown - ),   | COMIRNATY 30<br>MICROGRAMS/DOSE<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a - | Not reported | <u>I</u> ! |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       |  | 1{DF} -<br>Intramuscular use])   |              |            |
|    | EU-EC-<br>10013306925 | 23/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No    | Not Recovered/Not<br>Resolved - ),<br>Cyanosis (n/a - Not  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - n/a - n/a])                      | Not reported | <u>I</u> ! |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | Recovered/Not<br>Resolved - ),<br>Neurodermatitis (n/a   |  |              |            |
|    | EU-EC-                | 23/08/2022 | Spontaneous | Non                               | European                            | Not available | 12-17          | Not              | Male   | No    | - Not Recovered/Not<br>Resolved - )<br>Lymphadenopathy   | COMIRNATY  | Not reported | 1          |
|    | 10013307272           | 25,00,2022 | Sportaneous | Healthcare<br>Professional        | Economic                            |               | Years          | Specified        | . raic |       | (3d - Recovered/Resolved - ),  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -                                    | not reported | -          |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | Recovered/Resolved   | n/a - n/a])  |              |            |
|    | EU-EC-<br>10013308927 | 23/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No    | Abdominal pain<br>(172h -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a                                | Not reported | <u>I</u>   |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | Chest pain (172h -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),  | - Intramuscular use])  |              |            |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | Decreased appetite<br>(172h -<br>Recovered/Resolved<br>- Caused/Prolonged  |  |              |            |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | Hospitalisation),  Dizziness (172h - Recovered/Resolved - Caused/Prolonged   |  |              |            |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | Hospitalisation), Headache (172h - Recovered/Resolved - Caused/Prolonged   |  |              |            |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | Hospitalisation),<br>Loss of personal<br>independence in<br>daily activities (172h   |  |              |            |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | - Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),  |  |              |            |
|    |                       |            |             |                                   |                                     |               | 10.17          |                  |        |       | Nausea (172h -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation)   |  |              |            |
|    | EU-EC-<br>10013309963 | 23/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No    | Abdominal pain<br>upper (2h -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition), | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])                      | Not reported | <u>I</u>   |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | Pain (2h -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important Condition)                        |  |              |            |
|    | EU-EC-<br>10013310045 | 23/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No    | Blood creatine<br>phosphokinase MB<br>(n/a -<br>Recovering/Resolving<br>-),  | applicable - [1d - n/a   | Not reported | <u>I</u>   |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | Blood creatine<br>phosphokinase<br>increased (n/a -<br>Recovering/Resolving<br>- ),  | - n/a])  |              |            |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | Chest pain (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),   |  |              |            |
|    |                       |            |             |                                   |                                     |               |                |                  |        |       | Troponin I increased<br>(n/a -<br>Recovering/Resolving   |  |              |            |

|                 |            |             |                                   |                                     |               |                |                  |        |    | -),  |  |   |          |
|-----------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|--|--|---|----------|
|                 |            |             | 1                                 |                                     |               |                |                  | I      |    | L  |  | I   |          |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Vomiting (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged  |  |   |          |
| EC-<br>13310226 | 23/08/2022 | Spontaneous | Healthcare<br>Professional        | Economic                            | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Hospitalisation)<br>  Chest discomfort<br>(n/a -<br>  Recovering/Resolving   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19  | Not reported  | 10       |
|                 |            |             |                                   | Area                                |               |                |                  |        |    | Chest pain (n/a -<br>Recovering/Resolving<br>- Other Medically   | immunisation - Not<br>applicable - [1d - n/a<br>- n/a])  |   |          |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Important<br>Condition),<br>Palpitations (n/a -  |  |   |          |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Recovering/Resolving - ), Pupil dilation   |  |   |          |
|                 |            |             |                                   |                                     |               |                |                  |        |    | procedure (n/a -<br>Recovering/Resolving<br>-)   |  |   |          |
| EC-<br>13310547 | 23/08/2022 | Spontaneous |                                   | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Heart rate (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)  | COVID-19   | [DIPHENHYDRAMINE<br>HYDROCHLORIDE] (C -<br>n/a - n/a - [1d - n/a -<br>n/a]) | <u>I</u> |
| EC-<br>13310552 | 23/08/2022 | Spontaneous |                                   | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Cold sweat (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -   | [PARACETAMOL] (C - n/a<br>- n/a - [n/a - n/a - n/a])                        | I        |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Dyspnoea (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),   | n/a - n/a])  |   |          |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Fatigue (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition).  |  |   |          |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Hot flush (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important   |  |   |          |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Malaise (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),  |  |   |          |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Pain (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   |  |   |          |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Pyrexia (n/a -<br>Recovering/Resolving<br>- Other Medically  |  |   |          |
| EC-<br>13310579 | 23/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Headache (2d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),  | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a  | [PARACETAMOL] (C -<br>Dysmenorrhoea - n/a -<br>[1d - n/a - n/a])            | I        |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Hypoaesthesia (1d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition).   | - n/a])  |   |          |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Monoparesis (2d -<br>Recovered/Resolved<br>- Other Medically<br>Important  |  |   |          |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Vaccination site pain<br>(2d -<br>Recovered/Resolved<br>- Other Medically  |  |   |          |
| EC-<br>13310679 | 23/08/2022 | Spontaneous |                                   | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Arthralgia (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -   | Not reported  | I        |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Dry throat (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition).   | n/a - n/a])  |   |          |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Fatigue (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important   |  |   |          |
|                 |            |             |                                   |                                     |               |                |                  |        |    | Headache (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important  |  |   |          |
| EC-<br>13310679 | 23/08/2022 |             | Non<br>Healthcare<br>Professional | Non European Economic Area          |               | Years          | Specified        |        |    | Important Condition),  Dyspnoea (n/a - Recovered/Resolved - Other Medically Important Condition),  Fatigue (n/a - Recovered/Resolved - Other Medically Important Condition),  Hot flush (n/a - Recovering/Resolving - Other Medically Important Condition),  Malaise (n/a - Recovering/Resolving - Other Medically Important Condition),  Pain (n/a - Recovering/Resolving - Other Medically Important Condition),  Pain (n/a - Recovering/Resolving - Other Medically Important Condition),  Pyrexia (n/a - Recovering/Resolving - Other Medically Important Condition),  Pyrexia (n/a - Recovered/Resolving - Other Medically Important Condition),  Headache (2d - Recovered/Resolved - Other Medically Important Condition),  Hypoaesthesia (1d - Recovered/Resolved - Other Medically Important Condition),  Monoparesis (2d - Recovered/Resolved - Other Medically Important Condition),  Vaccination site pain (2d - Recovered/Resolved - Other Medically Important Condition),  Vaccination site pain (2d - Recovered/Resolved - Other Medically Important Condition),  Pry throat (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Pry throat (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Patigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Patigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), | immunisation - Not applicable - [n/a - n/a])  TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])  TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a]) | Dysmenorrhoea<br>[1d - n/a - n/a])  | - n/a -  |

| 1.11.2022             | 13.23      |             |                                   |                                     |                | Ru             | n Line L         | isting r | teport | L  |   |  |            |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|----------------|----------------|------------------|----------|--------|--|---|--|------------|
|                       |            |             |                                   |                                     |                |                |                  |          |        | Recovering/Resolving - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - Other Medically - Other Medically |   |  |            |
| EU-EC-<br>10013310681 | 23/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available  |                | Not<br>Specified | Female   | No     | - Other Medically Important Condition)  Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Musculoskeletal stiffness (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)    | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                  | METHOTREXATE [METHOTREXATE] (C - n/a | I          |
| EU-EC-                | 23/08/2022 | Spontaneous | Non                               | Non                                 | Not available  | 12-17          | Not              | Female   | No     | Neck pain (n/a - Not   | TOZINAMERAN   | TARTRATE BP] (C - n/a - n/a - [n/a - n/a - n/a]),  [ONDANSETRON] (C - n/a - n/a - [n/a - n/a - n/a])  Not reported   | I          |
| 10013310690           | 23,00,2022 | Spontaneous |                                   | European                            | ivot available |                | Specified        | remae    | INO    | Recovered/Not Resolved - Other Medically Important Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                                 | Not reported   | 1          |
| EU-EC-<br>10013310739 | 23/08/2022 | Spontaneous |                                   | Non<br>European<br>Economic<br>Area | Not available  | 12-17<br>Years | Not<br>Specified | Female   | No     | Arthralgia (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),<br>Fatigue (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)                                       | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                  | Not reported   | 1          |
| EU-EC-<br>10013311227 | 23/08/2022 | Spontaneous | Healthcare<br>Professional        |                                     | Not available  | 12-17<br>Years | Adolescent       | Male     | No     | Confusional state (n/a - Not Recovered/Not Resolved - ),  Pyrexia (n/a - Not Resolved - ),  Tendonitis (n/a - Not Resolved - ),  Tendonitis (n/a - Not Recovered/Not Resolved - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} -<br>Intramuscular use]) | Not reported   | <u>]</u>   |
| EU-EC-<br>10013311248 | 23/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Female   | No     | Resolved - ) Heavy menstrual bleeding (n/a - Not Recovered/Not Resolved - ), Hypotension (n/a - Not Recovered/Not  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])                  | [TRANEXAMIC ACID] (C -<br>n/a - n/a - [n/a - n/a -<br>n/a])  | . <u>1</u> |
| EU-EC-<br>10013311328 | 23/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Female   | No     | Resolved - ) Menstruation irregular (n/a - Not Recovered/Not Resolved - ), Uterine pain (n/a - Not Recovered/Not Resolved - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[1d - 1{DF} -<br>Intramuscular use])               | Not reported   | 1          |
| EU-EC-<br>10013311336 | 23/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Female   | No     | Oligomenorrhoea<br>(n/a - Not<br>Recovered/Not<br>Resolved - ),<br>Uterine pain (n/a -<br>Not Recovered/Not<br>Resolved - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[1d - 1{DF} -<br>Intramuscular use])               | Not reported   | 1          |
| EU-EC-<br>10013312640 | 23/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available  |                | Not<br>Specified | Female   | No     | COVID-19 (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),<br>Drug ineffective (n/a -<br>Unknown - Other<br>Medically Important<br>Condition)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                   | Not reported   | I          |
| EU-EC-<br>10013313061 | 23/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available  |                | Not<br>Specified | Female   | No     | Dizziness (30min - Recovered/Resolved - ), Expired product administered (30min - Recovered/Resolved - ), Immunisation (n/a - Unknown - Other Medically Important Condition),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])      | Not reported   | I          |

| J.11.2022             | 15.25      |             |                                   |                                     |   | Rι             | ın Line L        | isting R         | epori | Į.   |  |              |            |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---|----------------|------------------|------------------|-------|--|--|--------------|------------|
|                       |            |             |                                   |                                     |   |                |                  |                  |       | Off label use (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),  |  |              |            |
|                       |            |             |                                   |                                     |   |                |                  |                  |       | Syncope (30min -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)  |  |              |            |
| EU-EC-<br>10013313531 |            | Spontaneous | Healthcare<br>Professional        |                                     | Not available   | Years          | Not<br>Specified | Male             | No    | Vaccination site pain<br>(n/a - Unknown - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])                   | Not reported | <u>I</u>   |
| EU-EC-<br>10013313589 | 23/08/2022 | Spontaneous | Healthcare                        | Non<br>European<br>Economic<br>Area | Not available   | 12-17<br>Years | Not<br>Specified | Female           | No    | Insomnia (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),<br>Pain in extremity<br>(n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important Condition)     | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                               | Not reported | <u>I</u> 1 |
| EU-EC-<br>10013313721 | 23/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available   | 12-17<br>Years | Not<br>Specified | Male             | No    | Vaccination site pain<br>(34d -<br>Recovered/Resolved<br>-)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])                   | Not reported | 1          |
| EU-EC-<br>10013314204 | 23/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available   | 12-17<br>Years | Adolescent       | Female           | No    | Vaccination site<br>lymphadenopathy<br>(n/a -<br>Recovering/Resolving<br>-)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use -<br>More in ICSR]) | Not reported | <u>I</u>   |
| EU-EC-<br>10013314236 | 23/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available   | 12-17<br>Years | Adolescent       | Male             | No    | Headache (2d -<br>Recovered/Resolved<br>- ),<br>Pyrexia (2d -<br>Recovered/Resolved<br>- ),<br>Vomiting (2d -<br>Recovered/Resolved<br>- )                                       | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [n/a - n/a - Intramuscular use])                                 | Not reported | 1          |
| EU-EC-<br>10013314276 | 23/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available   | 12-17<br>Years | Adolescent       | Female           | No    | Lymphadenopathy<br>(n/a -<br>Recovering/Resolving<br>-)  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])                                  | Not reported | Ī          |
| EU-EC-<br>10013314279 | 23/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available   | 12-17<br>Years | Adolescent       | Female           | No    | Lymphadenopathy<br>(n/a -<br>Recovering/Resolving<br>-)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use])                   | Not reported | Ī          |
| EU-EC-<br>10013314340 | 23/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available   | 12-17<br>Years | Adolescent       | Female           | No    | Headache (3d -<br>Recovered/Resolved<br>- ),<br>Malaise (3d -<br>Recovered/Resolved<br>- ),<br>Vaccination site pain<br>(3d -<br>Recovered/Resolved<br>- )                       | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])                   | Not reported | <u>I</u>   |
| EU-EC-<br>10013314844 | 23/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Economic                            | Not available   | 12-17<br>Years | Not<br>Specified | Female           | No    | Heavy menstrual<br>bleeding (n/a - Not<br>Recovered/Not<br>Resolved - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} - n/a])                              | Not reported | Ī          |
| EU-EC-<br>10013315062 | 23/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Farinazzo, E Cutaneous adverse reactions after m-RNA COVID-19 vaccine: early reports from Northeast Italy. J Eur Acad Dermatol Venereol. 2021;35:e548-e551. doi:10.1111/jdv.17343   | 12-17<br>Years | Not<br>Specified | Not<br>Specified | No    | Multisystem inflammatory syndrome (n/a - Unknown - Life Threatening, Other Medically Important Condition), Rash maculo-papular (n/a - Unknown - )                                | TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])   | Not reported | <u>I</u>   |
| EU-EC-<br>10013294869 | 22/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Kirpalani, A Thrombotic thrombocytopenic purpura temporally associated with BNT162b2 vaccination in an adolescent successfully treated with caplacizumab. British Journal of Haematology. 2022;196 (1):e11-e14. doi:10.1111/bjh.17782 Kirpalani, A Thrombotic thrombocytopenic purpura temporally associated with BNT162b2 vaccination in an adolescent successfully treated with caplacizumab. British Journal of Haematology. 2021;10.1111/bjh.17782. doi:10.1111/bjh.17782 | 12-17<br>Years | Not<br>Specified | Female           | No    | Thrombotic thrombocytopenic purpura (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition)  | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                              | Not reported | Ī          |
| EU-EC-<br>10013294873 | 22/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available   | 12-17<br>Years | Not<br>Specified | Male             | No    | Chest pain<br>(11480min -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),<br>Dyspnoea (11480min -<br>Recovered/Resolved<br>- Other Medically<br>Important | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                                 | Not reported | Ī          |

| 30.11.2022 15.25                     |  |                    | Ru             | ın Line Li       | sting R | eport | t  |  |              |          |
|--------------------------------------|--|--------------------|----------------|------------------|---------|-------|--|--|--------------|----------|
|                                      |  |                    |                |                  |         |       | Condition), Electrocardiogram ST segment elevation (11480min - Recovered/Resolved - Other Medically Important Condition), Headache (244h - Recovered/Resolved - ), Hypoaesthesia (11480min - Recovered/Resolved - Other Medically Important Condition), Inflammation (7d - Recovered/Resolved - ), Myocarditis (11480min - Recovered/Resolved - Other Medically Important Condition), Inflammation (7d - Recovered/Resolved - Other Medically Important Condition), Pyrexia (11480min - Recovered/Resolved - Other Medically Important Condition), Pyrexia (n/a - Recovering/Resolving - ), Troponin I increased (11480min - Recovered/Resolved                        |  |              |          |
|                                      | pontaneous Non Europ   | pean Not available | 12-17          | Adolescent       | Female  | No    | - Other Medically<br>Important Condition)<br>Asthenia (n/a -   | COMIRNATY  | Not reported | <u> </u> |
| 10013295479                          | Non Europe Econo Professional Area   |                    | 12-17<br>Years | Adolescent       | Female  | No    | Asthenia (n/a - Recovering/Resolving - ), Diarrhoea (n/a - Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ), Headache (n/a - Recovering/Resolving - ), Hypoaesthesia (n/a - Recovering/Resolving - ), Hypoaesthesia (n/a - Recovering/Resolving - ), Oropharyngeal pain (n/a - Recovering/Resolving - ), Pain (n/a - Recovering/Resolving - ), Pain in extremity (n/a - Recovering/Resolving - ), Pryrexia (n/a - Recovering/Resolving - ), Rhinitis (n/a - Recovering/Resolving - ), Vaccination site discolouration (n/a - Recovering/Resolving - ), Vision blurred (n/a - Recovering/Resolving - ), Vision blurred (n/a - Recovering/Resolving - ) | [TOZINAMERAN] (S - n/a - n/a - 1/a - 1/a - n/a - 1/a - n/a - 1/a - n/a - | Not reported |          |
| EU-EC-<br>10013295770 22/08/2022 Spc | Non Healthcare Professional Pro | omic               | 12-17<br>Years | Not<br>Specified | Female  | No    | Chest pain (n/a -<br>Unknown - Other<br>Medically Important  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a - More in<br>ICSR])  | Not reported | 1/67     |

| .11.2022              |            |             |                                   |                                     |               |                | <br>             |        |    | Recovered/Resolved  |   |              |          |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|---|---|--------------|----------|
| EU-EC-                | 22/08/2022 | Spontaneous |                                   | Non                                 | Not available | 12-17          |                  | Male   | No | - Other Medically<br>Important Condition)<br>COVID-19 (n/a -  | TOZINAMERAN   | Not reported | 1        |
| .0013296059           |            |             | Healthcare<br>Professional        | European<br>Economic<br>Area        |               | Years          | Specified        |        |    | - Other Medically<br>Important<br>Condition),   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a  |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Vaccination failure<br>(n/a -<br>Recovering/Resolving<br>- Other Medically                                  | - Intramuscular use])   |              |          |
| EU-EC-<br>10013296681 | 22/08/2022 | Spontaneous |                                   | European                            | Not available |                | Adolescent       | Male   | No | Important Condition) Arthralgia (n/a - Not  | COMIRNATY   | Not reported | I        |
| 10013290081           |            |             | Professional                      | Economic<br>Area                    |               | Years          |                  |        |    | Recovered/Not<br>Resolved - ),<br>Blood pressure<br>increased (n/a - Not<br>Recovered/Not                   | [TOZINAMERAN] (S -<br>n/a - n/a - [1d - n/a -<br>n/a])                          |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Resolved - ), Fatigue (n/a - Not Recovered/Not Resolved - ),  |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Fear of injection (n/a<br>- Not Recovered/Not<br>Resolved - ),  |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Hyperhidrosis (n/a -<br>Not Recovered/Not<br>Resolved - ),  |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Lymphadenopathy<br>(n/a - Not<br>Recovered/Not<br>Resolved - ),   |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Muscle twitching<br>(n/a - Not<br>Recovered/Not<br>Resolved - ),  |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Pyrexia (n/a - Not<br>Recovered/Not<br>Resolved - ),  |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Syncope (n/a - Not<br>Recovered/Not   |   |              |          |
| EU-EC-<br>10013296958 | 22/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Resolved - )  Cough (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),               | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a | Not reported | <u>I</u> |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Headache (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),              | - n/a])   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Myalgia (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),               |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Oropharyngeal pain<br>(n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition), |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Pyrexia (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),               |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Suspected COVID-19<br>(n/a - Not<br>Recovered/Not<br>Resolved - )   |   |              |          |
| EU-EC-<br>10013297269 | 22/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No | Lymphadenitis (10d -<br>Recovered/Resolved<br>- ),  | [TOZINAMERAN] (S -<br>COVID-19  | Not reported | 1        |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Lymphadenopathy<br>(10d -<br>Recovered/Resolved   | immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])     |              |          |
| EU-EC-<br>10013297703 | 22/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available |                | Not<br>Specified | Female | No | Swelling (n/a - Not<br>Recovered/Not<br>Resolved -<br>Disabling),   | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not             | Not reported | Ī        |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Vaccination site<br>erythema (n/a -<br>Unknown -<br>Disabling),   | applicable - [1d - n/a<br>- n/a])   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Vaccination site pain<br>(n/a - Unknown -<br>Disabling),  |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Vaccination site<br>swelling (n/a -<br>Unknown -<br>Disabling),   |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Vaccination site<br>warmth (n/a -<br>Unknown -  |   |              |          |
| EU-EC-                | 22/08/2022 | Spontaneous | Non                               | European                            | Not available | 12-17          | Not              | Female | No | Disabling)<br>Nausea (n/a -   | COMIRNATY   | Not reported | 1        |

| ).11.2022 <i>1</i>    | 15.25      |             |                            |                                     |               | RL             | ın Line L        | isting R | epori | Į.  |  |              |   |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|----------|-------|---|--|--------------|---|
| 10013297900           |            |             | Healthcare<br>Professional |                                     |               | Years          | Specified        |          |       | Unknown - ), Pyrexia (n/a - Not Recovered/Not   | [TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- n/a])  |              |   |
| EU-EC-<br>10013298613 | 22/08/2022 | Spontaneous | Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Resolved - ) Acute hepatic failure (n/a - Not Recovered/Not Resolved - Life Threatening, Caused/Prolonged Hospitalisation, Disabling, Other Medically Important Condition),             | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- n/a])                                   | Not reported |   |
|                       |            |             |                            |                                     |               |                |                  |          |       | Budd-Chiari<br>syndrome (n/a - Not<br>Recovered/Not<br>Resolved - Life<br>Threatening,<br>Caused/Prolonged<br>Hospitalisation,<br>Disabling, Other<br>Medically Important<br>Condition) |  |              |   |
| EU-EC-<br>10013299347 | 22/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Chest discomfort<br>(n/a - Not<br>Recovered/Not<br>Resolved - ),<br>Chest pain (n/a - Not<br>Recovered/Not  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a]) | Not reported |   |
|                       |            |             |                            |                                     |               |                |                  |          |       | Resolved - ), Dizziness postural (n/a - Not Recovered/Not Resolved - ),   |  |              |   |
|                       |            |             |                            |                                     |               |                |                  |          |       | Dyspnoea (n/a - Not<br>Recovered/Not<br>Resolved - ),   |  |              |   |
|                       |            |             |                            |                                     |               |                |                  |          |       | Electrocardiogram ST<br>segment depression<br>(n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),   |  |              |   |
|                       |            |             |                            |                                     |               |                |                  |          |       | Electrocardiogram T<br>wave inversion (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),   |  |              |   |
|                       |            |             |                            |                                     |               |                |                  |          |       | Influenza A virus test<br>positive (n/a - Not<br>Recovered/Not<br>Resolved - ),   |  |              |   |
|                       |            |             |                            |                                     |               |                |                  |          |       | Microcytosis (n/a -<br>Not Recovered/Not<br>Resolved - ),   |  |              |   |
|                       |            |             |                            |                                     |               |                |                  |          |       | Myocarditis (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),   |  |              |   |
|                       |            |             |                            |                                     |               |                |                  |          |       | Troponin increased<br>(n/a - Not<br>Recovered/Not<br>Resolved - )   |  |              |   |
| EU-EC-<br>10013299475 | 22/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Anaemia (n/a -<br>Recovered/Resolved<br>- ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not                                      | Not reported |   |
|                       |            |             |                            | Alea                                |               |                |                  |          |       | Arthralgia (n/a -<br>Recovered/Resolved<br>- ),   | applicable - [1d - n/a<br>- n/a])  |              |   |
|                       |            |             |                            |                                     |               |                |                  |          |       | Chest discomfort<br>(n/a -<br>Recovered/Resolved  |  |              |   |
|                       |            |             |                            |                                     |               |                |                  |          |       | Chest pain (n/a -<br>Recovered/Resolved   |  |              |   |
|                       |            |             |                            |                                     |               |                |                  |          |       | Neutropenia (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)   |  |              |   |
| EU-EC-<br>10013300517 | 22/08/2022 | Spontaneous | Healthcare                 | European<br>Economic                | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Abdominal pain (n/a<br>- Unknown - ),   | COMIRNATY<br>[TOZINAMERAN] (S -  | Not reported |   |
|                       |            |             | Professional               | Area                                |               |                |                  |          |       | Chest pain (n/a -<br>Unknown - ),   | COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                                   |              |   |
|                       |            |             |                            |                                     |               |                |                  |          |       | Dyspnoea (n/a -<br>Unknown - ),   |  |              |   |
|                       |            |             |                            |                                     |               |                |                  |          |       | Menstrual disorder<br>(n/a - Unknown - ),   |  |              |   |
|                       |            |             |                            | _                                   |               | 1-             |                  |          |       | Pain (n/a - Unknown<br>- )  |  |              |   |
| EU-EC-<br>10013301099 | zz/u8/2022 | Spontaneous | Healthcare<br>Professional |                                     | Not available | 12-17<br>Years | Adolescent       | ıশale    | No    | Neuralgic<br>amyotrophy (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -               | Not reported | 2 |

|                     |            |             |                                   |                                     |               |                |                  |        |    |   | 1{DF} -<br>Intramuscular use])   |  |
|---------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|---|--|--|
| U-EC-<br>0013301353 | 22/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | Heavy menstrual<br>bleeding (14d -<br>Recovered/Resolved<br>- ),<br>Heavy menstrual<br>bleeding (21d -<br>Recovered/Resolved<br>- )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [2d -<br>1{DF} -<br>Intramuscular use])              | Not reported   |
| J-EC-<br>0013301388 | 22/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No | Lymphadenitis (16d -<br>Recovered/Resolved<br>- )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[1d - 1{DF} -<br>Intramuscular use])                            | Not reported   |
| J-EC-<br>013301483  | 22/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | Amenorrhoea (1a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])             | Not reported   |
| J-EC-<br>0013302322 | 22/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | COVID-19 (n/a - Unknown - Other Medically Important Condition), Cough (n/a - Unknown - ), Nasal congestion (n/a - Unknown - ), Nausea (n/a - Unknown - ), Pyrexia (n/a - Unknown - ), Rhinorrhoea (n/a - Unknown - ), Vaccination failure (n/a - Unknown - Other Medically  | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])                 | Not reported   |
| J-EC-<br>0013302467 | 22/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available |                | Not<br>Specified | Female | No | Important Condition) Epileptic encephalopathy (n/a - Unknown - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Seizure (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Status epilepticus (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition), | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                               | BRIVARACETAM [BRIVARACETAM] (C - Lennox-Gastaut syndrome - n/a - [n/a - n/a - n/a]),  CANNABIDIOL [CANNABIDIOL] (C - Lennox-Gastaut syndrome - n/a - [n/a - n/a - n/a]),  PERAMPANEL [PERAMPANEL] (C - Lennox-Gastaut syndrome - n/a - [n/a - n/a - n/a]),  [CLOBAZAM] (C - Lennox-Gastaut syndrome - n/a - [n/a - n/a - n/a]),  [LANSOPRAZOLE] (C - n/a - n/a - [n/a - n/a] |
| J-EC-<br>013303236  | 22/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | Malaise (n/a -<br>Unknown - ),<br>Pyrexia (n/a -<br>Unknown - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} - n/a])                               | Not reported   |
| 0013303258          | 22/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No | Lymphadenopathy<br>(n/a - Not<br>Recovered/Not<br>Resolved - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use -<br>More in ICSR]) | Not reported   |
| J-EC-<br>013303331  | 22/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Economic                            | Not available | 12-17<br>Years | Adolescent       | Male   | No | Vaccination site<br>lymphadenopathy<br>(7d -<br>Recovered/Resolved<br>-)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use -<br>More in ICSR]) | Not reported   |
| J-EC-<br>1013303389 | 22/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No | Arthralgia (0d - Recovered/Resolved - ), Fatigue (0d - Recovered/Resolved - ), Nausea (0d - Recovered/Resolved - ), Pyrexia (0d - Recovered/Resolved - ), Vaccination site pain (1d - Recovered/Resolved - )  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])                   | Not reported   |
| I-EC-<br>013303392  | 22/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | Headache (n/a - Not<br>Recovered/Not<br>Resolved - ),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug   | Not reported   |

|                       |            |             |                                   |                                     |               |                |                  |        |    | Pyrexia (n/a - Not<br>Recovered/Not<br>Resolved - )   | withdrawn - [n/a -<br>n/a - Intramuscular<br>use])  |              |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|---|---|--------------|
| :U-EC-<br>0013292066  | 20/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available |                | Not<br>Specified | Female | No | Syncope (n/a -  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use]) | Not reported |
| U-EC-<br>0013283109   | 19/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | Dyspnoea exertional<br>(n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation), | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- Intramuscular use])                    | Not reported |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Lymphadenopathy<br>(n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),     |   |              |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Lymphoma (n/a -<br>Not Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),               |   |              |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Palpitations (n/a -<br>Not Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),           |   |              |
| U-EC-                 | 19/08/2022 | Spontaneous | Non                               | European                            | Not available | 12-17          | Not              | Female | No | Pyrexia (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation)                 | COMIRNATY   | Not reported |
| 0013283856            | , -, -     | ,           | Healthcare<br>Professional        | Economic                            |               |                | Specified        |        |    | - Recovered/Resolved - ), Fatigue (n/a - Unknown - ),   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])            | ,            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Myalgia (n/a -<br>Unknown - )   |   |              |
| U-EC-<br>0013284229   | 19/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available |                | Not<br>Specified | Male   | No | Drug ineffective (6d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),             | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a           | Not reported |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Suspected COVID-19<br>(6d -   | - n/a])   |              |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Recovered/Resolved - Other Medically  |   |              |
| U-EC-<br>0013285242   | 19/08/2022 | Spontaneous | Healthcare                        | European<br>Economic<br>Area        | Not available |                | Not<br>Specified | Female | No | Important Condition) Anosmia (7d - Recovered/Resolved - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -                                   | Not reported |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Bone pain (7d -<br>Recovered/Resolved<br>- ),<br>Chills (7d -   | [n/a - 30{DF} - n/a])   |              |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Recovered/Resolved -), Cough (7d - Recovered/Resolved   |   |              |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Decreased appetite  |   |              |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Recovered/Resolved - ), Dizziness (7d - Recovered/Resolved  |   |              |
|                       |            |             |                                   |                                     |               |                |                  |        |    | - ),  Dyspnoea (7d - Recovered/Resolved - ),  |   |              |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Insomnia (7d -<br>Recovered/Resolved<br>-),   |   |              |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Myalgia (7d -<br>Recovered/Resolved   |   |              |
| EU-EC-<br>10013285385 | 19/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Hypotension (5min -<br>Recovered/Resolved - ),  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not  | Not reported |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Malaise (5min -<br>Recovered/Resolved<br>- ),<br>Syncope (5min -<br>Recovered/Resolved                    | applicable - [1d - n/a<br>- Intramuscular use])   |              |
|                       |            |             |                                   |                                     |               |                |                  | _      |    | - Other Medically<br>Important Condition)   |   |              |
| EU-EC-<br>10013285417 | 19/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Hypotension (5min -<br>Recovered/Resolved<br>- ),<br>Malaise (n/a -                                       | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a           | Not reported |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Unknown - ),  Myalgia (10min - Recovered/Resolved   | - Intramuscular use])   |              |

| .11.2022            |            |             |                                   |                                     |               |                |                  |        |     | Syncope (5min -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)   |   |   |
|---------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|-----|--|---|---|
| U-EC-<br>0013285676 | 19/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female | No  | Abdominal pain<br>upper (n/a -<br>Unknown - ),<br>Chills (n/a -<br>Recovering/Resolving<br>- ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- n/a])  | [DROSPIRENONE,<br>LACTOSE, LACTOSE<br>MONOHYDRATE] (C - n/a<br>- n/a - [n/a - n/a - Oral<br>use]) |
|                     |            |             |                                   |                                     |               |                |                  |        |     | Dizziness (n/a - Not<br>Recovered/Not<br>Resolved - ),<br>Nausea (n/a -<br>Recovering/Resolving  |   |   |
|                     |            |             |                                   |                                     |               |                |                  |        |     | - ),<br>Pain (n/a -<br>Recovering/Resolving  |   |   |
| J-EC-<br>0013285718 | 19/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female | No  | - )<br>  Inflammation (0d -<br>  Recovered/Resolved<br> - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - 30{DF} - n/a])                              | Not reported  |
| U-EC-<br>0013286466 | 19/08/2022 | Spontaneous |                                   | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No  | Facial paralysis (n/a -<br>Recovering/Resolving<br>- Disabling, Other<br>Medically Important<br>Condition)   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])                     | Not reported  |
| U-EC-<br>0013286897 | 19/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | Yes | Circulatory collapse<br>(n/a -<br>Recovered/Resolved -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),                                    | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                    | Not reported  |
|                     |            |             |                                   |                                     |               |                |                  |        |     | Febrile convulsion<br>(1d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),                                       |   |   |
|                     |            |             |                                   |                                     |               |                |                  |        |     | Loss of<br>consciousness (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important Condition)  |   |   |
| U-EC-<br>0013286908 | 19/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male   | No  | Dyspnoea (33d -<br>Recovered/Resolved - ),<br>Fatigue (33d -<br>Recovered/Resolved - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                    | Not reported  |
|                     |            |             |                                   |                                     |               |                |                  |        |     | Groin pain (33d -<br>Recovered/Resolved<br>- ),<br>Myalgia (n/a -<br>Recovered/Resolved  |   |   |
|                     |            |             |                                   |                                     |               |                |                  |        |     | - ),<br>Pain (33d -<br>Recovered/Resolved<br>- )   |   |   |
| U-EC-<br>0013287264 | 19/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male   | No  | Injection site reaction (1d - Recovered/Resolved - ), Pruritus (1d - Recovered/Resolved  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                   | Not reported  |
|                     |            |             |                                   |                                     |               |                |                  |        |     | - ),<br>Rash (1d -<br>Recovered/Resolved   |   |   |
| U-EC-<br>0013287751 | 19/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No  | - ) Dysmenorrhoea (n/a Recovering/Resolving - Other Medically Important Condition),  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -                                       | Not reported  |
|                     |            |             |                                   |                                     |               |                |                  |        |     | Menstruation irregular (n/a - Recovering/Resolving - Other Medically   | Intramuscular use])   |   |
| U-EC-<br>0013287798 | 19/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No  | Important Condition) Amenorrhoea (n/a - Recovered/Resolved - Other Medically Important Condition), Oligomenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} -<br>Intramuscular use]) | Not reported  |
| U-EC-               | 19/08/2022 | Spontaneous | Non                               | European                            | Not available | 12-17          | Adolescent       | Female | No  | Condition)  Dysphagia (n/a - Not   | COMIRNATY   | Not reported  |

| J.11.2022             |            |             |                                   | I                            | 1             |                | in Line Li<br>   | <br>   | (epoi |   | immunisation - Not  |              |      |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|--------|-------|---|---|--------------|------|
|                       |            |             |                                   |                              |               |                |                  |        |       | Menstruation<br>irregular (n/a - Not<br>Recovered/Not<br>Resolved - )                       | applicable - [1d -<br>1{DF} -<br>Intramuscular use])  |              |      |
| EU-EC-<br>10013287948 | 19/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Female | No    | Epistaxis (3d -<br>Recovered/Resolved<br>- ),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug                                  | Not reported | Ī    |
|                       |            |             |                                   |                              |               |                |                  |        |       | Immunisation<br>reaction (n/a -<br>Recovered/Resolved<br>-)                                 | withdrawn - [n/a -<br>1{DF} -<br>Intramuscular use])  |              |      |
| EU-EC-<br>10013287998 | 19/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional |                              | Not available | 12-17<br>Years | Adolescent       | Male   | No    | Lymphadenopathy<br>(n/a - Unknown - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [n/a -<br>1{DF} - | Not reported | Ī    |
| EU-EC-<br>10013288244 | 19/08/2022 | Spontaneous | Healthcare                        | European<br>Economic         | Not available | 12-17<br>Years | Not<br>Specified | Female | No    | Depressed mood<br>(20d -  | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S -  | Not reported | Ŀ    |
|                       |            |             | Professional                      | Area                         |               |                |                  |        |       | Recovering/Resolving -), Heavy menstrual bleeding (20d - Recovering/Resolving -),           | COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                                |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Hypovitaminosis<br>(20d -<br>Recovering/Resolving<br>-),                                    |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Injection site reaction (20d - Recovering/Resolving - ),                                    |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Menstruation<br>irregular (20d -<br>Recovering/Resolving<br>- )                             |   |              |      |
| EU-EC-<br>10013289224 | 19/08/2022 | Spontaneous |                                   |                              | Not available | 12-17<br>Years | Not<br>Specified | Female | No    | Alopecia (n/a - Not<br>Recovered/Not<br>Resolved - ),                                       | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19   | Not reported | Ī    |
|                       |            |             |                                   | Area                         |               |                |                  |        |       | Arthralgia (n/a - Not<br>Recovered/Not<br>Resolved - ),                                     | immunisation - Not<br>applicable - [1d - n/a<br>- n/a])   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Asthenia (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation), |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Confusional state<br>(n/a - Unknown - ),  |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Cough (n/a -<br>Unknown - ),  |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Disturbance in attention (n/a - Unknown - ),  |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Ear inflammation (n/a - Unknown - ),  |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Ear pain (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation), |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Ear tube insertion<br>(n/a - Unknown -<br>Caused/Prolonged<br>Hospitalisation),             |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Emotional disorder<br>(n/a - Unknown - ),   |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Eye pain (n/a - Not<br>Recovered/Not<br>Resolved - ),                                       |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Fatigue (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),  |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Feeling abnormal<br>(n/a - Not<br>Recovered/Not<br>Resolved - ),                            |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Fibromyalgia (n/a -<br>Unknown - ),   |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Gait disturbance (n/a<br>- Not Recovered/Not<br>Resolved - ),                               |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Headache (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation), |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Hypersensitivity (n/a<br>- Not Recovered/Not<br>Resolved - ),                               |   |              |      |
|                       |            |             |                                   |                              |               |                |                  |        |       | Hypoaesthesia (n/a -<br>Not Recovered/Not   |   |              |      |
| ps://dap.e            | ema.euro   | pa.eu/ana   | lytics/sav                        | v.dll?Go                     |               | ,              | •                | •      |       | •   | -   |              | 21/6 |

| Healthcare Professional Recovered/Resolved Commic Area  Healthcare Professional Recovered/Resolved Recovered/Resolved Commic Area  Wears Specified Recovered/Resolved Commic Loss of consciousness (n/a - Unknown - Other Medically Important Condition), Neck pain (n/a - Not Recovered/Not Resolved - ), Pain (n/a - Unknown - )  EU-EC- 10013290715  Non Healthcare Professional Recovered/Resolved Professional Recovered/ |  |  |          |
|--|--|--|----------|
| Calcalate of products   Calc   |  |  |          |
| Cultiforms   Comment   C   |  |  |          |
| EU-EC-   19y88/2022   Sporteneous   Non   Not available   12-17   Net   Ness    |  |  |          |
| Building   Price   March   Price   Price   March   Price   March   Price   March   Price   P   |  |  |          |
| EU-EC-   19/08/2022   Spontaneous   Non-   |  |  |          |
| Movement disorder (CVa - Uniform - ),   Multipayers inflammatory inflammation of the control o   |  |  |          |
| Inflammatory   Infl   |  |  |          |
| EL-EC-   19/08/2022   Spontaneous   Non   Not available   No   |  |  |          |
| Recovered / Not Resolved - ),   Nauses (r/a - Not Recovered Not Resolved - ),   Pain (r/a - Not Recovered Not Resolved - ),   Pain (r/a - Not Recovered Not Resolved - ),   Pain (r/a - Not Recovered Not Resolved - Caused Protonged Hospitalisation),   Pyrosis (r/a - Not Recovered Not Resolved - Caused Protonged Hospitalisation),   Rehumatoid arthritis (r/a - Unknown - ),   Vitamin D decressed (r/a - Not Recovered Not Resolved - ),   Vitamin D decressed (r/a - Not Recovered Not Resolved - ),   Vitamin D decressed (r/a - Not Recovered Not Recovered Not Resolved - ),   Vitamin D decressed (r/a - Not Recovered Not Recovered Not Resolved - ),   Loss of Consciousness (r/a - Vitamin D decressed (r/a - Not Recovered Not Resolved - ),   Loss of Consciousness (r/a - Not Recovered Not Resolved - ),   Loss of Consciousness (r/a - Not Recovered Not Resolved - ),   Recovered Resolved - ),      |  |  |          |
| Recovered/Not Resolved - ).  Pain (n/a - Not Recovered/Not Resolved - ).  Pain (n/a - Not Recovered/Not Resolved - ).  Phin (n/a - Not Recovered/Not Resolved - ).  Phin (n/a - Not Recovered/Not Resolved - ).  Phin (n/a - Not Recovered/Not Resolved - ).  Phyrexia (n/a - Not Recovered/Not Resolved - ).  Pyrexia (n/a - Not Recovered/Not Resolved - ).  Vitamin D decreased (n/a - Not Recovered/Not Resolved - ).  Vitamin D decreased (n/a - Not Recovered/Not Resolved - ).  Vitamin D decreased (n/a - Not Recovered/Not Resolved - ).  Vitamin D decreased (n/a - Not Recovered/Not Resolved - ).  Pain (n/a - Not Recovered/Not Resolved - ).  Point (n/a - Not Recovered/Resolved - ).  Point (n/a - Not Recovered |  |  |          |
| Recovered/Not Resched - Caused/Prolonged Hospitalisation), Premia (n/a - Not Recovered/Not Resched - Caused/Prolonged Hospitalisation), Premia (n/a - Not Recovered/Not Resched - Caused/Prolonged Hospitalisation), Rheumatoid arthritis (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - Other Medically Important Condition), Tate disorder (n/a - Unknown - O |  |  |          |
| EU-EC-   19/08/2022   Spontaneous   Non   Healthcare   Professional   European   Professional   European   Non   Healthcare   Professional   Healthcare   Profes   |  |  |          |
| EU-EC- 10013289659 Professional Professional Professional Professional Professional Recovered/Not Recovered/Resolved - ), Palin (n/a - Not Recovered/Resolved - ), Palin (n/a - Not Recovered/Resolved - ), Palin (n/a - Not Recovered/Not Resolved - ), Palin (n/a - Not Recovered/Not Resolved - ), Palin (n/a - Not Recovered/Resolved - ), Malaise (4d - Recovered/Resolved - )   |  |  |          |
| EU-EC- 10013289659  19/08/2022 Spontaneous Non Healthcare Professional Recovered/Not Resolved - )  EU-EC- 10013289659  19/08/2022 Spontaneous Non Healthcare Professional Recovered/Resolved - )  EU-EC- 10013290715  19/08/2022 Spontaneous Non Healthcare Professional Recovered/Resolved - )  EU-EC- 10013290715  19/08/2022 Spontaneous Non Healthcare Professional Recovered/Resolved - )  EU-EC- 10013290715  19/08/2022 Spontaneous Non Healthcare Professional Recovered/Resolved - )  Healthcare Professional Recovered/Resolved - )  European European Not available Recovered/Resolved - )  European European Not available Recovered/Resolved - )  Healthcare Professional Recovered/Resolved - )  Headache (4d - Recovered/Resolved - )  Headache (4d - Recovered/Resolved - )  Malaise (4d - Recovered/Resolved - )  |  |  |          |
| EU-EC- 10013289659  In the second of the sec |  |  |          |
| Healthcare Professional Economic Area  Healthcare Professional Economic Area  Healthcare Professional Economic Area  Healthcare Professional Economic Area  Specified Recovered/Resolved - ),  |  |  |          |
| EU-EC- 10013290715  EU-EC- 10013290715  EU-FC- 10013290715  EUropean Eur | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not                                | Not reported                             | <u>I</u> |
| EU-EC- 10013290715    19/08/2022   Spontaneous   Non Healthcare Professional   Healthcare Profes | applicable - [n/a -<br>n/a - n/a])   |  |          |
| EU-EC- 10013290715   19/08/2022   Spontaneous   Non Healthcare Professional   Non Healthcare Professional   Non Headache (4d - Recovered/Resolved Professional   Non Headache (4d - Recovered/R |  |  |          |
| Professional Area  - ), Co imi Headache (4d - Recovered/Resolved - Ir - ), Malaise (4d - Recovered/Resolved Recovered/Resolved Recovered/Resolved Recovered/Resolved Recovered/Resolved Recovered/Resolved Recovered/Resolved  | COMIRNATY  | Not reported                             | <u>I</u> |
| - ), Malaise (4d - Recovered/Resolved  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a                     |  |          |
|  | - Intramuscular use])  |  |          |
| Pyrexia (4d -  |  |  |          |
|  | COMIRNATY  | Not reported                             | 1        |
| 10013290716 Healthcare Professional Professional Recovered/Not Professional Recovered/Not Professional Recovered/Not Professional Recovered/Not Professional Recovered/Not Professional Recovered/Not Not Not Not Not Not Not Not Not Not  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [n/a -<br>n/a - Intramuscular |  |          |
| EU-EC- 19/08/2022 Spontaneous Non European Not available 12-17 Adolescent Female No Vaccination site CO  | use])<br>COMIRNATY<br>[TOZINAMERAN] (S -   | [AMOXICILLIN] (C -<br>Pharyngitis - Drug | 1        |

| 0.11.2022             | 15.25      |             |                                   |                                     |               | Ru             | in Line L        | isting F | Report | t   |  |  |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|----------|--------|---|--|--|
|                       |            |             |                                   |                                     |               |                |                  |          |        | Recovered/Not<br>Resolved - )   | immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use -<br>More in ICSR])                                  | n/a]), [IBUPROFEN, IBUPROFEN ARGININE] (C - Oropharyngeal pain - Drug withdrawn - [3d - n/a - n/a]),  [PARACETAMOL] (C - Headache - Drug withdrawn - [2d - n/a - n/a]) |
| EU-EC-<br>10013290719 | 19/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male     | No     | Headache (n/a -<br>Recovering/Resolving<br>-),<br>Malaise (n/a -<br>Recovering/Resolving<br>-),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use])     | Not reported   |
|                       |            |             |                                   |                                     |               |                |                  |          |        | Pyrexia (n/a -<br>Recovering/Resolving  |  |  |
| EU-EC-<br>10013290925 | 19/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male     | No     | Diarrhoea (n/a -<br>Recovering/Resolving - ),<br>Pyrexia (n/a -<br>Recovering/Resolving   | COVID-19<br>immunisation - Not<br>applicable - [1d -   | Not reported   |
| EU-EC-<br>10013290952 | 19/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male     | No     | Pyrexia (n/a -<br>Unknown - )   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d -  | Not reported   |
| EU-EC-<br>10013271378 | 18/08/2022 | Spontaneous | Healthcare                        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male     | No     | Dysentery (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),<br>Leukaemia (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),<br>Pyrexia (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -                                   | Not reported   |
| EU-EC-<br>10013272008 | 18/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female   | No     | Hospitalisation) COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Vaccination failure (n/a - Not Recovered/Not Resolved - Other Medically Important   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use]) | Not reported   |
| EU-EC-<br>10013273224 | 18/08/2022 | Spontaneous | Healthcare<br>Professional        |                                     | Not available | 12-17<br>Years | Adolescent       | Female   | No     | Condition)  COVID-19 (n/a - Unknown - Other Medically Important Condition),  Vaccination failure (n/a - Unknown - Other Medically Important Condition)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- Intramuscular use])                                       | Not reported   |
| EU-EC-<br>10013273341 | 18/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male     | Yes    | Herpes virus infection (n/a - Unknown - Other Medically Important Condition),  Pain in extremity (n/a - Unknown - Other Medically Important Condition)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [0d -<br>.3mt - Intramuscular<br>use]) | Not reported   |
| EU-EC-<br>10013273583 | 18/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male     | No     |   | COMIRNATY<br>[TOZINAMERAN] (S -<br>Immunisation - n/a -<br>[n/a - 3{DF} - n/a])  | Not reported   |
| EU-EC-<br>10013273683 | 18/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male     | No     | Hospitalisation)  Dizziness (137d - Recovered/Resolved - ),  Headache (137d - Recovered/Resolved - ),  Visual impairment  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - n/a - n/a])                                | Not reported   |
| EU-EC-<br>10013273913 | 18/08/2022 | Spontaneous |                                   | European                            | Not available | 12-17<br>Years | Adolescent       | Female   | No     | (137d -<br>Recovered/Resolved<br>-)<br>Bedridden (309d -  | COMIRNATY  | Not reported   |
| 10013273913           |            |             | Healthcare<br>Professional        | Economic<br>Area                    |               | Years          |                  |          |        | Not Recovered/Not<br>Resolved - ),<br>Depression (309d -<br>Not Recovered/Not<br>Resolved - ),<br>Fatigue (309d - Not<br>Recovered/Not<br>Resolved - ),<br>Oropharyngeal pain   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - n/a - n/a])   |  |

| .11.2022            | 15.25      |             |                            |                                     |               | ΚU             | ın Line L        | isting R         | eport  |   |   |              |
|---------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|------------------|--|---|---|--------------|
|                     |            |             |                            |                                     |               |                |                  |                  |  | (309d - Not<br>Recovered/Not<br>Resolved - ),   |   |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Recovered/Not<br>Resolved - )   |   |              |
| J-EC-<br>0013274277 | 18/08/2022 | Spontaneous | Healthcare<br>Professional |                                     | Not available | 12-17<br>Years | Not<br>Specified | Not<br>Specified | No   | Lymph node pain<br>(n/a - Unknown - ),  | COMIRNATY<br>[TOZINAMERAN] (S -   | Not reported |
|                     |            |             |                            | Area                                |               |                |                  |                  |  | Lymphadenopathy<br>(n/a - Unknown - ),  | COVID-19<br>immunisation - Not<br>applicable - [n/a -   |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Neoplasm (n/a -<br>Unknown - ),   | n/a - Intramuscular<br>use])  |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Vaccination site pain   |   |              |
| J-EC-               | 18/08/2022 | Spontaneous | Healthcare                 | European                            | Not available | 12-17          | Adolescent       | Female           | No   | (n/a - Unknown - )<br>COVID-19 (n/a -   | COMIRNATY   | Not reported |
| 013274841           |            | ·           | Professional               | Economic<br>Area                    |               | Years          |                  |                  |  | Unknown - Other<br>Medically Important<br>Condition),   | [TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- Intramuscular use])                                       | ·            |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Vaccination failure<br>(n/a - Unknown -<br>Other Medically  |   |              |
| I-EC-               | 18/08/2022 | Spontaneous | Non                        | European                            | Not available | 12-17          | Not              | Male             | No   | Important Condition) Alopecia areata (n/a   | COMIRNATY   | Not reported |
| 013275487           | 10,00,2022 | Sportaneous |                            | Economic                            | Not available | Years          | Specified        | ridic            | 140  | - Not Recovered/Not<br>Resolved -<br>Disabling),  | [TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- n/a])   | Not reported |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Alopecia totalis (n/a -<br>Not Recovered/Not<br>Resolved - Disabling)   |   |              |
| I-EC-               | 18/08/2022 | Spontaneous |                            | European                            | Not available | 12-17          |                  |                  | No   | Loss of   | COMIRNATY   | Not reported |
| 013275750           |            |             | Professional               | Area                                |               | Years          | Specified        | Specified        |  | consciousness (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition), | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use]) |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Pyrexia (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),   |   |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Seizure (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),       |   |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Wound (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged  |   |              |
|                     | 18/08/2022 | Spontaneous |                            | Non                                 | Not available | 12-17          | Not              | Female           | Yes  | Hospitalisation) Asthenia (n/a -  | COMIRNATY   | Not reported |
| 0013276047          |            |             | Healthcare<br>Professional | European<br>Economic<br>Area        |               | Years          | Specified        |                  |  | Recovered/Resolved<br>- ),<br>Headache (n/a -   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a                              |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Recovered/Resolved - ), Pyrexia (n/a -  | - n/a])   |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Recovered/Resolved - ), Syncope (n/a -  |   |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Recovered/Resolved - Other Medically Important Condition)   |   |              |
| J-EC-<br>0013278125 | 18/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male             | No   | Cardiac dysfunction<br>(n/a - Unknown -<br>Other Medically<br>Important<br>Condition),  | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a               | Not reported |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Cardiac failure (n/a -<br>Fatal - Results in<br>Death, Other<br>Medically Important<br>Condition),                                  | - n/a])   |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Chest pain (n/a -<br>Unknown - ),   |   |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Dyspepsia (n/a -<br>Unknown - ),  |   |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Heart rate increased<br>(n/a - Unknown -<br>Other Medically<br>Important<br>Condition),   |   |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Myocardial injury<br>(n/a - Unknown -<br>Other Medically<br>Important<br>Condition),  |   |              |
|                     |            |             |                            |                                     |               |                |                  |                  | Myocarditis (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically |   |   |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  | Important<br>Condition),  |   |              |
|                     |            |             |                            |                                     |               |                |                  |                  |  |   |   |              |

|                         |            |             |                            |                                     |               |                |                  |        |    | test decreased (n/a -<br>Unknown - ),<br>Troponin increased   |  |              |    |
|-------------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|---|--|--------------|----|
|                         |            |             |                            |                                     |               |                |                  |        |    | , ,   |  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | (n/a - Unknown -<br>Caused/Prolonged<br>Hospitalisation),   |  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | Vaccination site pain   |  |              |    |
| EU-EC-<br>10013278341   | 18/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available |                | Not<br>Specified | Female | No | (n/a - Unknown - )  Arthralgia (n/a - Recovered/Resolved - Other Medically Important Condition),            | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a            | Not reported | 10 |
|                         |            |             |                            |                                     |               |                |                  |        |    | Erythema (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),              | - n/a])  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | Erythema (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),                    |  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | Feeling hot (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),           |  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | Feeling hot (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),                                 |  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | Inappropriate<br>schedule of product<br>administration (n/a -<br>Unknown - ),                               |  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | Joint swelling (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),        |  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | Peripheral swelling<br>(n/a - Unknown -<br>Other Medically<br>Important<br>Condition),                      |  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | Swelling (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),              |  |              |    |
| EU-EC- 1                | 18/08/2022 | Spontaneous | Non                        | Furonean                            | Not available | 12-17          | Child            | Female | No | Swelling (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)<br>Heavy menstrual       | COMIRNATY  | Not reported | I  |
| 10013278572             | 10/00/2022 | Sportaneous | Healthcare<br>Professional | Economic                            | Not available | Years          | Cilia            | remaje | No | bleeding (n/a -<br>Recovering/Resolving<br>- ),   | [TOZINAMERAN] (S -   | Not reported | 1  |
|                         |            |             |                            |                                     |               |                |                  |        |    | Immunisation<br>reaction (n/a -<br>Recovered/Resolved<br>- ),   | applicable - [n/a -<br>1{DF} -<br>Intramuscular use])  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | Polymenorrhoea (n/a<br>-<br>Recovering/Resolving  |  |              |    |
| EU-EC- 1<br>10013279951 | 18/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Amnesia (n/a - Not<br>Recovered/Not<br>Resolved - Disabling,<br>Other Medically<br>Important<br>Condition), | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a]) | Not reported | Iı |
|                         |            |             |                            |                                     |               |                |                  |        |    | Fatigue (n/a - Not<br>Recovered/Not<br>Resolved - Disabling,<br>Other Medically<br>Important<br>Condition), |  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | Fatigue (n/a -<br>Recovering/Resolving<br>- Disabling, Other<br>Medically Important<br>Condition),          |  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | Folate deficiency<br>(n/a - Unknown -<br>Disabling, Other<br>Medically Important<br>Condition),             |  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | Haematochezia (n/a  |  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | Recovered/Resolved - Disabling, Other Medically Important Condition),                                       |  |              |    |
| 1                       |            |             | I                          |                                     |               |                |                  |        |    | Headache (n/a - Not   |  |              |    |
|                         |            |             |                            |                                     |               |                |                  |        |    | Recovered/Not<br>Resolved - Disabling,<br>Other Medically<br>Important<br>Condition),                       |  |              |    |

|                       |            |             |                                   |                                     |               |                |                  |        |    | Headache (n/a -<br>Recovering/Resolving<br>- Disabling, Other<br>Medically Important<br>Condition),  |  |  |            |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|--|--|--|------------|
|                       |            |             |                                   |                                     |               |                |                  |        |    | Lymphadenopathy<br>(n/a - Unknown -<br>Disabling, Other<br>Medically Important<br>Condition),  |  |  |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Malaise (n/a -<br>Recovering/Resolving<br>- Disabling, Other<br>Medically Important<br>Condition),   |  |  |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Nausea (n/a - Not<br>Recovered/Not<br>Resolved - Disabling,<br>Other Medically<br>Important<br>Condition),   |  |  |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Pain (n/a - Unknown<br>- Disabling, Other<br>Medically Important<br>Condition),  |  |  |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Palpitations (n/a -<br>Not Recovered/Not<br>Resolved - Disabling,<br>Other Medically<br>Important<br>Condition),                                   |  |  |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Urinary tract<br>infection (n/a -<br>Unknown - Disabling,<br>Other Medically<br>Important<br>Condition),   |  |  |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Vaccination site pain<br>(n/a - Unknown -<br>Disabling, Other<br>Medically Important<br>Condition)   |  |  |            |
| EU-EC-<br>10013279957 | 18/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Myocarditis (n/a -<br>Recovered/Resolved<br>With Sequelae -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition), | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                   | Not reported   | <u>I</u>   |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Pericarditis (n/a -<br>Recovered/Resolved<br>With Sequelae -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important Condition)    |  |  |            |
| EU-EC-<br>10013280077 | 18/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available |                | Not<br>Specified | Female | No | Dyskinesia (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a   | [DROSPIRENONE,<br>ETHINYLESTRADIOL] (C<br>- Polycystic ovaries - n/a -<br>[n/a - n/a - n/a]),<br>[LEVOTHYROXINE, | <u>I</u> ) |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Myalgia (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),  | - n/a])  | LEVOTHYROXINE,<br>SODIUM] (C -<br>Hypothyroidism - n/a -<br>[n/a - n/a - n/a])                                   |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Sleep disorder (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),   |  |  |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Tic (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)   |  |  |            |
| EU-EC-<br>10013280919 | 18/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | Injection site erythema (n/a - Unknown - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -                                  | Not reported   | <u>I</u> ) |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Vaccination site<br>induration (n/a -<br>Unknown - ),<br>Vaccination site  | 1{DF} - n/a])  |  |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | reaction (n/a -<br>Unknown - )   |  |  | L          |
| EU-EC-<br>10013280937 | 18/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No | Pyrexia (n/a -<br>Recovering/Resolving - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [n/a -<br>n/a - Intramuscular<br>use]) | Not reported   | <u>I</u> ) |
|                       |            |             |                                   |                                     |               |                |                  |        | _  |  |  |  |            |
| EU-EC-<br>10013280941 | 18/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No | Arthralgia (n/a - Not<br>Recovered/Not<br>Resolved - ),<br>Fatigue (n/a - Not  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a                              | Not reported   | Ī          |
|                       | 18/08/2022 | Spontaneous | Healthcare                        | Economic                            | Not available |                | Adolescent       | Male   | No | Recovered/Not<br>Resolved - ),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug   | Not reported   | <u>I</u>   |

| 1.11.2022              | ·OLLO      |              |                                   |                                     |               |                | ın Line Li       |        | •  |  |  |              |
|------------------------|------------|--------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|--|--|--------------|
| EU-EC-<br>10013280949  | 18/08/2022 | Spontaneous  | Non<br>Healthcare<br>Professional | Economic                            | Not available | 12-17<br>Years | Adolescent       | Female | No | Chills (n/a - Not<br>Recovered/Not<br>Resolved - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use -<br>More in ICSR]) | Not reported |
| EU-EC-<br>10013281156  | 18/08/2022 | Spontaneous  | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | Vaccination site<br>urticaria (2d -<br>Recovered/Resolved<br>-)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use])                   | Not reported |
| EU-EC-<br>1.0013281163 | 18/08/2022 | Spontaneous  | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | Vaccination site<br>lymphadenopathy<br>(n/a - Unknown - )  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])                                  | Not reported |
| U-EC-<br>0013281193    | 18/08/2022 | Spontaneous  | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No | Lymphadenopathy<br>(n/a - Unknown - )  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [4d - n/a - Intramuscular use - More in ICSR])                   | Not reported |
| U-EC-<br>0013281196    | 18/08/2022 | Spontaneous  | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | Lymphadenopathy<br>(n/a - Unknown - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use])                   | Not reported |
| U-EC-<br>0013281222    | 18/08/2022 | Spontaneous  | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No | Pyrexia (n/a - Not<br>Recovered/Not<br>Resolved - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use -<br>More in ICSR]) | Not reported |
| 0013281224             |            | Spontaneous  | Professional                      | Area                                | Not available | 12-17<br>Years | Adolescent       |        | No | Urticaria (n/a -<br>Recovering/Resolving<br>- )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use])                   | Not reported |
| :U-EC-<br>0013281245   | 18/08/2022 | Spontaneous  | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No | - ),<br>Headache (n/a -  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use -<br>More in ICSR]) | Not reported |
|                        |            |              |                                   |                                     |               |                |                  |        |    | Pyrexia (n/a - Recovering/Resolving - ), Rash (n/a -   |  |              |
| 11.50                  | 17/00/2022 | Casatassassa | Nan                               | No.                                 | Not a vilable | 12.17          | Nat              | Mala   | Na | Recovering/Resolving -)  | COMIDNIATY   | Nat          |
| EU-EC-<br>10013259128  | 17/08/2022 | Spontaneous  | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Specified        | Male   | No | Myopericarditis (n/a -<br>Not Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important Condition) | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                                | Not reported |
| U-EC-<br>0013259410    | 17/08/2022 | Spontaneous  | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Fatigue (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),  | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                              | Not reported |
|                        |            |              |                                   |                                     |               |                |                  |        |    | Influenza like illness<br>(n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),                                      |  |              |
|                        | 17/00/2022 |              |                                   |                                     |               | 12.17          |                  |        |    | Micturition urgency<br>(n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)   |  |              |
| EU-EC-<br>10013260258  | 17/08/2022 | Spontaneous  | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Specified        | Female | No | - Other Medically<br>Important<br>Condition),  | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                               | Not reported |
|                        |            |              |                                   |                                     |               |                |                  |        |    | Illness (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),  |  |              |
|                        |            |              |                                   |                                     |               |                |                  |        |    | Myalgia (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),  |  |              |
|                        |            |              |                                   |                                     |               |                |                  |        |    | Nausea (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   |  |              |
|                        |            |              |                                   |                                     |               |                |                  |        |    | Pruritus (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   |  |              |
|                        |            |              |                                   |                                     |               |                |                  |        |    | Rash pruritic (n/a -<br>Recovering/Resolving<br>- Other Medically  |  |              |

| 00.11.2022            | 10.20      |             |                                   |                                     |               | 1 (0           | III LIIIC L      | oung i           | орон |   |   |              |          |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|------------------|------|---|---|--------------|----------|
| EU-EC-<br>10013260290 |            | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years |                  |                  |      | Condition), Vaccination site erythema (n/a - Unknown - Other Medically Important Condition), Vaccination site pain (n/a - Unknown - Other Medically Important Condition), Vaccination site pruritus (n/a - Unknown - Other Medically Important Condition), Vaccination site pruritus (n/a - Unknown - Other Medically Important Condition), Vaccination site swelling (n/a - Unknown - Other Medically Important Condition) Injury (n/a - Unknown - ), Nausea (n/a - Unknown - ), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -  | Not reported | <u>I</u> |
| EU-EC-<br>10013260379 | 17/08/2022 | Spontaneous | Healthcare                        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female           | No   | Syncope (3min -<br>Recovered/Resolved -<br>Other Medically<br>Important Condition)<br>Menstruation<br>irregular (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - ſn/a -  | Not reported | <u>I</u> |
| EU-EC-<br>10013260484 | 17/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female           | No   | Condition)  Chest pain (2d - Recovered/Resolved - Other Medically Important Condition),   | applicable - [I/Ja - n/a - Intramuscular use])  TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [Id - n/a - n/a]) | Not reported | Ī        |
|                       |            |             |                                   |                                     |               |                |                  |                  |      | Chills (1d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),<br>Fatigue (2d -<br>Recovered/Resolved<br>- Other Medically<br>Important  | 1,70,1  |              |          |
|                       |            |             |                                   |                                     |               |                |                  |                  |      | Pain (n/a - Unknown - Other Medically Important Condition), Painful respiration   |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |                  |      | (n/a - Unknown -<br>Other Medically<br>Important<br>Condition),<br>Palpitations (n/a -<br>Unknown - Other<br>Medically Important  |   |              |          |
| EU-EC-<br>10013260577 | 17/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Not<br>Specified | No   | Condition) Headache (n/a - Unknown - ), Pyrexia (n/a - Unknown - )  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular use - More in ICSR])                     |              | <u>I</u> |
| EU-EC-<br>10013262267 | 17/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female           | No   | Allergy to vaccine<br>(n/a - Unknown - ),<br>Vomiting (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation)   | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                                  | ·            | <u>I</u> |
| EU-EC-<br>10013262268 | 17/08/2022 | Spontaneous | Healthcare                        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female           | No   | COVID-19 (n/a -<br>Recovered/Resolved -<br>Other Medically<br>Important<br>Condition),<br>Vaccination failure<br>(n/a -<br>Recovered/Resolved -<br>Other Medically  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use])                  | Not reported | <u>I</u> |
| EU-EC-<br>10013262758 | 17/08/2022 | Spontaneous | Healthcare                        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female           | No   | Condition), Pain in extremity (n/a - Not Recovered/Not Resolved - Other   | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                                 | Not reported | Ī        |
| EU-EC-<br>10013262841 | 17/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female           | No   | Medically Important<br>Condition)<br>Asthenia (n/a –<br>Unknown - ),<br>Balance disorder (n/a<br>– Unknown - ),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -  | Not reported | Ī        |

| 0.11.2022             | 15.25      |             |                                   |                                     |               | RI             | ın Line L        | isting F | kepori | ι  |  |              |   |
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|                       |            |             |                                   |                                     |               |                |                  |          |        | Dizziness (n/a -<br>Unknown - ),<br>Loss of<br>consciousness (0d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),  | 1{DF} -<br>Intramuscular use])   |              |   |
|                       |            |             |                                   |                                     |               |                |                  |          |        | Presyncope (0d -<br>Recovered/Resolved   |  |              |   |
| EU-EC-<br>10013263615 | 17/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male     | No     | Fatigue (7h - Recovered/Resolved -), Headache (7h - Recovered/Resolved   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                    | Not reported | Ī |
| EU-EC-<br>10013265022 | 17/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female   | No     | - ) Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -  | Not reported | Ī |
| EU-EC-<br>10013266212 | 17/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Economic                            | Not available | 12-17<br>Years | Adolescent       | Female   | No     | Important Condition) Dysmenorrhoea (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menometrorrhagia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Menometrorrhagia (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), |  | Not reported | Ī |
| EU-EC-                | 17/09/2022 | Spontaneous | Haaltheara                        | European                            | Not available | 12-17          | Adolescent       | Fomalo   | No     | Menstruation delayed<br>(n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)<br>Guillain-Barre   | COMIRNATY  | Not reported | Ī |
| 10013266300           | 17/06/2022 | Spontaneous |                                   | Economic<br>Area                    | NOT AVAILABLE | Years          | Addrescent       | Temale   | INO    | syndrome (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),<br>Motor dysfunction<br>(n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation)  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} -<br>Intramuscular use])               | Not reported | F |
| EU-EC-<br>10013266369 | 17/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No     | Dysaesthesia (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),<br>Mydriasis (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation)   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use]) | Not reported | Ī |
| EU-EC-<br>10013266499 | 17/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No     | Amenorrhoea (140d  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[1d - 1{DF} -<br>Intramuscular use])                | Not reported | Ī |
| EU-EC-<br>10013266606 | 17/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No     | Diplopia (n/a - Not<br>Recovered/Not<br>Resolved -<br>Disabling),<br>Heavy menstrual<br>bleeding (n/a - Not<br>Recovered/Not<br>Resolved - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} -<br>Intramuscular use])  | Not reported | Ī |
| EU-EC-<br>10013266745 | 17/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male     | No     | Herpes zoster (12d -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} -<br>Intramuscular use])  | Not reported | Ī |
| EU-EC-<br>10013267086 | 17/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No     | Tension headache<br>(n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - 1{DF} - n/a])                                | Not reported | Ī |
| EU-EC-<br>10013268127 | 17/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adult            | Male     | No     | Palpitations (7d -<br>Recovered/Resolved<br>- )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - n/a - n/a])                                  | Not reported | 1 |
| EU-EC-<br>10013268167 | 17/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adult            | Female   | No     | Pain in extremity<br>(n/a - Unknown - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - n/a -<br>Intramuscular use])                 | Not reported | Ī |

|                       | 10.20      |             |                                   |                                     |               |                | an Line L        |                  |    | •   |  |   |            |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|------------------|----|---|--|---|------------|
| EU-EC-<br>10013268770 | 17/08/2022 | Spontaneous | Healthcare<br>Professional        |                                     | Not available | 12-17<br>Years | Not<br>Specified | Female           | No | Seizure (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important Condition)                | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                                | Not reported  | Ī          |
| EU-EC-<br>10013268975 | 17/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male             | No | Lymphadenopathy<br>(n/a -<br>Recovering/Resolving<br>-)   | COMIRNATY<br>[TOZINAMERAN] (S -  | Not reported  | Ŀ          |
| EU-EC-<br>10013268978 | 17/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female           | No | Malaise (n/a - Not<br>Recovered/Not<br>Resolved - ),<br>Pyrexia (n/a -<br>Unknown - ),<br>Vaccination site pain<br>(n/a - Not | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use -<br>More in ICSR]) | Not reported  | Ŀ          |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Recovered/Not<br>Resolved - )   |  |   |            |
| EU-EC-<br>10013269750 | 17/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Not<br>Specified | No | Vaccination site<br>inflammation (n/a -<br>Not Recovered/Not<br>Resolved - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use -<br>More in ICSR]) | PROTOPIC 0,03%<br>POMADA [TACROLIMUS]<br>(C - Pruritus - n/a - [14d<br>- n/a - n/a])        | <u>I</u>   |
| EU-EC-<br>10013269753 | 17/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male             | No | Vaccination site<br>lymphadenopathy<br>(n/a - Unknown - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [n/a -<br>n/a - Intramuscular                        | Not reported  | <u>I</u> ) |
| EU-EC-<br>10013269754 |            | Spontaneous | Professional                      | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       |                  | No | Lymphadenopathy<br>(n/a - Unknown - )   | use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])                            |   | <u>I</u>   |
| EU-EC-<br>10013269756 | 17/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female           | No | - ),<br>Pyrexia (2d -   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use])                   | Not reported  | <u>I</u> ) |
| EU-EC-<br>10013269862 |            | Spontaneous | Professional                      | Area                                | Not available | 12-17<br>Years | Adolescent       |                  | No | Glossitis (n/a -<br>Unknown - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} - n/a])                               | Not reported  | <u>I</u>   |
| EU-EC-<br>10013269903 | 17/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female           | No | - ),<br>Presyncope (0d -  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use])                   | Not reported  | <u>I</u> ) |
| 10013269914           | 17/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Economic                            | Not available | 12-17<br>Years | Adolescent       | Female           | No | Dizziness postural<br>(n/a - Not<br>Recovered/Not<br>Resolved - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use])                   | Not reported  | <u>I</u>   |
| EU-EC-<br>10013243613 | 16/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male             | No | Hyperhidrosis (n/a - Recovered/Resolved - ),  Pyrexia (n/a - Recovered/Resolved - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                                 | Not reported  | <u>I</u> ) |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Syncope (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)   |  |   |            |
| EU-EC-<br>10013244277 | 16/08/2022 | Spontaneous | Healthcare                        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female           | No | Vomiting (1d -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                                 | [DESOGESTREL,<br>ETHINYLESTRADIOL] (C<br>- Oral contraception - n/a<br>- [n/a - n/a - n/a]) | <u>I</u>   |
| EU-EC-<br>10013244387 | 16/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female           | No | Haemorrhage (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),<br>Menstruation<br>irregular (n/a - Not           | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                               | Not reported  | <u>I</u>   |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)  |  |   |            |
| EU-EC-<br>10013245777 | 16/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female           | No | Pallor (n/a -<br>Unknown - ),<br>Syncope (n/a -<br>Unknown - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -                                    | Not reported  | <u>I</u>   |
| EU-EC-<br>10013245834 | 16/08/2022 | Spontaneous | Healthcare                        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female           | No | Palpitations (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)                             | Intramuscular use]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a                                  | [PARACETAMOL] (C - n/a<br>- n/a - [n/a - n/a - n/a])  | ľ          |
| EU-EC-<br>10013246043 | 16/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female           | No | Chills (n/a -<br>Recovering/Resolving<br>- ),<br>Fatigue (n/a -   | - n/a])  COMIRNATY  [TOZINAMERAN] (S - COVID-19  immunisation - Not  | Not reported  | Ī          |

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|                       |            |             |                                   |                                     |               |                |                  |          |       | Recovering/Resolving   | applicable - [n/a -<br>n/a - n/a])   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Headache (n/a -<br>Recovering/Resolving<br>- ),  |  |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Malaise (n/a -<br>Recovering/Resolving<br>- ),   |  |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Myalgia (n/a -<br>Recovering/Resolving<br>- ),   |  |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Nausea (n/a -<br>Recovering/Resolving<br>- ),  |  |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Pyrexia (n/a -<br>Recovering/Resolving   |  |              |          |
| EU-EC-<br>10013246500 | 16/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Haematemesis (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),<br>Malaise (n/a -<br>Recovered/Resolved<br>- ),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])       | Not reported | Ī        |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Pyrexia (n/a -<br>Recovered/Resolved<br>-)   |  |              |          |
| EU-EC-<br>10013246501 | 16/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Lip swelling (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                     | Not reported | Ī        |
| EU-EC-<br>10013246563 | 16/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Pseudoallergic<br>reaction (n/a -<br>Recovered/Resolved<br>- ),<br>Rash macular (n/a -<br>Recovered/Resolved<br>- ),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])       | Not reported | Ī        |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Urticaria (n/a -<br>Recovered/Resolved<br>- ),<br>Viral rash (n/a -<br>Unknown - )   |  |              |          |
| EU-EC-<br>10013247076 | 16/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Nausea (n/a -<br>Recovered/Resolved<br>- ),<br>Syncope (n/a -<br>Recovered/Resolved<br>- Other Medically   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                     | Not reported | Ŀ        |
| EU-EC-<br>10013247152 | 16/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Economic                            | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Important Condition) Fatigue (n/a - Not Recovered/Not Resolved - )   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])                   | Not reported | <u>I</u> |
| EU-EC-<br>10013247442 | 16/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Syncope (n/a -<br>Unknown - )  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])                   | Not reported | <u>I</u> |
| EU-EC-<br>10013247471 | 16/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Orthostatic<br>hypotension (n/a -<br>Unknown - ),<br>Syncope (n/a -<br>Unknown - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use]) | Not reported | Ī        |
| EU-EC-<br>10013247731 | 16/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Somnolence (30min -<br>Recovered/Resolved<br>- ),<br>Syncope (30min -<br>Recovered/Resolved<br>- ),<br>Vomiting (30min -<br>Recovered/Resolved   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{OF} -<br>Intramuscular use]) | Not reported | <u>I</u> |
| EU-EC-<br>10013247741 | 16/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Dizziness (n/a -<br>Unknown - ),<br>Head discomfort (n/a -<br>Unknown - ),   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -                                       | Not reported | <u>I</u> |
| EU-EC-<br>10013248143 | 16/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Headache (n/a -<br>Unknown - )<br>Heart rate increased<br>(n/a - Unknown -<br>Other Medically<br>Important<br>Condition),<br>Inappropriate<br>schedule of product<br>administration (n/a - | Intramuscular use])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])               | Not reported | <u>I</u> |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Unknown - ), Pyrexia (2d - Recovered/Resolved  |  |              |          |

|                       |            |             |                                   |                                     |               |                |                  |        |    | - Other Medically<br>Important Condition)   |  |   |            |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|---|--|---|------------|
| EU-EC-<br>10013248202 | 16/08/2022 | Spontaneous | Healthcare                        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Axillary pain (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),<br>Inappropriate<br>schedule of product<br>administration (n/a -<br>Unknown - Other<br>Medically Important<br>Condition), | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])   | Not reported  | <u>I</u> 0 |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Lymphadenopathy<br>(n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)   |  |   |            |
| EU-EC-<br>10013248258 | 16/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Myopericarditis (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])   | Not reported  | <u>I</u> ) |
| EU-EC-<br>10013249036 | 16/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Back pain (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),   | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a]) | Not reported  | Þ          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Fatigue (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),<br>Pain (n/a - Not  |  |   |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),   |  |   |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Vaccination site pain<br>(n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)   |  |   |            |
| EU-EC-<br>10013249128 | 16/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Fatigue (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),   | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a            | Not reported  | Ī          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Headache (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),  | - n/a])  |   |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Hot flush (2d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),  |  |   |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Pain (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),  |  |   |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Pain in extremity<br>(n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),  |  |   |            |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Vaccination site<br>bruising (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important Condition)  |  |   |            |
| EU-EC-<br>10013249132 | 16/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Myopericarditis (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation)  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])                  | Not reported  | <u>I</u>   |
| EU-EC-<br>10013249488 | 16/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No | COVID-19 (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- Intramuscular use])                       | Not reported  | <u>1</u>   |
| EU-EC-                | 16/08/2022 | Spontaneous | Non                               | Non                                 | Not available | 12-17          | Not              | Female | No | Vaccination failure<br>(n/a - Unknown -<br>Other Medically<br>Important Condition)<br>COVID-19 (6d -  | COMIRNATY  | Not reported  | I)         |
| 10013249694           | 19,00,2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        |               | Years          | Specified        | Cinale |    | Recovered/Resolved - Other Medically Important Condition), Drug ineffective (6d -   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                | net reported  | _          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Recovered/Resolved - Other Medically Important Condition)   |  |   |            |
| EU-EC-<br>10013249727 | 16/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Chills (n/a -<br>Unknown - ),<br>Poor quality sleep<br>(n/a - Unknown - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -                 | Not reported  | Ī          |
|                       |            |             |                                   |                                     |               |                |                  |        |    | Pulse abnormal (n/a<br>- Unknown - )  | 1{DF} -<br>Intramuscular use])   |   |            |
| EU-EC-<br>10013250096 | 16/08/2022 | Spontaneous | Non<br>Healthcare                 | Non<br>European                     | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Chills (1d -<br>Recovered/Resolved  | TOZINAMERAN<br>[TOZINAMERAN] (S -  | [OXCARBAZEPINE] (C -<br>Epilepsy - n/a - [n/a - n/a | Ī          |

| 0.11.2022             | 15.25      |             |                                   |                                     |               | Ru             | ın Line L        | isting H | eport | I   |  |              |          |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|----------|-------|---|--|--------------|----------|
|                       |            |             | Professional                      | Economic<br>Area                    |               |                |                  |          |       | - ), Focal dyscognitive seizures (n/a - Recovered/Resolved - Other Medically Important Condition), Vaccination site swelling (3d - Recovered/Resolved - )   | COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])  | - Oral use]) |          |
| EU-EC-<br>10013250427 | 16/08/2022 | Spontaneous |                                   | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Bell's palsy (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])   | Not reported | Ŀ        |
| EU-EC-<br>10013250715 | 16/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Drug ineffective (n/a - Unknown - Other Medically Important Condition), Suspected COVID-19 (n/a - Unknown - Other Medically Important Condition)  | [COVID-19 VACCINE]   | Not reported | <u>I</u> |
| EU-EC-<br>10013250755 | 16/08/2022 | Spontaneous | Healthcare                        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Decreased appetite (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition), Fatigue (n/a - Unknown - Other Medically Important Condition) | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])   | Not reported | Ī        |
| EU-EC-<br>10013251199 | 16/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No    | Hyperthermia (n/a -<br>Recovering/Resolving -<br>Other Medically<br>Important<br>Condition),<br>Urticaria (n/a -<br>Recovering/Resolving -<br>Other Medically<br>Important Condition)   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [n/a -<br>1{DF} -<br>Intramuscular use])   | Not reported | <u>I</u> |
| EU-EC-<br>10013251440 | 16/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No    | Henoch-Schonlein<br>purpura (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitallisation)   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [15d - 1{OF} - Intramuscular use]), [ISOTRETINOIN] (S - Acne - Drug withdrawn - [n/a - 35mg - Oral use]) | Not reported | 1        |
| EU-EC-<br>10013251807 | 16/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No    | Amenorrhoea (3mo -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),<br>Heavy menstrual<br>bleeding (9d -<br>Recovered/Resolved<br>- )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[1d - 30ug -<br>Intramuscular use])   | Not reported | 1        |
| EU-EC-<br>10013252340 | 16/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No    | Presyncope (20s -<br>Recovered/Resolved<br>- ),<br>Seizure (n/a -<br>Recovered/Resolved<br>- )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])   | Not reported | Ŀ        |
| EU-EC-<br>10013252373 | 16/08/2022 | Spontaneous | Healthcare                        | Non<br>European<br>Economic<br>Area | Not available |                | Not<br>Specified | Female   | No    | Menstrual disorder<br>(n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)  | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])   | Not reported | <u>I</u> |
| EU-EC-<br>10013253167 | 16/08/2022 | Spontaneous | Healthcare                        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No    | Dysmenorrhoea<br>(276d -<br>Recovered/Resolved<br>With Sequelae -<br>Caused/Prolonged<br>Hospitalisation),<br>Influenza like illness<br>(276d -<br>Recovered/Resolved<br>With Sequelae -<br>Caused/Prolonged<br>Hospitalisation)  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [n/a - n/a - Intramuscular use])  | Not reported | I        |
| EU-EC-<br>10013253888 | 16/08/2022 | Spontaneous | Healthcare                        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male     | No    | Chills (162d -<br>Recovered/Resolved<br>With Sequelae -<br>Caused/Prolonged<br>Hospitalisation),<br>Decreased appetite  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - n/a - n/a])  | Not reported | Ŀ        |

| 00.11.2022            | 10.20                                   |             |                                   |                                     |               | 110            | III LIIIC LI     | July 1 | Сроп |  |  |  |            |
|-----------------------|---|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|------|--|--|--|------------|
|                       |   |             |                                   |                                     |               |                |                  |        |      | (162d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Inflammation (162d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pleural effusion (162d - Recovered/Resolved With Sequelae - Caused/Prolonged Hospitalisation), Pyrexia (162d -  |  |  |            |
| EU-EC-<br>10013254254 | 16/08/2022                              | Spontaneous | Non<br>Healthcare                 | Non                                 | Not available | 12-17<br>Years | Not<br>Specified | Female | No   | Recovered/Resolved<br>With Sequelae -<br>Caused/Prolonged<br>Hospitalisation)<br>Lymph node pain<br>(n/a - Unknown -   | TOZINAMERAN<br>[TOZINAMERAN] (S -  | AVAMYS [FLUTICASONE<br>FUROATE] (C - n/a - n/a -   | <u>I</u>   |
| 10013234234           |   |             | Professional                      | European<br>Economic<br>Area        |               | Years          | Specified        |        |      | Other Medically Important Condition), Lymphadenopathy (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Paraesthesia (n/a - Unknown - Other  | [IOZINAMERAN] (S-COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                   | [n/a - n/a - n/a]),  [DROSPIRENONE, ETHINYLESTRADIOL] (C - n/a - n/a - [n/a - n/a - n/a]),  [FEXOFENADINE HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a]),  [ISOTRETINOIN] (C - n/a |            |
| EU-EC-<br>10013254291 | 16/08/2022                              | Spontaneous | Healthcare                        | European<br>Economic                | Not available | 12-17<br>Years | Adolescent       | Female | No   | Medically Important<br>Condition)  Dysmenorrhoea (276d -   | COMIRNATY<br>[TOZINAMERAN] (S -  | - n/a - [n/a - n/a - n/a])  Not reported   | <u>I</u> ) |
|                       |   |             | Professional                      | Area                                |               |                |                  |        |      | Recovered/Resolved<br>With Sequelae -<br>Caused/Prolonged<br>Hospitalisation),   | COVID-19<br>immunisation - n/a -<br>[n/a - n/a -<br>Intramuscular use])                                |  |            |
|                       |   |             |                                   |                                     |               |                |                  |        |      | Influenza like illness<br>(276d -<br>Recovered/Resolved<br>With Sequelae -<br>Caused/Prolonged<br>Hospitalisation)   |  |  |            |
| EU-EC-<br>10013254621 | 16/08/2022                              | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No   | Arrhythmia (185d -<br>Recovered/Resolved<br>With Sequelae -<br>Caused/Prolonged<br>Hospitalisation)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -                                    | Not reported   | <u>I</u>   |
| EU-EC-<br>10013257549 |   | Spontaneous | Professional                      | Non<br>European<br>Economic<br>Area | Not available | Years 12-17    | Not<br>Specified |        | No   | Blepharospasm (n/a - Unknown - ), Confusional state (n/a - Not Recovered/Not Resolved - ), Disorientation (n/a - Not Recovered/Not Resolved - ), Dizziness (n/a - Unknown - ), Hypoaesthesia (n/a - Unknown - ), Illness (n/a - Unknown - ), Malaise (n/a - Not Recovered/Not Resolved - ), Panic reaction (n/a - Not Recovered/Not Resolved - ), Seizure (n/a - Unknown - Other Medically Important Condition), Stress (n/a - Unknown - ), Syncope (n/a - Recovering/Resolving - Other Medically Important Condition) Ataxia (n/a - Not | [n/a - n/a]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported   | I.         |
| 10013257738           | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, |             | Healthcare<br>Professional        | Economic                            |               | Years          |                  |        |      | Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Disturbance in attention (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),  Fatigue (n/a - Not Recovered/Not Recovered/Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation),   | [TIOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - n/a - n/a])                          |  |            |

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|----|-----------------------|------------|-------------|----------------------------|-------------------------------------|--|----------------|------------------|-----------|------|--|--|--------------|----------|
|    |                       |            |             |                            |                                     |  |                |                  |           |      | Memory impairment<br>(n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),      |  |              |          |
|    |                       |            |             |                            |                                     |  |                |                  |           |      | Pain (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),                      |  |              |          |
|    |                       |            |             |                            |                                     |  |                |                  |           |      | Sensory level<br>abnormal (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation), |  |              |          |
|    |                       |            |             |                            |                                     |  |                |                  |           |      | Tachycardia (n/a -<br>Not Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation)                |  |              |          |
|    | EU-EC-<br>10013236462 | 15/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available  | 12-17<br>Years | Not<br>Specified | Male      | No   | Guillain-Barre<br>syndrome (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   | immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular                                       | Not reported | Ī        |
|    |                       |            |             |                            |                                     |  |                |                  |           |      | Muscular weakness<br>(n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important Condition)             | use])  |              |          |
|    | EU-EC-<br>10013237190 | 15/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available  | 12-17<br>Years | Not<br>Specified | Male      | No   | Myopericarditis (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation)                       | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a]) | Not reported | 1        |
|    | EU-EC-<br>10013237529 | 15/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available  | 12-17<br>Years | Not<br>Specified | Male      | No   | Myopericarditis (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation)                       |  | Not reported | <u>I</u> |
|    | EU-EC-<br>10013237994 | 15/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available  | 12-17<br>Years | Not<br>Specified | Female    | No   | Headache (n/a -<br>Recovered/Resolved<br>- ),<br>Syncope (n/a -  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a            | Not reported | Ī        |
|    | EU-EC-                | 15/00/2022 | Casakansons | Liosikh anua               | Non                                 | Not available  | 12-17          | Not              | Female    | No   | Recovered/Resolved - Other Medically Important Condition) Myopericarditis (n/a -                             | - n/a])  | Networked    | <u>I</u> |
|    | 10013238568           | 13/06/2022 | Spontaneous | Professional               |                                     | NUL available  | Years          | Specified        | remale    | INO  | Recovered/Resolved - Caused/Prolonged Hospitalisation)   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])              | Not reported | <u>P</u> |
|    | EU-EC-<br>10013238714 | 15/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available  | 12-17<br>Years | Not<br>Specified | Male      | No   | Nausea (n/a -<br>Recovered/Resolved - ),<br>Syncope (n/a -<br>Recovered/Resolved - Other Medically           | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a]) | Not reported | Ī        |
|    | EU-EC-<br>10013239084 | 15/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Novak, B., Vulvar Ulcerations in<br>Adolescents Following Both COVID-<br>19 Infection and Vaccination, Journal<br>of Pediatric and Adolescent<br>Gynecology, 2022;35(2):225-226. | 12-17<br>Years | Not<br>Specified | Female    | No   | Important Condition)  Dysuria (n/a - Recovered/Resolved - Other Medically Important Condition),              | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -             | Not reported | <u>I</u> |
|    |                       |            |             |                            |                                     | doi:/10.1016/j.jpag.2022.01,087  |                |                  |           |      | Vaginal discharge<br>(n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),           | n/a - n/a])  |              |          |
|    |                       |            |             |                            |                                     |  |                |                  |           |      | Vulval ulceration (n/a   |  |              |          |
|    |                       |            |             |                            |                                     |  |                |                  |           |      | Recovered/Resolved - Other Medically Important Condition),   |  |              |          |
|    |                       |            |             |                            |                                     |  |                |                  |           |      | Vulvovaginal pruritus<br>(n/a -  |  |              |          |
|    |                       |            |             |                            |                                     |  |                |                  |           |      | Recovered/Resolved - Other Medically Important Condition),   |  |              |          |
|    |                       |            |             |                            |                                     |  |                |                  |           |      | Vulvovaginal swelling<br>(n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)           |  |              |          |
|    | EU-EC-<br>10013239548 | 15/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available  | 12-17<br>Years | Not<br>Specified | Male      | No   | Nausea (n/a -<br>Recovered/Resolved<br>-),<br>Syncope (n/a -<br>Recovered/Resolved                           | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a            | Not reported | Ī        |
|    | EU 50                 | AE (0.0 %  |             |                            |                                     | <br>   | 40.7-          |                  |           |      | - Other Medically<br>Important Condition)  | - n/a])  |              |          |
|    | EU-EC-<br>10013239578 | 15/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available  | 12-17<br>Years | Not<br>Specified | Male      | No   | Abdominal pain (8d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),<br>Chills (8d -        | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a]) | Not reported | Ī        |
|    |                       |            |             |                            |                                     |  |                |                  |           |      | Chills (8d -<br>Recovered/Resolved   |  |              |          |

| 30.11.2022            | 15.25      |             |                                   |                                     |               | Rι             | n Line Li        | sting R | eport |  |  |  |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|---------|-------|--|--|--|
|                       |            |             |                                   |                                     |               |                |                  |         |       | - Caused/Prolonged<br>Hospitalisation),  |  |  |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Headache (8d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),  |  |  |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Pyrexia (8d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),   |  |  |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Rash (8d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),  |  |  |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Vomiting (8d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation)   |  |  |
| EU-EC-<br>10013240067 | 15/08/2022 | Spontaneous | Professional                      | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Specified        | Male    | No    | Abdominal pain (n/a<br>-<br>Recovered/Resolved<br>- Caused/Prolonged   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not  | Not reported <u>I</u>  |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Hospitalisation),  Arthralgia (n/a - Unknown - ),  | applicable - [1d - n/a<br>- Intramuscular use])  |  |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Chills (n/a -<br>Unknown - ),  |  |  |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Headache (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),   |  |  |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Malaise (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),  |  |  |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Myalgia (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),  |  |  |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Pyrexia (5d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),   |  |  |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Rash (n/a - Unknown<br>- )   |  |  |
| EU-EC-<br>10013240251 | 15/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female  | No    | Lennox-Gastaut<br>syndrome (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation,<br>Disabling, Other<br>Medically Important<br>Condition), | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a]) | BRIVARACETAM [RIVARACETAM] (C - Toxicity to various agents - n/a - [n/a - n/a]),  CANNABIDIOL [CANNABIDIOL] (C - n/a - n/a - [n/a - n/a - n/a]), |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Seizure (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged  |  | PERAMPANEL [PERAMPANEL] (C - n/a - n/a - [n/a - n/a - n/a]),   |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Hospitalisation,<br>Disabling, Other<br>Medically Important  |  | [CLOBAZAM] (C - Toxicity<br>to various agents - n/a -<br>[n/a - n/a - n/a]),   |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Condition)   |  | [HYOSCINE] (C - n/a - n/a - [n/a - n/a - n/a]),  |
|                       |            |             |                                   |                                     |               |                |                  |         |       |  |  | [LANSOPRAZOLE] (C -<br>n/a - n/a - [n/a - n/a -<br>n/a])   |
| EU-EC-<br>10013240330 | 15/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female  | No    |  | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -               | Not reported I   |
| EU-EC-<br>10013240443 | 15/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male    | No    | Condition)  COVID-19 (7d - Recovered/Resolved - Other Medically Important Condition),  | n/a - n/a])  COMIRNATY  [TOZINAMERAN] (S - COVID-19  immunisation - Not applicable - [1d - n/a           | Not reported <u>I</u>  |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Drug ineffective (7d -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)  | - n/a])  |  |
| EU-EC-<br>10013241504 | 15/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male    | No    | Dyspnoea (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -                 | Not reported 1   |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Myocarditis (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important Condition)  | n/a - Intramuscular<br>use])   |  |
| EU-EC-<br>10013241728 | 15/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female  | No    | Fatigue (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a              | Not reported <u>I</u>  |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Pain (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),   | - n/a])  |  |
|                       |            |             |                                   |                                     |               |                |                  |         |       | Pain in extremity<br>(n/a - Not  |  |  |

| ٠. | J.11.2022             | 10.20      |             |                            |                                     |               | 110            | III LIIIC LI     | July 1 | сроп |   |   |              |            |
|----|-----------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|--------|------|---|---|--------------|------------|
|    |                       |            |             |                            |                                     |               |                |                  |        |      | Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),   |   |              |            |
|    |                       |            |             |                            |                                     |               |                |                  |        |      | Tension headache<br>(n/a -<br>Recovered/Resolved<br>With Sequelae -<br>Other Medically<br>Important                               |   |              |            |
|    |                       |            |             |                            |                                     |               |                |                  |        |      | Condition), Urticaria (n/a - Recovering/Resolving - Other Medically   |   |              |            |
|    | EU-EC-<br>10013241922 | 15/08/2022 | Spontaneous | Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female | No   | Important Condition) Lip swelling (n/a - Recovered/Resolved - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not   | Not reported | <u>I</u>   |
|    |                       |            |             |                            |                                     |               |                |                  |        |      | Rash (n/a -<br>Recovered/Resolved<br>- ),<br>Urticaria (n/a -   | applicable - [1d - n/a<br>- Intramuscular use])   |              |            |
|    | EU-EC-                | 15/08/2022 | Spontaneous | Non                        | Non                                 | Not available | 12-17          | Not              | Male   | No   | Recovered/Resolved - Caused/Prolonged Hospitalisation) Seizure (n/a -   | TOZINAMERAN   | Not reported | I.         |
|    | 10013241952           | 13/00/2022 | Sportaneous | Healthcare<br>Professional | European<br>Economic<br>Area        | NOT AVAILABLE | Years          | Specified        | riae   | INO  | Unknown - Other<br>Medically Important<br>Condition)  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])       | Not reported | <u> </u>   |
|    | EU-EC-<br>10013242104 | 15/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No   | Myopericarditis (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important Condition) | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a                                | Not reported | <u>I</u>   |
|    | EU-EC-<br>10013242164 | 15/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No   | Nausea (n/a -<br>Recovered/Resolved<br>- ),<br>Syncope (n/a -   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -                      | Not reported | <u>I</u>   |
|    | EU-EC-                | 15/08/2022 | Spontaneous | Non                        | Non                                 | Not available | 12-17          | Not              | Male   | No   | Recovered/Resolved - Other Medically Important Condition) COVID-19 (n/a -   | n/a - n/a]) COMIRNATY   | Not reported | I          |
|    | 10013242409           | , ,        |             | Healthcare<br>Professional | European                            |               | Years          | Specified        |        |      | Unknown - Other<br>Medically Important<br>Condition),<br>Drug ineffective (n/a  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                     | ·            | _          |
|    | EU-EC-                | 12/08/2022 | Spontaneous | Healthcare                 | European                            | Not available | 12-17          | Not              | Female | No   | - Unknown - Other<br>Medically Important<br>Condition)<br>Vaccination site  | COMIRNATY   | Not reported | I.         |
|    | 10013225254           | 12/06/2022 | Sportaneous | Professional               |                                     | NOL available | Years          | Specified        | remaje | INO  | vaccination site erythema (n/a - Unknown - ),  Vaccination site oedema (n/a - Unknown - ),  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use]) | Not reported | Ψ.         |
|    | EU-EC-                | 12/08/2022 | Spontaneous | Non                        | Non                                 | Not available | 12-17          | Not              | Male   | No   | Vaccination site pain<br>(n/a - Unknown - )<br>Eye swelling (n/a -  | COMIRNATY   | Not reported | 10         |
|    | 10013225918           | ,,         |             | Healthcare<br>Professional | European<br>Economic<br>Area        |               | Years          | Specified        |        |      | Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                     |              |            |
|    |                       |            |             |                            |                                     |               |                |                  |        |      | Fatigue (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),                                     |   |              |            |
|    |                       |            |             |                            |                                     |               |                |                  |        |      | Headache (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),                                    |   |              |            |
|    |                       |            |             |                            |                                     |               |                |                  |        |      | Pyrexia (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)                                      |   |              |            |
|    | EU-EC-<br>10013226328 | 12/08/2022 | Spontaneous | Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No   | Lymphadenopathy<br>(46d -<br>Recovering/Resolving<br>-)   | immunisation - Not<br>applicable - [n/a -<br>1{DF} -  | Not reported | <u>I</u> ! |
|    | EU-EC-<br>10013226871 | 12/08/2022 | Spontaneous | Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female | No   | positive vasculitis<br>(n/a - Not   | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not                                  | Not reported | <u>I</u> ! |
|    |                       |            |             |                            |                                     |               |                |                  |        |      | Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),                | applicable - [1d - n/a<br>- n/a])   |              |            |
|    |                       |            |             |                            |                                     |               |                |                  |        |      | Asthma exercise induced (n/a - Recovering/Resolving - ),  |   |              |            |
|    |                       |            |             |                            |                                     |               |                |                  |        |      | Back pain (n/a -<br>Unknown -<br>Caused/Prolonged   |   |              |            |

| 30.11.2022            | 15.25      |             |                                   |                              |               | Ru                          | n Line Li        | isting R | Report |  |  |              |          |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|-----------------------------|------------------|----------|--------|--|--|--------------|----------|
| 1                     |            |             |                                   |                              |               |                             |                  |          |        | Hospitalisation),  |  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Blood incompatibility<br>haemolytic anaemia<br>of newborn (n/a -<br>Not Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation), |  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Dyspnoea (n/a -  |  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Unknown - ), Glomerulonephritis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  |  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Headache (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation),  |  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Hyperparathyroidism<br>secondary (n/a -<br>Unknown - ),  |  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Oropharyngeal pain<br>(n/a - Unknown -<br>Caused/Prolonged<br>Hospitalisation),  |  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Pain in extremity<br>(n/a - Unknown -<br>Caused/Prolonged<br>Hospitalisation),   |  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Performance status<br>decreased (n/a -<br>Unknown - ),   |  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Proteinuria (n/a -<br>Not Recovered/Not<br>Resolved - ),   |  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Pyrexia (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation),   |  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Renal failure (n/a -<br>Not Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important Condition)   |  |              |          |
| EU-EC-<br>10013227158 | 12/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Economic                     | Not available | 12-17<br>Years              | Not<br>Specified | Female   | No     | Chills (4d -<br>Recovered/Resolved<br>-),<br>Fatigue (4d -<br>Recovered/Resolved   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a]) | Not reported | <u>I</u> |
|                       |            |             |                                   |                              |               |                             |                  |          |        | - ),<br>Headache (4d -<br>Recovered/Resolved<br>- ),   | , , , , , , , , , , , , , , , , , , ,  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Lymphadenopathy<br>(4d -<br>Recovered/Resolved<br>-),  |  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Pyrexia (4d -<br>Recovered/Resolved<br>-)  |  |              |          |
| EU-EC-<br>10013227560 | 12/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available | 12 <del>-</del> 17<br>Years | Not<br>Specified | Female   | No     | Malaise (n/a -<br>Unknown - ),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19  | Not reported | Ī        |
|                       |            |             |                                   | , u cu                       |               |                             |                  |          |        | Pain (n/a - Unknown<br>- ),  | immunisation - Not<br>applicable - [n/a -<br>1{DF} -                                     |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Pain in extremity<br>(n/a - Unknown - ),   | Intramuscular use])  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Skin plaque (n/a -<br>Unknown - ),   |  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Vaccination site<br>erythema (n/a -<br>Unknown - ),  |  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Vaccination site<br>oedema (n/a -<br>Unknown - ),<br>Vaccination site pain   |  |              |          |
| EU-EC-                | 12/08/2022 | Spontaneous | Healthcare                        | European                     | Not available |                             | Not              | Male     | No     | (n/a - Unknown - )<br>Nausea (n/a -  | COMIRNATY  | Not reported | <u>I</u> |
| 10013227605           |            |             | Professional                      | Economic<br>Area             |               | Years                       | Specified        |          |        | Unknown - ),<br>Pyrexia (n/a -   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not                                     |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Unknown - ),<br>Rash (n/a - Unknown<br>- ),  | applicable - [n/a - 1{DF} -  |              |          |
|                       |            |             |                                   |                              |               |                             |                  |          |        | Vomiting (n/a -<br>Unknown - )   |  |              | $\perp$  |
| EU-EC-<br>10013227809 | 12/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available |                             | Not<br>Specified | Male     | No     | Nausea (n/a -<br>Unknown - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not                        | Not reported | 10       |

|                     |             |             |                                   |                                     |               | 1              |                  |        |    | Pyrexia (n/a -   | applicable - [n/a -   |   |
|---------------------|-------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|--|---|---|
|                     |             |             |                                   |                                     |               |                |                  |        |    | Unknown - )  | 1{DF} -   |   |
|                     | 12/08/2022  | Spontaneous |                                   | Non                                 | Not available | 12-17          | Not              | Male   | No | Diarrhoea (n/a -   | Intramuscular use]) COMIRNATY   | Not reported  |
| 0013229030          |             |             | Professional                      | European<br>Economic                |               | Years          | Specified        |        |    | Recovering/Resolving - ),  | [TOZINAMERAN] (S -<br>COVID-19  |   |
|                     |             |             |                                   | Area                                |               |                |                  |        |    | Headache (n/a -  | immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])                                   |   |
|                     |             |             |                                   |                                     |               |                |                  |        |    | Pyrexia (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important Condition)            |   |   |
|                     | 12/08/2022  | Spontaneous |                                   | European                            | Not available | 12-17          | Adolescent       | Female | No | Immunisation   | COMIRNATY   | Not reported  |
| 0013229705          |             |             | Professional                      | Economic<br>Area                    |               | Years          |                  |        |    | reaction (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),         | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [n/a -<br>1{DF} -                  |   |
|                     |             |             |                                   |                                     |               |                |                  |        |    | Loss of<br>consciousness (n/a -<br>Unknown - Other<br>Medically Important                      | Intramuscular use])   |   |
|                     |             |             |                                   |                                     |               |                |                  |        |    | Condition),  Malaise (n/a - Unknown - Other  |   |   |
|                     |             |             |                                   |                                     |               |                |                  |        |    | Medically Important<br>Condition)  |   |   |
| U-EC-<br>0013229732 | 12/08/2022  | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Amenorrhoea (n/a -<br>Not Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation), | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -                 | [ETHINYLESTRADIOL,<br>LEVONORGESTREL,<br>PLACEBO] (C - Hormo<br>contraception - Dose of<br>changed - [n/a - n/a - |
|                     |             |             |                                   |                                     |               |                |                  |        |    | Crohn's disease (n/a<br>- Not Recovered/Not<br>Resolved -                                      | 1{DF} - Oral use])  | n/a])   |
|                     |             |             |                                   |                                     |               |                |                  |        |    | Caused/Prolonged<br>Hospitalisation)   |   |   |
| U-EC-<br>0013229851 | 12/08/2022  | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic                | Not available | 12-17<br>Years | Adolescent       | Female | No | Angina pectoris (n/a<br>-<br>Recovered/Resolved  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19   | Not reported  |
|                     |             |             | I O COSIUI Idi                    | nica                                |               |                |                  |        |    | - Other Medically<br>Important<br>Condition),  | immunisation - Not<br>applicable - [1d - n/a<br>- n/a])   |   |
|                     |             |             |                                   |                                     |               |                |                  |        |    | Pelvic pain (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)          |   |   |
| J-EC-<br>0013229871 | 12/08/2022  | Spontaneous | Healthcare                        | European<br>Economic                | Not available | 12-17<br>Years | Adolescent       | Female | No | Abdominal pain (n/a  | COMIRNATY<br>[TOZINAMERAN] (S -   | Not reported  |
|                     |             |             | Professional                      | Area                                |               |                |                  |        |    | Recovering/Resolving - Other Medically Important Condition),                                   | COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} -<br>Intramuscular use])                  |   |
|                     |             |             |                                   |                                     |               |                |                  |        |    | Amenorrhoea (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),      | Intramuscular usej)   |   |
|                     |             |             |                                   |                                     |               |                |                  |        |    | Headache (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important                      |   |   |
|                     |             |             |                                   |                                     |               |                |                  |        |    | Condition),  Nausea (n/a - Recovering/Resolving - Other Medically                              |   |   |
|                     | 12/08/2022  | Spontaneous |                                   | European                            | Not available | 12-17          | Adolescent       | Male   | No | Important Condition) Epistaxis (3wk -  | COMIRNATY   | Not reported  |
| 0013229951          |             |             | Healthcare<br>Professional        | Economic<br>Area                    |               | Years          |                  |        |    | Recovered/Resolved   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [n/a -<br>1{DF} -                  |   |
| U-EC-               | 12/08/2022  | Spontaneous | Non                               | European                            | Not available | 12-17          | Adolescent       | Female | No | Epistaxis (n/a -   | Intramuscular use]) COMIRNATY   | Not reported  |
| 0013229952          | _, 50, 2022 |             | Healthcare<br>Professional        | Economic                            |               | Years          | - State III      |        |    | Unknown - )  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [n/a -<br>1{DF} -                  |   |
|                     | 12/08/2022  | Spontaneous |                                   | European                            | Not available | 12-17          | Adolescent       | Female | No | Menstrual disorder   | Intramuscular use]) COMIRNATY   | [PARACETAMOL] (C -  |
| 0013229965          |             |             | Healthcare<br>Professional        | Economic<br>Area                    |               | Years          |                  |        |    | (n/a - Not<br>Recovered/Not<br>Resolved - )  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -                  | - Unknown - [n/a - n,<br>n/a])  |
| J-EC-<br>0013230651 | 12/08/2022  | Spontaneous | Non<br>Healthcare                 | European<br>Economic                | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Decreased appetite<br>(n/a - Unknown - ),  | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S -  | Not reported  |
|                     |             |             | Professional                      |                                     |               | 13413          |                  |        |    | Weight decreased (n/a - Unknown - )  | COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                                    |   |
| J-EC-<br>0013230713 | 12/08/2022  | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Pityriasis rosea (n/a -<br>Not Recovered/Not<br>Resolved - )                                   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a]) | Not reported  |
| U-EC-<br>0013230873 | 12/08/2022  | Spontaneous |                                   | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Chest pain (n/a - Not<br>Recovered/Not<br>Resolved - ),  |   | Not reported  |
|                     |             |             |                                   | Aica                                |               |                |                  |        |    | Dizziness (n/a - Not<br>Recovered/Not<br>Resolved - ),   | applicable - [n/a -<br>n/a - n/a])  |   |

| J.11.2022             | 15.25      |             |                                   |                              |   | RI             | ın Line L        | sung R | kepor | ι  |   |                |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|---|----------------|------------------|--------|-------|--|---|----------------|
|                       |            |             |                                   |                              |   |                |                  |        |       | Facial paralysis (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition), |   |                |
|                       |            |             |                                   |                              |   |                |                  |        |       | Hypotension (n/a -<br>Not Recovered/Not<br>Resolved - ),   |   |                |
|                       |            |             |                                   |                              |   |                |                  |        |       | Presyncope (n/a -<br>Not Recovered/Not<br>Resolved - )   |   |                |
| EU-EC-<br>10013231013 | 12/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available   | 12-17<br>Years | Not<br>Specified | Male   | No    | Eating disorder (n/a<br>- Unknown - ),<br>Illness (n/a -   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not                                       | Not reported   |
| EU-EC-                | 12/08/2022 | Spontaneous | Healthcare                        | Non                          | Not available   | 12-17          | Not              | Male   | No    | Unknown - )  Diarrhoea (4d - Fatal   | applicable - [n/a -<br>n/a - n/a])<br>COMIRNATY   | Not reported   |
| 10013232277           | 12/00/2022 | Sportaneous | Professional                      |                              | Not available   | Years          | Specified        | riale  | NO    | - Results in Death),  Myalgia (4d - Fatal - Results in Death),   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -                             | Not reported . |
|                       |            |             |                                   |                              |   |                |                  |        |       | Pyrexia (4d - Fatal -<br>Results in Death),  | n/a - Intramuscular<br>use])  |                |
|                       |            |             |                                   |                              |   |                |                  |        |       | Septic shock (4d -<br>Fatal - Results in<br>Death, Other<br>Medically Important<br>Condition),         |   |                |
|                       |            |             |                                   |                              |   |                |                  |        |       | Vomiting (4d - Fatal -<br>Results in Death)  |   |                |
| EU-EC-<br>10013232775 | 12/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area | Not available   | 12-17<br>Years | Not<br>Specified | Female | No    | Hypoaesthesia (46d - Recovered/Resolved - ),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not                                       | Not reported   |
|                       |            |             |                                   |                              |   |                |                  |        |       | Paraesthesia (46d -<br>Recovered/Resolved<br>-)  | applicable - [1d -<br>30ug - n/a])  |                |
| EU-EC-<br>10013233543 | 12/08/2022 | Spontaneous | Healthcare<br>Professional        |                              | Not available   | 12-17<br>Years | Adolescent       | Male   | No    | Pyrexia (n/a -<br>Unknown - )  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])               | Not reported   |
| EU-EC-<br>10013233555 | 12/08/2022 | Spontaneous | Healthcare                        | European<br>Economic         | Not available   | 12-17<br>Years | Adolescent       | Female | No    | Ageusia (n/a -<br>Recovering/Resolving   | COMIRNATY<br>[TOZINAMERAN] (S -   | Not reported   |
|                       |            |             | Professional                      | Area                         |   |                |                  |        |       | Anosmia (n/a -<br>Recovering/Resolving   | COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use])                       |                |
| EU-EC-<br>10013233604 | 12/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available   | 12-17<br>Years | Adolescent       | Female | No    | Epistaxis (1d -<br>Recovered/Resolved<br>-)  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use])   | Not reported   |
| EU-EC-<br>10013233637 | 12/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available   | 12-17<br>Years | Adolescent       | Female | No    | Lymphadenopathy<br>(n/a -<br>Recovering/Resolving<br>-)  | COMIRNATY<br>[TOZINAMERAN] (S -   | Not reported   |
| EU-EC-<br>10013233638 | 12/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available   | 12-17<br>Years | Adolescent       | Male   | No    | Headache (n/a -<br>Recovering/Resolving<br>- ),<br>Pyrexia (n/a -<br>Recovering/Resolving              | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [n/a -                | Not reported   |
| EU-EC-<br>10013233689 | 12/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available   | 12-17<br>Years | Adolescent       | Female | No    | - ) Axillary pain (n/a - Recovering/Resolving - ),   | use]) COMIRNATY [TOZINAMERAN] (S - COVID-19   | Not reported   |
|                       |            |             |                                   |                              |   |                |                  |        |       | Diarrhoea (n/a -<br>Recovering/Resolving<br>- ),   | immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use])                                   |                |
|                       |            |             |                                   |                              |   |                |                  |        |       | Headache (n/a -<br>Recovering/Resolving<br>-),   |   |                |
|                       |            |             |                                   |                              |   |                |                  |        |       | Pyrexia (n/a -<br>Recovering/Resolving   |   |                |
| EU-EC-<br>10013233720 | 12/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available   | 12-17<br>Years | Adolescent       | Male   | No    | Parotitis (n/a - Recovering/Resolving - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a             | Not reported   |
| EU-EC-                | 12/08/2022 | Spontaneous |                                   | European                     | Not available   | 12-17          | Adolescent       | Male   | No    | Decreased appetite   | - Intramuscular use]) COMIRNATY   | Not reported   |
| 10013233724           |            |             | Healthcare<br>Professional        | Economic<br>Area             |   | Years          |                  |        |       | (n/a<br>Recovering/Resolving<br>- ),<br>Fatigue (n/a -   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use]) |                |
|                       |            |             |                                   |                              |   |                |                  |        |       | Recovering/Resolving -),  Pyrexia (n/a - Recovering/Resolving  |   |                |
|                       | 11/00/2022 | Spontaneous | Healthcare                        | European                     | Marziali, E Acute Rejection   | 12-17          | Not              | Male   | No    | - )<br>Corneal graft   | TOZINAMERAN<br>[TOZINAMERAN] (S -   | Not reported   |
| EU-EC-                | 11/08/2022 |             | Drofossi                          |                              | Following COVID 10 Va : +: :  |                |                  |        |       |  |   | '              |
| EU-EC-<br>10013215888 | 11/08/2022 |             | Professional                      | Economic<br>Area             | Following COVID-19 Vaccination in<br>Penetrating Keratoplasty in a Young<br>Male - A Case Report and Review of<br>Literature. Ocular Immunology and<br>Inflammation. 2022;1-4.<br>doi:10.1080/09273948.2022.2106248 | Years          | Specified        |        |       | rejection (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important Condition)                  |   |                |

| J.11.2022             | 15.25      |             |                                   |                                     |               | RL             | ın Line L        | isting R | ероги |  |   |              |          |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|----------|-------|--|---|--------------|----------|
|                       |            |             | Professional                      | Area                                |               |                |                  |          |       | Unknown - ),   | COVID-19<br>immunisation - n/a -  |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Chronic fatigue<br>syndrome (n/a -<br>Recovering/Resolving<br>- ),                                     | [n/a - 2{DF} - n/a])  |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Dizziness (n/a -<br>Recovering/Resolving<br>- ),   |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Fatigue (n/a - Not<br>Recovered/Not<br>Resolved - ),   |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Headache (n/a -<br>Recovering/Resolving<br>- ),  |   |              |          |
|                       |            |             |                                   |                                     |               | 1              |                  |          |       | Migraine (n/a - Not<br>Recovered/Not<br>Resolved - )   |   |              |          |
| 10013217393           |            | Spontaneous | Healthcare<br>Professional        |                                     | Not available | Years          | Not<br>Specified | Male     | No    | Myocarditis (48d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation)                     | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- n/a])                                      | Not reported | <u>I</u> |
| EU-EC-<br>10013217499 | 11/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Chest discomfort<br>(n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation), | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])    | Not reported | Ī        |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Constipation (n/a -<br>Not Recovered/Not<br>Resolved - ),  |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Dyspepsia (n/a -<br>Unknown - ),   |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Flatulence (n/a -<br>Unknown - ),<br>Lymphadenitis (n/a -  |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Not Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),                               |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Nausea (n/a - Not<br>Recovered/Not<br>Resolved - ),  |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Pain in extremity<br>(n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation) |   |              |          |
| EU-EC-<br>10013218259 | 11/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Urticaria (n/a - Not<br>Recovered/Not<br>Resolved - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} - n/a]) | Not reported | Ī        |
| EU-EC-<br>10013218428 | 11/08/2022 | Spontaneous | Healthcare<br>Professional        | le                                  | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Headache (n/a -<br>Unknown - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19   | Not reported | <u>I</u> |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Vaccination site<br>erythema (n/a -<br>Unknown - ),  | immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])                               |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Vaccination site<br>oedema (n/a -<br>Unknown - ),  |   |              |          |
| EU-EC-                | 11/08/2022 | Spontaneous | Healthcare                        | European                            | Not available | 12-17          | Not              | Male     | No    | Vaccination site pain<br>(n/a - Unknown - )<br>Pallor (n/a -   | COMIRNATY   | Not reported | <u>I</u> |
| 10013218444           | ,          |             | Professional                      |                                     |               |                | Specified        |          |       | Unknown - ), Presyncope (n/a -   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not  |              | _        |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Unknown - ), Syncope (n/a -  | applicable - [n/a -<br>1{DF} -<br>Intramuscular use])   |              |          |
| EU-EC-<br>10013219620 | 11/08/2022 | Spontaneous | Healthcare                        | Non<br>European                     | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Unknown - )  Dysuria (n/a - Unknown - ),   | TOZINAMERAN<br>[TOZINAMERAN] (S -   | Not reported | <u>I</u> |
|                       |            |             | Professional                      | Economic<br>Area                    |               |                |                  |          |       | Gait disturbance (n/a<br>- Unknown - ),  | COVID-19<br>immunisation - Not<br>applicable - [n/a -   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Immune system<br>disorder (n/a -<br>Unknown - ),   | n/a - Intramuscular<br>use])  |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Oedema genital (n/a<br>- Unknown - ),  |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Pain (n/a - Unknown<br>- Other Medically<br>Important<br>Condition),                                   |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Pyrexia (2d -<br>Recovered/Resolved<br>-),   |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Vaginal ulceration   |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Recovering/Resolving - ),  |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Vulval disorder (n/a -<br>Unknown - ),   |   |              |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Vulval ulceration (n/a   |   |              |          |

|                       | 4440       |             |                            |                              |               |                |                  | _      |    | - Other Medically<br>Important Condition)   | leastration :  |  | $\perp$    |
|-----------------------|------------|-------------|----------------------------|------------------------------|---------------|----------------|------------------|--------|----|---|--|--|------------|
| EU-EC-<br>10013219764 | 11/08/2022 | Spontaneous | Healthcare<br>Professional | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Syncope (n/a -<br>Unknown - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])   | Not reported   | <u>I</u> ! |
| EU-EC-<br>10013219981 | 11/08/2022 | Spontaneous |                            | European<br>Economic<br>Area | Not available |                | Not<br>Specified | Male   | No | Vaccination site<br>erythema (n/a -<br>Unknown - ),<br>Vaccination site<br>oedema (n/a -<br>Unknown - ),      | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])   | Not reported   | 10         |
|                       |            |             |                            |                              |               |                |                  |        |    | Vaccination site pain<br>(n/a - Unknown - ),<br>Vaccination site<br>pruritus (n/a -                           |  |  |            |
| EU-EC-<br>10013220248 | 11/08/2022 | Spontaneous |                            | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Unknown - )  Malaise (n/a - Recovered/Resolved - ),  Syncope (n/a - Recovered/Resolved                        | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -                          | Not reported   | <u>I</u>   |
| EU-EC-<br>10013220267 | 11/08/2022 | Spontaneous |                            | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | - ) Headache (n/a - Unknown - ), Syncope (n/a - Unknown - ), Vertigo (n/a -                                   | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported   | <u>I</u>   |
| 10013220376           |            | Spontaneous | Healthcare<br>Professional |                              | Not available | 12-17<br>Years | Adolescent       |        | No | Unknown - ) Rheumatoid arthritis (n/a - Not Recovered/Not Resolved - Caused/Prolonged Hospitalisation)        | COMIRNATY<br>[TOZINAMERAN] (S -<br>Immunisation - n/a -<br>[n/a - n/a - n/a])  | Not reported   | <u>I</u>   |
| EU-EC-<br>10013220391 | 11/08/2022 | Spontaneous |                            | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Female | No | Chronic fatigue<br>syndrome (n/a - Not<br>Recovered/Not<br>Resolved -<br>Disabling),                          | COMIRNATY<br>[TOZINAMERAN] (S -<br>Immunisation - n/a -<br>[n/a - n/a - n/a])  | Not reported   | <u>I</u>   |
|                       |            |             |                            |                              |               |                |                  |        |    | Disturbance in<br>attention (18d - Not<br>Recovered/Not<br>Resolved - ),                                      |  |  |            |
|                       |            |             |                            |                              |               |                |                  |        |    | Fatigue (n/a - Not<br>Recovered/Not<br>Resolved -<br>Disabling),  |  |  |            |
|                       |            |             |                            |                              |               |                |                  |        |    | Headache (18d - Not<br>Recovered/Not<br>Resolved - ),<br>Hyperacusis (n/a -                                   |  |  |            |
|                       |            |             |                            |                              |               |                |                  |        |    | Not Recovered/Not<br>Resolved - ),<br>Malaise (n/a - Not<br>Recovered/Not                                     |  |  |            |
| EU-EC-<br>10013220584 | 11/08/2022 | Spontaneous |                            | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Female | No | Resolved - ) Intermenstrual bleeding (n/a - Not Recovered/Not Resolved - Other Medically Important Condition) | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>.3mL - Intramuscular<br>use])     | Not reported   | <u>I</u> ! |
| EU-EC-<br>10013220821 | 11/08/2022 | Spontaneous |                            | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Male   | No | Chest pain (n/a -<br>Recovering/Resolving<br>- )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - n/a -  | Not reported   | <u>I</u>   |
| EU-EC-<br>10013221580 | 11/08/2022 | Spontaneous |                            | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Fatigue (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),                 | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - n/a - n/a - [n/a - n/a - n/a])  | Not reported   | <u>I</u>   |
| EU-EC-                | 11/00/2022 | Canadana    | Nee                        | F                            | Natarilable   | 12.17          | Net              | Mala   | No | Syncope (0d -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)                              | COMIDNATIV   | [FCCTTALODDAM] (C  |            |
| 10013221610           | 11/08/2022 | Spontaneous | Healthcare<br>Professional | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Chest pain (2d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),                       | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- n/a])   | [ESCITALOPRAM] (C - n/a - n/a - [n/a - n/a - Oral use]),  [METHYLPHENIDATE HYDROCHLORIDE] (C - | <u>I</u>   |
|                       |            |             |                            |                              |               |                |                  |        |    | Discomfort (3d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),                       |  | n/a - n/a - [n/a - n/a -<br>Oral use])   |            |
|                       |            |             |                            |                              |               |                |                  |        |    | Headache (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),                      |  |  |            |
|                       |            |             |                            |                              |               |                |                  |        |    | Malaise (2d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),                          |  |  |            |

| 0.11.2022             | 15.25      |             |                                   |                                     |   | Rι             | ın Line Li       | isting R | teport | I  |  |  |            |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---|----------------|------------------|----------|--------|--|--|--|------------|
|                       |            |             |                                   |                                     |   |                |                  |          |        | Nausea (1d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),  |  |  |            |
|                       |            |             |                                   |                                     |   |                |                  |          |        | Pyrexia (1d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),   |  |  |            |
|                       |            |             |                                   |                                     |   |                |                  |          |        | Syncope (1d -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)   |  |  |            |
| EU-EC-<br>10013221630 | 11/08/2022 | Spontaneous | Healthcare                        | European<br>Economic<br>Area        | Not available   | 12-17<br>Years | Not<br>Specified | Male     | No     | Epilepsy (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- n/a])   | Not reported   | 10         |
| EU-EC-<br>10013222099 | 11/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available   | 12-17<br>Years | Not<br>Specified | Female   | No     | Chest discomfort<br>(n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),                                | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])           | Not reported   | <u>I</u>   |
|                       |            |             |                                   |                                     |   |                |                  |          |        | Dyspnoea (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important Condition)   |  |  |            |
| EU-EC-<br>10013222429 | 11/08/2022 | Spontaneous | Healthcare                        | Non<br>European<br>Economic<br>Area | Not available   | 12-17<br>Years | Not<br>Specified | Female   | No     | Loss of<br>consciousness (1d -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)                                  | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                       | [PROPANTHELINE<br>BROMIDE] (C -<br>Hyperhidrosis - n/a - [n/a<br>- n/a - n/a]) | <u>I</u>   |
| EU-EC-<br>10013222563 | 11/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available   | 12-17<br>Years | Adolescent       | Male     | No     | Pyrexia (n/a -<br>Unknown - )  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - n/a])                                      | Not reported   | <u>I</u>   |
| EU-EC-<br>10013222614 | 11/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available   | 12-17<br>Years | Adolescent       | Female   | No     | Malaise (n/a -<br>Unknown - ),<br>Myalgia (n/a -<br>Unknown - ),<br>Pyrexia (n/a -   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} - n/a])                       | Not reported   | <u>I</u>   |
| EU-EC-<br>10013222971 | 11/08/2022 | Spontaneous |                                   | Non<br>European<br>Economic<br>Area | Takase, B Delayed Vasovagal<br>Reaction with Reflex Syncope<br>Following COVID-19 Vaccination,<br>Internal Medicine, 2022;61(14):2167–<br>2170.<br>doi:10.2169/internalmedicine,9318- | 12-17<br>Years | Not<br>Specified | Female   | No     | Unknown - ) Syncope (n/a - Recovered/Resolved - Other Medically  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                        | Not reported   | <u>I</u>   |
| EU-EC-<br>10013222997 | 11/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | 21<br>Not available   | 12-17<br>Years | Adolescent       | Female   | No     | Lymphadenopathy<br>(n/a -<br>Recovering/Resolving<br>-)  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a - Intramuscular use - More in ICSR])           | Not reported   | <u>I</u>   |
| EU-EC-<br>10013223018 | 11/08/2022 | Spontaneous |                                   | Economic                            | Not available   | 12-17<br>Years | Adolescent       | Male     | No     | Headache (n/a -<br>Unknown - ),<br>Pyrexia (n/a -<br>Unknown - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [n/a -<br>n/a - Intramuscular<br>use])       | Not reported   | Ī          |
| EU-EC-<br>10013223044 | 11/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available   | 12-17<br>Years | Adolescent       | Male     | No     | Fatigue (n/a -<br>Recovering/Resolving<br>-),<br>Pyrexia (n/a -  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a                                    | Not reported   | <u>I</u>   |
| EU-EC-<br>10013223209 | 11/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available   | 12-17<br>Years | Adolescent       | Female   | No     | Unknown - ) Arthralgia (n/a - Not Recovered/Not Resolved - ), Vaccination site pain (n/a - Unknown - )                             | - Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported   | <u>I</u>   |
| EU-EC-<br>10013205466 | 10/08/2022 | Spontaneous |                                   | Non<br>European<br>Economic<br>Area | Not available   | 12-17<br>Years | Not<br>Specified | Male     | No     | Dizziness (n/a -<br>Recovered/Resolved - ),<br>Seizure (n/a -<br>Recovered/Resolved - Other Medically<br>Important<br>Condition),  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])                          | Not reported   | <u>I</u> ! |
|                       |            |             |                                   |                                     |   |                |                  |          |        | Syncope (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)  |  |  |            |
| EU-EC-<br>10013205515 | 10/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available   | 12-17<br>Years | Not<br>Specified | Female   | No     | Asthenia (10d -<br>Recovered/Resolved - ),<br>Asthmatic crisis (1d -<br>Recovered/Resolved - Caused/Prolonged<br>Hospitalisation), | COMIRNATY<br>[TOZINAMERAN] (S -<br>Immunisation -<br>Unknown - [n/a -<br>.3mL - Intramuscular<br>use])                         | Not reported   | <u>I</u> ! |
|                       |            |             |                                   |                                     |   |                |                  |          |        | Chest discomfort<br>(11d -<br>Recovered/Resolved<br>- ),<br>Cyanosis (1d -   |  |  |            |
|                       |            |             |                                   |                                     |   |                |                  |          |        |  |  |  |            |

| 30.11.2022            | 10.20      |             |                                   |                              |               | 1 (0           | III LIIIC L      | oung i           | орон |  |  |              |          |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|------------------|------|--|--|--------------|----------|
|                       |            |             |                                   |                              |               |                |                  |                  |      | Dyspnoea (11d -<br>Recovered/Resolved  |  |              |          |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Fatigue (10d -<br>Recovered/Resolved   |  |              |          |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Hyperpyrexia (1d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),                      |  |              |          |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Hyperventilation<br>(11d -<br>Recovered/Resolved   |  |              |          |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Paraesthesia (1d -<br>Recovered/Resolved   |  |              |          |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Pharyngotonsillitis<br>(n/a -<br>Recovered/Resolved<br>-),   |  |              |          |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Tachycardia (10d -<br>Recovered/Resolved<br>-)   |  |              |          |
| EU-EC-<br>10013205621 | 10/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female           | No   | Chest pain (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),                  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - 300uL -   | Not reported | <u>I</u> |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Dyspnoea (n/a - Not<br>Recovered/Not<br>Resolved - ),  | Intramuscular use])  |              |          |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Hyperhidrosis (n/a -<br>Not Recovered/Not<br>Resolved - ),   |  |              |          |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Loss of<br>consciousness (n/a -<br>Not Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),    |  |              |          |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Pain in extremity<br>(n/a - Not<br>Recovered/Not<br>Resolved - ),  |  |              |          |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Pericarditis (n/a -<br>Not Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),                |  |              |          |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Tachycardia (n/a -<br>Unknown - )  |  |              |          |
| EU-EC-<br>10013207036 | 10/08/2022 | Spontaneous | Healthcare<br>Professional        |                              | Not available | 12-17<br>Years | Not<br>Specified | Not<br>Specified | No   | Facial paralysis (n/a -<br>Unknown - Other<br>Medically Important<br>Condition)                                | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use]) | Not reported | Ī        |
| EU-EC-<br>10013207328 | 10/08/2022 | Spontaneous | Healthcare                        | European<br>Economic         | Not available | 12-17<br>Years | Not<br>Specified | Male             | No   | Dizziness (n/a -<br>Unknown - ),   | COMIRNATY [TOZINAMERAN] (S - COVID-19  | Not reported | ľ        |
|                       |            |             | Professional                      |                              |               |                |                  |                  |      | Nausea (n/a -<br>Unknown - )   | immunisation - Not<br>applicable - [1d - n/a<br>- n/a])  |              |          |
| EU-EC-<br>10013207858 | 10/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male             | No   | Asthenia (n/a -<br>Unknown - ),  | COMIRNATY [TOZINAMERAN] (S - COVID-19  | Not reported | <u>I</u> |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Headache (n/a -<br>Unknown - ),<br>Malaise (n/a -  | immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])  |              |          |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Unknown - ), Pyrexia (n/a -  | anadanascalar asejj  |              |          |
| EU-EC-<br>10013207936 | 10/08/2022 | Spontaneous |                                   | European<br>Economic         | Not available | 12-17<br>Years | Not<br>Specified | Female           | No   | Unknown - ) Hyperhidrosis (n/a - Unknown - ),  | COMIRNATY [TOZINAMERAN] (S -   | Not reported | <u>I</u> |
|                       |            |             |                                   | Area                         |               |                | ·                |                  |      | Hypotension (n/a -<br>Unknown - ),   | COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -   |              |          |
| EU-EC-                | 10/08/2022 | Spontaneous | Healthcare                        | European                     | Not available | 12-17          | Not              | Female           | No   | Nausea (n/a -<br>Unknown - )<br>Syncope (n/a -   | Intramuscular use]) COMIRNATY  | Not reported | 1        |
| 10013207941           | 10,00,2022 | Sportaneous | Professional                      | Economic<br>Area             | Tot available | Years          | Specified        | remale           | 140  | Unknown - )  | [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])                           | Not reported | <u> </u> |
| EU-EC-<br>10013208139 | 10/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Not<br>Specified | No   | Seizure (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important Condition) | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular          | Not reported | <u>I</u> |
| EU-EC-<br>10013208883 | 10/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Not<br>Specified | No   | Headache (1d -<br>Recovered/Resolved<br>-),  | use]) COMIRNATY [TOZINAMERAN] (S - COVID-19  | Not reported | <u>I</u> |
|                       |            |             |                                   |                              |               |                |                  |                  |      | Inappropriate<br>schedule of product<br>administration (n/a -  | immunisation - Not<br>applicable - [1d - n/a<br>- n/a])  |              |          |

|                       |            |             |                            |                                     |                    |                |                  |                  |     | Unknown - ),   |  |               |   |
|-----------------------|------------|-------------|----------------------------|-------------------------------------|--------------------|----------------|------------------|------------------|-----|--|--|---------------|---|
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Pyrexia (2d -<br>Recovered/Resolved<br>-)  |  |               |   |
| EU-EC-<br>10013208890 | 10/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available      | 12-17<br>Years | Not<br>Specified | Male             | No  | Cardiac dysfunction<br>(n/a - Unknown -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),                       | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a]) | Not reported  |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Cardiomegaly (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation),  |  |               |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Chest pain (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),   |  |               |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Dyspnoea (n/a -<br>Unknown - ),  |  |               |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Electrocardiogram ST<br>segment elevation<br>(n/a - Unknown -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition), |  |               |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Haemodynamic<br>instability (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation),   |  |               |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Hyperhidrosis (n/a -<br>Unknown - ),   |  |               |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Myocardial necrosis<br>marker increased<br>(n/a - Unknown -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),   |  |               |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Myocarditis (n/a -<br>Unknown - Life<br>Threatening,<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),          |  |               |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Nausea (n/a -<br>Unknown - ),  |  |               |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Paraesthesia (n/a -<br>Unknown - ),  |  |               |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Pyrexia (1d -<br>Recovered/Resolved<br>- ),  |  |               |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Ventricular<br>hypokinesia (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),                |  |               |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Vomiting (n/a -<br>Unknown - )   |  |               |   |
| J-EC-<br>0013209298   | 10/08/2022 | Spontaneous | Healthcare<br>Professional |                                     | Not available      | 12-17<br>Years | Not<br>Specified | Not<br>Specified | No  | Noninfective sialoadenitis (n/a - Unknown - ),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not                                      | Not reported  |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Pyrexia (48h -<br>Recovered/Resolved<br>-),  | applicable - [n/a -<br>.3mL - Intramuscular<br>use])   |               |   |
| 1.50                  | 10/00/2022 | C           | 11144                      | F                                   | Nick comillability | 12.17          | Niet             | 84-1-            | NI- | Swelling face (n/a -<br>Unknown - )  | COMPRIATO  | Not you subod |   |
| U-EC-<br>0013209727   | 10/08/2022 | Spontaneous |                            | European<br>Economic<br>Area        | Not available      |                | Not<br>Specified | Male             | No  | Eyelid oedema (n/a -<br>Unknown - ),<br>Hypersensitivity (n/a<br>- Unknown - )   | [TOZINAMERAN] (S -<br>COVID-19   | Not reported  |   |
| U-EC-<br>0013209817   | 10/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available      | 12-17<br>Years | Not<br>Specified | Male             | No  | Chest discomfort<br>(n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),  | [TOZINAMERAN] (S -   | Not reported  | _ |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Chest pain (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),   |  |               |   |
|                       |            |             |                            |                                     |                    |                |                  |                  |     | Myocarditis (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),                  |  |               |   |

|                       |            |             |                                   |                                     |  |                |                  |        |    | Pain (n/a -  |  |              |   |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|--|----------------|------------------|--------|----|--|--|--------------|---|
|                       |            |             |                                   |                                     |  |                |                  |        |    | Recovering/Resolving - Caused/Prolonged Hospitalisation)   |  |              |   |
| EU-EC-<br>10013210788 | 10/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Female | No | Asthmatic crisis (1d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),                  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -                                    | Not reported |   |
|                       |            |             |                                   |                                     |  |                |                  |        |    | Heavy menstrual<br>bleeding (5wk -<br>Recovered/Resolved<br>-),  | .3mL - Intramuscular<br>use])  |              |   |
|                       |            |             |                                   |                                     |  |                |                  |        |    | Menstruation<br>irregular (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition) |  |              |   |
| EU-EC-<br>10013210790 | 10/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Female | No | Dysmenorrhoea (n/a<br>- Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),            | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -                        | Not reported |   |
|                       |            |             |                                   |                                     |  |                |                  |        |    | Menstruation<br>irregular (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition) | Intramuscular use])  |              |   |
| EU-EC-<br>10013210844 | 10/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Female | No | Amenorrhoea (65d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),                      | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - n/a - [1d - 1{DF} - Intramuscular use])                               | Not reported |   |
|                       |            |             |                                   |                                     |  |                |                  |        |    | Nausea (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),                         | ,  |              |   |
|                       |            |             |                                   |                                     |  |                |                  |        |    | Oligomenorrhoea<br>(n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),             |  |              |   |
|                       |            |             |                                   |                                     |  |                |                  |        |    | Uterine pain (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important Condition)                       |  |              |   |
| EU-EC-<br>10013210973 | 10/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Male   | No | Immunisation<br>reaction (7d -<br>Recovered/Resolved<br>- )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use]) | Not reported |   |
| EU-EC-<br>10013211006 | 10/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Economic                            | Not available  | 12-17<br>Years | Adolescent       | Female | No | Amenorrhoea (n/a -<br>Recovered/Resolved<br>- )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} -                         | Not reported |   |
| EU-EC-<br>10013211078 | 10/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Male   | No | Ear discomfort (n/a -<br>Not Recovered/Not<br>Resolved - ),<br>Ear pain (n/a - Not<br>Recovered/Not            | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} -                    | Not reported |   |
| EU-EC-<br>10013211643 | 10/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Bloise, S Adenomesenteritis<br>following SARS-CoV-2 Vaccination in<br>Children: A Case Report and Review<br>of The Literature, Children, 2022;9<br>(7):993.<br>doi:10.3390/children9070993 | 12-17<br>Years | Not<br>Specified | Female | No | Resolved - ) Lymphadenitis (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation)                       | Intramuscular use]) TOZINAMERAN [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])             | Not reported | _ |
| EU-EC-<br>10013211768 | 10/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Not<br>Specified | Female | No | Blood pressure<br>decreased (n/a -<br>Unknown - ),<br>Malaise (n/a -   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -   | Not reported |   |
|                       |            |             |                                   |                                     |  |                |                  |        |    | Unknown - ), Pallor (n/a - Unknown - ), Syncope (n/a -   | 1{DF} -<br>Intramuscular use])   |              |   |
| EU-EC-<br>10013211818 | 10/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Not<br>Specified | Female | No | Unknown - ) Blood pressure decreased (n/a - Unknown - ), Malaise (n/a -  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -   | Not reported | _ |
|                       |            |             |                                   |                                     |  |                |                  |        |    | Unknown - ), Syncope (n/a - Unknown - )  | 1{DF} -<br>Intramuscular use])   |              |   |
| EU-EC-<br>10013212372 | 10/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Not<br>Specified | Male   | No | Dizziness (n/a -<br>Unknown - )  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -                                       | Not reported |   |
| EU-EC-<br>10013212726 | 10/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available  | 12-17<br>Years | Not<br>Specified | Male   | No | COVID-19 (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically                        | Intramuscular use])  COMIRNATY  [TOZINAMERAN] (S - COVID-19  immunisation - Not applicable - [1d - n/a                     | Not reported | _ |

|                     |            |             |                            |                                     |               |                |                  |        |    | - Unknown -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important Condition)   |  |   |
|---------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|--------|----|--|--|---|
| U-EC-<br>0013214100 | 10/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | - Other Medically<br>Important<br>Condition),<br>Nausea (n/a -   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])               | [WARFARIN, WARFARIN<br>SODIUM] (C - n/a - n/a<br>[n/a - n/a - n/a]) |
| U-EC-<br>0013195915 | 09/08/2022 | Spontaneous | Healthcare                 | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | Unknown - ) COVID-19 (5d - Recovered/Resolved - Other Medically Important Condition), Drug ineffective (n/a - Unknown - Other Medically Important Condition)   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])               | Not reported  |
| U-EC-<br>0013195974 | 09/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No | COVID-19 (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Dehydration (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Drug ineffective (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation), Gastritis (2d - Recovered/Resolved - Caused/Prolonged Hospitalisation)                               | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use]) | Not reported  |
| U-EC-<br>0013196215 | 09/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Dizziness (2d – Recovered/Resolved – Caused/Prolonged Hospitalisation), Headache (n/a – Recovered/Resolved – Caused/Prolonged Hospitalisation), Pyrexia (3d – Recovered/Resolved – Caused/Prolonged Hospitalisation), Systemic viral infection (n/a – Unknown – Other Medically Important Condition), Urinary tract infection (n/a – | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use]) | Not reported  |
| U-EC-<br>0013196817 | 09/08/2022 | Spontaneous | Healthcare                 | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | Unknown - )  Arthralgia (n/a - Unknown - ),  Bell's palsy (n/a - Unknown - Other Medically Important Condition),  Facial discomfort (n/a - Unknown - ),  Headache (n/a - Unknown - ),  Hypoaesthesia (n/a - Unknown - ),  Myalgia (n/a - Unknown - ),  Neck pain (n/a - Unknown - ),  Sluggishness (n/a - Unknown - ),               | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])               | Not reported  |
| U-EC-<br>0013197078 | 09/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No | ·  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use]) | Not reported  |

| ).11.2022             | 15.25      |             |                                   |                                     |               | RI             | ın Line L        | isting F | kepor | ι  |  |              |   |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|----------|-------|--|--|--------------|---|
|                       |            |             |                                   | Area                                |               |                |                  |          |       | Dizziness (2min -<br>Recovered/Resolved - ), Syncope (2min -<br>Recovered/Resolved   | COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])                                      |              |   |
| EU-EC-<br>10013197191 | 09/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Blood pressure decreased (n/a - Unknown - ), Heart rate abnormal (n/a - Unknown - ), Oxygen saturation (n/a - Unknown - ), Syncope (n/a - Unknown - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])   | Not reported | Ī |
| EU-EC-<br>10013197293 | 09/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Malaise (n/a -<br>Unknown - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])   | Not reported | 1 |
| EU-EC-<br>10013197316 | 09/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Hypoaesthesia (10d -<br>Recovered/Resolved<br>- Disabling),<br>Muscular weakness<br>(10d -<br>Recovered/Resolved<br>- Disabling),<br>Pyrexia (3d -   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - Intramuscular use])                        | Not reported | 1 |
| EU-EC-<br>0013197320  | 09/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Recovered/Resolved - Disabling) Syncope (5min - Recovered/Resolved - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -                          | Not reported | - |
| EU-EC-<br>0013197359  | 09/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Hypertension (n/a -<br>Unknown - )   | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported | - |
| EU-EC-<br>10013197527 | 09/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male     | No    | Lymphadenopathy<br>(n/a - Not<br>Recovered/Not<br>Resolved - )   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])                     | Not reported |   |
| :U-EC-<br>0013197598  | 09/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | COVID-19 (n/a - Not Recovered/Not Resolved - Other Medically Important Condition),  Cough (n/a - Not Recovered/Not Resolved - ),  Decreased appetite (n/a - Not Recovered/Not Resolved - ),  Oropharyngeal pain (n/a - Not Recovered/Not Resolved - Not Recovered/Not Resolved - Not Recovered/Not Recovered/Not Recovered/Not Recovered/Not | COMIRNATY  [TOZINAMERAN] (S - COVID-19  immunisation - Not applicable - [1d - n/a - Intramuscular use])                      | Not reported |   |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Resolved - ),  Pyrexia (0d - Recovered/Resolved - ),  Vaccination failure (n/a - Unknown - Other Medically Important Condition)  |  |              |   |
| EU-EC-<br>10013198718 | 09/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Malaise (n/a -<br>Unknown - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])   | Not reported | ] |
| U-EC-<br>0013200026   | 09/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Blood pressure<br>decreased (n/a -<br>Unknown - ),<br>Dizziness (n/a -<br>Unknown - ),<br>Hyperhidrosis (n/a -<br>Unknown - ),<br>Pallor (n/a -<br>Unknown - )   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])                     | Not reported |   |
| EU-EC-<br>10013200429 | 09/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Vaccination site erythema (n/a - Unknown - ),  Vaccination site oedema (n/a - Unknown - ),  Vaccination site pain (n/a - Unknown - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])   | Not reported | - |

| 0 | J.11.2022             | 10.20      |             |                                   |                                     |               | 1 (0           | II LIIIC L       | isting it | Сроп |   |  |              |          |
|---|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|-----------|------|---|--|--------------|----------|
|   | EU-EC-<br>10013200664 | 09/08/2022 | Spontaneous | Healthcare<br>Professional        |                                     | Not available | 12-17<br>Years | Not<br>Specified | Male      |      | Arrhythmia (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),<br>Chest pain (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),<br>Left ventricular<br>hypertrophy (n/a -<br>Recovered/Resolved<br>- Other Medically   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])   | Not reported | Ī        |
|   | EU-EC-<br>10013200681 | 09/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male      | No   | Important Condition) COVID-19 (35d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Chest discomfort (31d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Dizziness (31d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (35d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Drug ineffective (35d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Oropharyngeal pain (35d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Viral infection (30d - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition), Viral infection (30d - Recovered/Resolved - Caused/Prolonged | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a - More in ICSR])   | Not reported | D        |
|   | EU-EC-<br>10013200726 | 09/08/2022 | Spontaneous | Healthcare<br>Professional        |                                     | Not available | 12-17<br>Years | Not<br>Specified | Male      |      | Important Condition) Vertigo (n/a - Unknown - )   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported | Ī        |
|   | EU-EC-<br>10013201417 | 09/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female    |      | Back pain (n/a -<br>Unknown - ),<br>Lymphadenopathy<br>(n/a - Unknown - ),<br>Neck pain (n/a -  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])  | Not reported | <u>I</u> |
|   | 10013201421           |            | Spontaneous | Professional                      | Economic<br>Area                    | Not available | 12-17<br>Years | Not<br>Specified |           | No   | Unknown - ) Eyelid oedema (n/a - Not Recovered/Not Resolved - Other Medically Important Condition), Lip swelling (n/a - Recovering/Resolving - Other Medically Important Condition), Oedema (n/a - Unknown - Other Medically Important Condition), Swelling of eyelid (n/a - Unknown - Other Medically Important Condition), Swelling of eyelid (n/a - Unknown - Other Medically Important Condition), Swollen tongue (n/a - Unknown - Other Medically Important Condition), Throat tightness (n/a - Unknown - Other Medically Important Condition), Throat tightness (n/a - Unknown - Other Medically Important Condition)   | COMIRNATY  [TOZINAMERAN] (S - COVID-19  immunisation - Not applicable - [1d - n/a - n/a])                | Not reported | <u>r</u> |
|   | EU-EC-<br>10013201488 | 09/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female    | No   | Chest discomfort<br>(n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -                  | Not reported | 1        |

| 0.11.2022              | 10.20      |             |                                   |                                     |  | 110            | III LIIIC L      | isting i | сроп |   |  |              |          |
|------------------------|------------|-------------|-----------------------------------|-------------------------------------|--|----------------|------------------|----------|------|---|--|--------------|----------|
|                        |            |             |                                   |                                     |  |                |                  |          |      | Chest pain (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),  | .3mL - Intramuscular<br>use])  |              |          |
|                        |            |             |                                   |                                     |  |                |                  |          |      | Myocarditis (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition), |  |              |          |
|                        |            |             |                                   |                                     |  |                |                  |          |      | Pain in extremity<br>(n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),                                      |  |              |          |
|                        |            |             |                                   |                                     |  |                |                  |          |      | Pyrexia (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),   |  |              |          |
|                        |            |             |                                   |                                     |  |                |                  |          |      | Vaccination site pain<br>(n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation)                                   |  |              |          |
| EU-EC-<br>10013201491  | 09/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Tanaka, A A case of female child<br>developing acute perimyocarditis<br>after COVID-19 vaccination. The 58th<br>Annual Meeting of Japanese Society<br>of Pediatric Cardiology and Cardiac. | 12-17<br>Years | Not<br>Specified | Female   | No   | Chest pain (5d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -                         | Not reported | I        |
|                        |            |             |                                   |                                     | 2022;58th  |                |                  |          |      | Electrocardiogram ST<br>segment elevation<br>(4d -<br>Recovered/Resolved<br>- Caused/Prolonged                                      | n/a - n/a])  |              |          |
|                        |            |             |                                   |                                     |  |                |                  |          |      | Hospitalisation),  Malaise (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),   |  |              |          |
|                        |            |             |                                   |                                     |  |                |                  |          |      | Myocarditis (107h -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),  |  |              |          |
|                        |            |             |                                   |                                     |  |                |                  |          |      | Myopericarditis (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),          |  |              |          |
|                        |            |             |                                   |                                     |  |                |                  |          |      | Pyrexia (2d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),  |  |              |          |
|                        |            |             |                                   |                                     |  |                |                  |          |      | Troponin I increased<br>(n/a - Unknown -<br>Caused/Prolonged<br>Hospitalisation),   |  |              |          |
|                        |            |             |                                   |                                     |  |                |                  |          |      | Troponin T increased<br>(4d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation)                                       |  |              |          |
| EU-EC-<br>10013202742  | 09/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available  | 12-17<br>Years | Not<br>Specified | Male     | No   | COVID-19 (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),  | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a                    | Not reported | I        |
|                        |            |             |                                   |                                     |  |                |                  |          |      | Vaccination failure<br>(n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important Condition)                                  | - Intramuscular use -<br>More in ICSR])  |              |          |
| EU-EC-<br>10013204459  | 09/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Male     | No   | Paraesthesia (n/a -<br>Recovering/Resolving<br>- )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a                      | Not reported | <u>I</u> |
| EU-EC-<br>10013204469  | 09/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Male     | No   | Vaccination site<br>lymphadenopathy<br>(n/a - Unknown - )   | - Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Drug withdrawn - [1d - n/a            | Not reported | 1        |
| EU-EC-<br>10013204571  | 09/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Male     | No   | (n/a - Unknown - )  | - Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - n/a]) | Not reported | <u>I</u> |
| EU-EC-<br>10013204601  | 09/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Female   | No   | Cough (n/a - Not<br>Recovered/Not<br>Resolved - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug   | Not reported | I        |
|                        |            |             |                                   |                                     |  |                |                  |          |      | Recovered/Not<br>Resolved - ),  | withdrawn - [1d - n/a<br>- Intramuscular use])   |              |          |
|                        |            |             |                                   |                                     |  |                |                  |          |      | Pyrexia (n/a - Not<br>Recovered/Not<br>Resolved - )   |  |              | $\perp$  |
| EU-EC-<br> 10013204657 | 09/08/2022 | Spontaneous | Non<br>Healthcare                 | European<br>Economic                | Not available  | 12-17<br>Years | Adolescent       | Female   | No   | Diarrhoea (n/a -<br>Recovering/Resolving  | COMIRNATY<br>[TOZINAMERAN] (S -  | Not reported | <u>I</u> |

| 22 Spontaneous  Spontaneous | Healthcare<br>Professional                   | European<br>Economic<br>Area  Non European Economic Area   | Not available  | Years 12-17  | Adolescent  | Female   | No   | Eye pain (n/a - Recovering/Resolving - ), Fatigue (n/a - Recovering/Resolving - ), Parosmia (n/a - Recovering/Resolving - ), Pyrexia (n/a - Recovering/Resolving - ), Rash macular (n/a - Recovering/Resolving - ),  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a   | Not reported   |
|-----------------------------|--|--|--|--|---|--|--|--|--|--|
| 22 Spontaneous              |  | European<br>Economic   | Not available  |  |   |  |  | Parosmia (n/a -<br>Recovering/Resolving - ),<br>Pyrexia (n/a -<br>Recovering/Resolving - ),<br>Rash macular (n/a -<br>Recovering/Resolving   |  |  |
| Spontaneous                 |  | European<br>Economic   | Not available  |  |   |  |  | Recovering/Resolving<br>-),<br>Rash macular (n/a -<br>Recovering/Resolving   |  |  |
| Spontaneous                 |  | European<br>Economic   | Not available  |  |   |  |  | Recovering/Resolving   |  |  |
| 222 Spontaneous             |  | European<br>Economic   | Not available  |  |   |  |  | Taste disorder (n/a -  |  |  |
| 22 Spontaneous              |  | European<br>Economic   | Not available  |  |   |  |  | Recovering/Resolving   |  |  |
|                             |  |  |  | Years  | Not<br>Specified  | Female   | No   | Chest pain (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular  | Not reported   |
|                             |  |  |  |  |   |  |  | Dyspnoea (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),   | use])  |  |
| 1                           |  |  |  |  |   |  |  | Eye swelling (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),   |  |  |
|                             |  |  |  |  |   |  |  | Hyperhidrosis (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),  |  |  |
|                             |  |  |  |  |   |  |  | Lip swelling (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),   |  |  |
|                             |  |  |  |  |   |  |  | Myocarditis (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),  |  |  |
|                             |  |  |  |  |   |  |  | Palpitations (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),   |  |  |
| 22 6                        |  |  | No. of State   | 42.43  | Net   | Note   | No   | Pruritus (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)   | COMPONED   |  |
| 22 Spontaneous              |  |  | Not available  |  | Specified   | Not<br>Specified   | No   | Unknown - Other<br>Medically Important<br>Condition),  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -  | Not reported   |
|                             |  |  |  |  |   |  |  | Unknown - Other<br>Medically Important<br>Condition),  | n/a - Intramuscular<br>use])   |  |
| 22.6                        |  |  |  | 42.47  |   |  |  | Unknown - Other<br>Medically Important<br>Condition)   | COMPUNE  |  |
| 22 Spontaneous              |  |  | NOT available  |  | Specified   | маје   | NO   | Syncope (n/a -<br>Unknown - )  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])  | Not reported   |
| 22 Spontaneous              |  |  | Not available  |  | Not<br>Specified  | Male   | No   | Syncope (n/a -<br>Unknown - )  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -   | Not reported   |
| 22 Spontaneous              |  |  | Not available  | 12-17<br>Years   | Not<br>Specified  | Male   | No   | Vaccination site<br>erythema (n/a -<br>Unknown - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not  | Not reported   |
|                             |  |  |  |  |   |  |  | Vaccination site oedema (n/a - Unknown - ),  | applicable - [n/a -<br>1{DF} -<br>Intramuscular use])  |  |
| 22 Spontaneous              | Healthcare                                   | Furonean   | Not available  | 12-17  | Not   | Male   | No   | (n/a - Unknown - )   | COMIRNATY  | Not reported   |
| 22 Spontaneous              |  |  | INOT AVAILABLE   | Years  | Specified   | riale  | INO  | erythema (n/a -<br>Unknown - ),  | [TOZINAMERAN] (S -   | пот геропеа  |
|                             | 22 Spontaneous 22 Spontaneous 22 Spontaneous | Professional  22 Spontaneous Healthcare Professional  22 Spontaneous Healthcare Professional  22 Spontaneous Healthcare Professional | Professional Economic Area  22 Spontaneous Healthcare Professional Economic Area  22 Spontaneous Healthcare Professional Economic Area  23 Spontaneous Healthcare Professional Economic Area  24 Spontaneous Healthcare Professional Economic Area | Professional Economic Area  22 Spontaneous Healthcare Professional Economic Area  23 Spontaneous Healthcare Professional Economic Area  24 Spontaneous Healthcare Professional Economic Area  25 Spontaneous Healthcare Professional Economic Area  26 Spontaneous Healthcare Professional Economic Area  27 Spontaneous Healthcare Professional Economic Area | Professional Economic Area  22 Spontaneous Healthcare Professional Economic Area  23 Spontaneous Healthcare Professional Economic Area  24 Spontaneous Healthcare Professional Economic Area  25 Spontaneous Healthcare Professional Economic Area  26 Spontaneous Healthcare Professional Economic Area  27 Spontaneous Healthcare Professional Economic Area  28 Spontaneous Healthcare Professional Economic Area  29 Spontaneous Healthcare Professional Economic Area  20 Spontaneous Healthcare Professional Economic Area  20 Spontaneous Healthcare Professional Economic Area  21 Spontaneous Healthcare Professional Economic Area  22 Spontaneous Healthcare Professional Economic Not available 12-17 Years | Professional Economic Area Specified  22 Spontaneous Healthcare Professional Economic Area Not available 12-17 Years Specified  22 Spontaneous Healthcare Professional Economic Area Not available 12-17 Years Specified  23 Spontaneous Healthcare Professional Economic Area Not available 12-17 Years Specified  24 Spontaneous Healthcare Professional Economic Area Not available 12-17 Not Specified  25 Spontaneous Healthcare Professional Economic Area Not available 12-17 Years Specified | Professional Economic Area Specified Specified Specified Specified Area Specified Spec | Professional Economic Area  Specified Specifie | Professional   Prof | Professional   Professional   Professional   Professional   European Profess |

| 5.11.2022             |            |             |                                   |                                     |               |                | <br>             |                  |    | Vaccination site pain  | [  |              |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|------------------|----|--|--|--------------|
| EU-EC-<br>10013187237 | 08/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male             | No | (n/a - Unknown - ) Fatigue (1d - Recovered/Resolved - ), Headache (1d - Recovered/Resolved           | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                  | Not reported |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | - ),<br>Injection site<br>reaction (1d -<br>Recovered/Resolved<br>- ),                               | .,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,  |              |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Pyrexia (1d -<br>Recovered/Resolved  |  |              |
| EU-EC-<br>10013187284 | 08/08/2022 | Spontaneous |                                   | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male             | No | Chest pain (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),                           | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -                                 | Not reported |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Dyspnoea (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),                             | n/a - Intramuscular<br>use])   |              |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Myocarditis (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),                          |  |              |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Palpitations (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),                         |  |              |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Vomiting (n/a -<br>Unknown - Other<br>Medically Important<br>Condition)                              |  |              |
| EU-EC-<br>10013187398 | 08/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Female           | No | Heart rate abnormal<br>(n/a - Unknown - ),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not  | Not reported |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Syncope (n/a -<br>Unknown - )  | applicable - [n/a - 1{DF} - Intramuscular use])  |              |
| EU-EC-<br>10013187402 | 08/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Not<br>Specified | No | Vaccination site<br>reaction (n/a -<br>Unknown - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19  | Not reported |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Vomiting (n/a -<br>Unknown - )   | immunisation - Not<br>applicable - [n/a -<br>.3mL - Intramuscular<br>use])   |              |
| EU-EC-<br>10013187431 | 08/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Not<br>Specified | No | Lymph node pain<br>(n/a - Unknown - ),<br>Lymphadenopathy  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not  | Not reported |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | (n/a - Unknown - )   | applicable - [n/a -<br>.3mL - Intramuscular<br>use])   |              |
| EU-EC-<br>10013187553 | 08/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female           | No | Seizure (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)                    | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use]) | Not reported |
| EU-EC-<br>10013187798 | 08/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male             | No | Chills (30min -<br>Recovered/Resolved<br>- ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not  | Not reported |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Deafness (15min -<br>Recovered/Resolved<br>-),   | applicable - [n/a -<br>1{DF} - n/a])   |              |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Fatigue (0d -<br>Recovered/Resolved<br>- ),  |  |              |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Injection site warmth<br>(15min -<br>Recovered/Resolved<br>-),                                       |  |              |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Malaise (n/a -<br>Recovered/Resolved<br>-),  |  |              |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Pallor (15min -<br>Recovered/Resolved<br>-),   |  |              |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Visual impairment<br>(15min -<br>Recovered/Resolved<br>-)  |  |              |
| EU-EC-<br>10013187933 | 08/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male             | No | COVID-19 (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),                             | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- Intramuscular use])                                       | Not reported |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Vaccination failure<br>(n/a - Unknown -<br>Other Medically<br>Important Condition)                   |  |              |
| EU-EC-<br>10013187944 | 08/08/2022 | Spontaneous |                                   | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female           | No | Dengue virus test<br>positive (5d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation), | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a  | Not reported |
|                       |            |             |                                   |                                     |               |                |                  |                  |    | Diarrhoea (5d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),                     | - Intramuscular use])  |              |

| 0.11.2022             | TOILE        |             |                            |                                     |               |                | III LIIIC L      | oung i           | орон |   |  |                       |
|-----------------------|--------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|------------------|------|---|--|-----------------------|
|                       |              |             |                            |                                     |               |                |                  |                  |      | Headache (5d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),   |  |                       |
|                       |              |             |                            |                                     |               |                |                  |                  |      | Pyrexia (5d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),  |  |                       |
|                       |              |             |                            | _                                   |               |                |                  |                  |      | Vomiting (5d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation)  |  |                       |
| EU-EC-<br>10013188152 | 08/08/2022   | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female           | No   | COVID-19 (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- Intramuscular use])   | Not reported <u>I</u> |
| 511.50                | 00 100 12022 |             |                            |                                     |               | 12.17          |                  |                  |      | Vaccination failure<br>(n/a - Unknown -<br>Other Medically<br>Important Condition)  | COMPANY  |                       |
| EU-EC-<br>10013188431 |              | Spontaneous | Professional               | Non<br>European<br>Economic<br>Area | Not available | Years          | Not<br>Specified | Male             | No   | Pyrexia (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation)   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])                    | Not reported I        |
| EU-EC-<br>10013188505 | 08/08/2022   | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available |                | Not<br>Specified | Male             | No   | Psychogenic seizure<br>(n/a - Unknown - ),<br>Syncope (n/a -<br>Unknown - Other   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -   | Not reported <u>I</u> |
|                       |              |             |                            |                                     |               |                |                  |                  |      | Medically Important<br>Condition)   | n/a - Intramuscular<br>use])   |                       |
| EU-EC-<br>10013188725 | 08/08/2022   | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male             | No   | Vaccination site<br>erythema (n/a -<br>Unknown - ),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not  | Not reported I        |
|                       |              |             |                            |                                     |               |                |                  |                  |      | Vaccination site<br>oedema (n/a -<br>Unknown - ),   | applicable - [n/a -<br>1{DF} -<br>Intramuscular use])  |                       |
| FILEC                 | 00/00/2022   | Ct          | Lizzikk zawa               | F                                   | Not or within | 12.17          | N-+              | Mala             | NI-  | Vaccination site pain<br>(n/a - Unknown - )   | COMIDNATY  | Not you subod         |
| EU-EC-<br>10013188733 | 08/08/2022   | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male             | No   | Syncope (n/a -<br>Unknown - )   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use])                   | Not reported <u>I</u> |
| EU-EC-<br>10013188783 | 08/08/2022   | Spontaneous |                            | European<br>Economic                | Not available | 12-17<br>Years | Not<br>Specified | Male             | No   | Vaccination site<br>erythema (n/a -   | COMIRNATY<br>[TOZINAMERAN] (S -  | Not reported <u>I</u> |
|                       |              |             |                            | Area                                |               |                |                  |                  |      | Unknown - ),  Vaccination site oedema (n/a - Unknown - ),  Vaccination site pain (n/a - Unknown - )                                 | COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use])                                    |                       |
| EU-EC-<br>10013188786 | 08/08/2022   | Spontaneous | Healthcare<br>Professional |                                     | Not available | 12-17<br>Years | Not<br>Specified | Female           | No   | Vaccination site<br>erythema (n/a -<br>Unknown - ),   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not   | Not reported I        |
|                       |              |             |                            |                                     |               |                |                  |                  |      | Vaccination site oedema (n/a - Unknown - ), Vaccination site pain   | applicable - [n/a -<br>1{DF} -<br>Intramuscular use])  |                       |
| EU-EC-<br>10013188856 | 08/08/2022   | Spontaneous |                            | Non<br>European                     | Not available | 12-17<br>Years | Not<br>Specified | Male             | No   | (n/a - Unknown - )<br>Herpes zoster (n/a -<br>Recovering/Resolving  | COMIRNATY<br>[TOZINAMERAN] (S -  | Not reported I        |
| 10013100030           |              |             | FIOLESSIONAL               | Economic<br>Area                    |               | leais          | эрестеч          |                  |      | -)  | immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use])  |                       |
| EU-EC-<br>10013189209 | 08/08/2022   | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Not<br>Specified | No   | Monoparesis (n/a -<br>Unknown -<br>Caused/Prolonged<br>Hospitalisation),  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -   | Not reported <u>I</u> |
|                       |              |             |                            |                                     |               |                |                  |                  |      | Sensory disturbance<br>(n/a - Unknown -<br>Caused/Prolonged<br>Hospitalisation)   | .3mL - Intramuscular<br>use])  |                       |
| EU-EC-<br>10013189443 | 08/08/2022   | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male             | No   | Syncope (n/a -<br>Unknown - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use]) | Not reported I        |
| EU-EC-<br>10013189461 | 08/08/2022   | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Not<br>Specified | No   | Chest pain (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>.3mL - Intramuscular<br>use])  | Not reported <u>I</u> |
|                       |              |             |                            |                                     |               |                |                  |                  |      | Myocarditis (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition), |  |                       |
|                       |              |             |                            |                                     |               |                |                  |                  |      | Pyrexia (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation,  |  |                       |

|                     |            |             |                            |                                     |   |                |                  |        |    | Important Condition)  |  |  |
|---------------------|------------|-------------|----------------------------|-------------------------------------|---|----------------|------------------|--------|----|---|--|--|
| J-EC-<br>0013189665 | 08/08/2022 | Spontaneous | Healthcare<br>Professional | European<br>Economic<br>Area        | Not available   |                | Not<br>Specified | Female | No |   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} - Intramuscular use]) | Not reported   |
| -EC-<br>013189680   | 08/08/2022 | Spontaneous | Healthcare<br>Professional |                                     | Not available   | 12-17<br>Years | Not<br>Specified | Female | No | Blood pressure<br>decreased (n/a -  | COMIRNATY<br>[TOZINAMERAN] (S -  | Not reported   |
|                     |            |             |                            | Area                                |   |                |                  |        |    | Unknown - ),<br>Heart rate increased  | COVID-19<br>immunisation - Not<br>applicable - [n/a -  |  |
|                     |            |             |                            |                                     |   |                |                  |        |    | (n/a - Unknown - ), Oxygen saturation normal (n/a - Unknown - ),  | 1{DF} -<br>Intramuscular use])   |  |
|                     |            |             |                            |                                     |   |                |                  |        |    | Syncope (n/a -<br>Unknown - )   |  |  |
| EC-<br>013189835    | 08/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Konno, A Cardiac MRI performed for<br>myocarditis after COVID-19<br>vaccination: A report of 3 pediatric<br>cases. The 58th Annual Meeting of<br>Japanese Society of Pediatric<br>Cardiology and Cardiac. 2022;58th | 12-17<br>Years | Not<br>Specified | Male   | No | Blood creatine<br>phosphokinase MB<br>increased (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),                                       | COVID-19   | [AMBROXOL, AMBROX<br>HYDROCHLORIDE] (C<br>n/a - n/a - [n/a - n/a<br>n/a]),<br>[CARBOCISTEINE] (C   |
|                     |            |             |                            |                                     |   |                |                  |        |    | Blood creatine<br>phosphokinase<br>increased (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged   |  | n/a - n/a - [n/a - n/a<br>n/a]),<br>[CLINDAMYCIN<br>PHOSPHATE] (C - n/a<br>n/a - [n/a - n/a - n/a] |
|                     |            |             |                            |                                     |   |                |                  |        |    | Hospitalisation),  C-reactive protein increased (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),  |  | [HYDROXYZINE,<br>HYDROXYZINE<br>HYDROCHLORIDE] (C<br>n/a - n/a - [n/a - n/a<br>n/a]),              |
|                     |            |             |                            |                                     |   |                |                  |        |    | Chest discomfort  |  | [MOMETASONE] (C -<br>- n/a - [n/a - n/a - n/a  |
|                     |            |             |                            |                                     |   |                |                  |        |    | (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),   |  | [MONTELUKAST,<br>MONTELUKAST SODI<br>(C - n/a - n/a - [n/a -<br>- n/a]),                           |
|                     |            |             |                            |                                     |   |                |                  |        |    | Chest pain (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),  |  | [NADIFLOXACIN] (C -<br>- n/a - [n/a - n/a - n/   |
|                     |            |             |                            |                                     |   |                |                  |        |    | Ejection fraction<br>decreased (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),  |  | [RUPATADINE,<br>RUPATADINE FUMAR,<br>(C - n/a - n/a - [n/a -<br>- n/a]),<br>[SUPLATAST TOSILAT     |
|                     |            |             |                            |                                     |   |                |                  |        |    | Electrocardiogram ST segment elevation (n/a -   |  | (C - n/a - n/a - [n/a -<br>- n/a]),<br>[TIPEPIDINE   |
|                     |            |             |                            |                                     |   |                |                  |        |    | Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  |  | HIBENZATE] (C - n/a<br>n/a - [n/a - n/a - n/a  |
|                     |            |             |                            |                                     |   |                |                  |        |    | Electrocardiogram T<br>wave inversion (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),   |  |  |
|                     |            |             |                            |                                     |   |                |                  |        |    | Heart rate increased<br>(n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),   |  |  |
|                     |            |             |                            |                                     |   |                |                  |        |    | Myocardial necrosis<br>marker increased<br>(n/a - Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition), |  |  |
|                     |            |             |                            |                                     |   |                |                  |        |    | Myocardial oedema<br>(n/a - Unknown -<br>Other Medically<br>Important<br>Condition),  |  |  |
|                     |            |             |                            |                                     |   |                |                  |        |    | Myocarditis (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),                             |  |  |
|                     |            |             |                            |                                     |   |                |                  |        |    | Myoglobin blood<br>increased (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),  |  |  |
|                     |            |             |                            |                                     |   |                |                  |        |    | Respiratory rate<br>increased (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),   |  |  |
|                     |            |             |                            |                                     | 1   | 1              | I                | I      | I  | Troponin I increased  |  |  |

| Column   |                       |            |             |              |                      |   |       |            |        |    | <br> Recovering/Resolving<br> - Caused/Prolonged  |  |                          |          |
|--|-----------------------|------------|-------------|--------------|----------------------|---|-------|------------|--------|----|---|--|--------------------------|----------|
| 1.5    | EU-EC-<br>10013190743 | 08/08/2022 | Spontaneous |              | European<br>Economic | Not available   |       |            | Female | No | Hospitalisation)  Abdominal pain (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation),    | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a | Not reported             | I        |
| ANALYSIS   System on   Part   Note   Part   Note   Part   Note   Part    |                       |            |             |              |                      |   |       |            |        |    | Recovered/Resolved - ), Headache (6d - Recovered/Resolved - ), Malaise (6d -                      | ,  |                          |          |
| See Gild Second of the part of |                       |            |             |              |                      |   |       |            |        |    | - Caused/Prolonged<br>Hospitalisation),<br>Pyrexia (6d -<br>Recovered/Resolved                    |  |                          |          |
| Part   |                       |            |             |              |                      |   |       |            |        |    | Hospitalisation),  Rash (6d - Recovered/Resolved  |  |                          |          |
| ACC   10,000   20,0   |                       |            |             |              |                      |   |       |            |        |    | Vomiting (6d -<br>Recovered/Resolved<br>- Caused/Prolonged  |  |                          |          |
| 1.55   | EU-EC-<br>10013190891 | 08/08/2022 | Spontaneous | Healthcare   | European<br>Economic | Not available   |       |            | Female | No | Asthma (n/a - Not<br>Recovered/Not<br>Resolved - Disabling,<br>Other Medically<br>Important       | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a | Not reported             | Ī        |
| LPEC-  DECTOR  ROS PROVIDES  GROWN COURS Spontaneous Non- Professional Professional Professional Construction  Area  Ros available  LPEC-  Ros available  LPEC-  ROS PROVIDES  ROS PROVI |                       |            |             |              |                      |   |       |            |        |    | Unknown - Disabling,<br>Other Medically<br>Important  |  |                          |          |
| Professional European   Professional European   Professional European   Professional European   Professional European   Professional   Prof   |                       |            |             |              |                      |   |       |            |        |    | - Unknown -<br>Disabling, Other<br>Medically Important<br>Condition)                              |  |                          |          |
| LifeCounty   Lif   | EU-EC-<br>10013191065 | 08/08/2022 | Spontaneous |              | European<br>Economic | Not available   |       |            | Female | No | Recovering/Resolving - Caused/Prolonged Hospitalisation), Pyrexia (8d -                           | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a | Not reported             | I.       |
| December   Personal Professional   Personal Professi   |                       |            |             |              |                      |   |       |            |        |    | - Caused/Prolonged<br>Hospitalisation),<br>Urinary tract<br>infection (n/a -                      |  |                          |          |
| LEC-   D8/08/2022   Spontaneous   Non   European   Not available   12-17   Adolescent   Female   No   Menistruation = Not   Condition      | EU-EC-<br>10013191238 | 08/08/2022 | Spontaneous | Healthcare   | Economic             | Not available   |       | Adolescent | Female | No | Amenorrhoea (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition), | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - 1{DF} -       | Not reported             | Ŀ        |
| Healthcare Professional Area Condition)  U-EC- D013191321  D08/08/2022 Spontaneous Professional Area  No Mot available Spontaneous Professional Area  No Mot available Spontaneous Professional Area  No Mot available Spontaneous Professional Area  Domain K. A case of mild Spontaneous Professional Area  Domain K. A case of mild Spontaneous Professional Area  Domain K. A case of mild Spontaneous Professional Area  Domain K. A case of mild Spontaneous Professional Area  Domain K. A case of mild Spontaneous Professional Area  Domain K. A case of mild Spontaneous Professional Area  Domain K. A case of mild Spontaneous Professional Area  Domain K. A case of mild Spontaneous Professional Area  Domain K. A case of mild Spontaneous Professional Area  Domain K. A case of mild Spontaneous Professional Area  Domain K. A case of mild Spontaneous Professional Economic Area  No Specified Spontaneous Professional Area  Domain K. A case of mild Spontaneous Professional Economic Area  No Specified Spontaneous Professional Area  No Male No Specified Spontaneous Professional Area Specified Spontaneous Professional Area Specified Professional Spontaneous Professional Spontane |                       |            |             |              |                      |   |       |            |        |    | (77d - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important                            |  |                          |          |
| UFEC- D013191321  OB/08/2022 Spontaneous Network Professional Professi | EU-EC-<br>10013191255 | 08/08/2022 | Spontaneous | Healthcare   | Economic             | Not available   |       | Adolescent | Female | No | irregular (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important                  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -                         | Not reported             | <u>I</u> |
| U-EC- 2013.1916.13  Doman. K. A case of mild european encephalitis/encephalopathy with a reversible splenial lesion (MERS) Area  Area  Non Congress of the Japaneses Society of Intensive. 2022;6th:46  Doman. K. A case of mild european encephalitis/encephalopathy with a reversible splenial lesion (MERS) a reversible splenial lesion (MERS) a reversible splenial lesion (MERS) and reversible splenial lesion (MERS) | EU-EC-<br>10013191321 | 08/08/2022 | Spontaneous | Healthcare   | Economic             | Not available   |       | Adolescent | Male   | No | Abdominal pain<br>(122d -<br>Recovered/Resolved<br>-),  | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - 1{DF} -       | Not reported             | 1        |
| U-EC- 0013191613  D-EC- 10- 10- 10- 10- 10- 10- 10- 10- 10- 10   |                       |            |             |              |                      |   |       |            |        |    | Recovered/Resolved - Other Medically Important Condition),  | Intramuscular usej)  |                          |          |
| Economic Area reversible splenial lesion (MERS) after SARS COV-2 vaccination, The 6th Chugoku/Shikoku Branch Congress of the Japanese Society of Intensive. 2022;6th:46  Economic Area after SARS COV-2 vaccination, The 6th Chugoku/Shikoku Branch Congress of the Japanese Society of Intensive. 2022;6th:46  Economic Area after SARS COV-2 vaccination, The 6th Chugoku/Shikoku Branch Congress of the Japanese Society of Intensive. 2022;6th:46  Economic Area after SARS COV-2 vaccination, The 6th Chugoku/Shikoku Branch Congress of the Japanese Society of Intensive. 2022;6th:46  Economic Area after SARS COV-2 vaccination, The 6th Chugoku/Shikoku Branch Congress of the Japanese Society of Intensive. 2022;6th:46  Cytotoxic lesions of corpus callosum (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  | EU-EC-                | 08/08/2022 | Spontaneous |              |                      |   |       |            | Male   | No | Recovered/Resolved - Other Medically Important Condition) Altered state of                        |  |                          | I.       |
| corpus callosum (n/a - Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  | 10013141613           |            |             | Professional | Economic             | reversible splenial lesion (MERS)<br>after SARS CoV-2 vaccination. The<br>6th Chugoku/Shikoku Branch<br>Congress of the Japanese Society of | Tedis | Specified  |        |    | Recovering/Resolving - Caused/Prolonged Hospitalisation, Other Medically Important                | COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular   | unknown indication - n/a |          |
| Important Condition),  |                       |            |             |              |                      |   |       |            |        |    | corpus callosum (n/a<br>-<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,         |  |                          |          |
|  |                       |            |             |              |                      |   |       |            |        |    | Important<br>Condition),  |  |                          |          |

| 30 | .11.2022              | 15.25      |             |                                   |                              |               | Ru             | ın Line Li       | isting R | eport |   |   |              |          |
|----|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|----------|-------|---|---|--------------|----------|
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  |   |              |          |
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Encephalopathy (n/a -<br>- Recovered/Resolved - Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),                                     |   |              |          |
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Fall (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),   |   |              |          |
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Incontinence (n/a -<br>Not Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),   |   |              |          |
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Magnetic resonance imaging abnormal (n/a - Unknown - ),   |   |              |          |
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Meningitis aseptic<br>(n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),                             |   |              |          |
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Middle East<br>respiratory syndrome<br>(n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition), |   |              |          |
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Seizure (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),   |   |              |          |
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Speech disorder (n/a<br>- Not Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),  |   |              |          |
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Unresponsive to<br>stimuli (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),   |   |              |          |
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Visual impairment<br>(n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation)  |   |              |          |
|    | EU-EC-<br>10013191709 | 08/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Female   | No    | Dysmenorrhoea (n/a<br>- Not Recovered/Not<br>Resolved - ),<br>Menstruation<br>irregular (n/a - Not<br>Recovered/Not   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use]) | Not reported | Ī        |
|    | EU-EC-<br>10013192050 | 08/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available |                | Not<br>Specified | Male     | No    | Resolved - ) Arthralgia (n/a - Recovering/Resolving - Other Medically Important Condition),   |   | Not reported | <u>I</u> |
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Chills (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),  | 1 <b>/</b> a - 1/a])  |              |          |
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Malaise (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   |   |              |          |
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Myalgia (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   |   |              |          |
|    |                       |            |             |                                   |                              |               |                |                  |          |       | Pyrexia (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important Condition)   |   |              |          |
|    | EU-EC-<br>10013192078 | 08/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Economic                     | Not available | 12-17<br>Years | Adolescent       | Male     | No    | Asthenia (n/a - Not<br>Recovered/Not<br>Resolved - ),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>Immunisation - n/a -<br>[n/a - n/a - n/a])                           | Not reported | <u>I</u> |

| .11.2022            | 10.20      |             |              |   |                | n Line L         | oung i | орог |   |   |              |
|---------------------|------------|-------------|--------------|---|----------------|------------------|--------|------|---|---|--------------|
|                     |            |             |              |   |                |                  |        |      | Dyspnoea (n/a - Not<br>Recovered/Not<br>Resolved - ),   |   |              |
|                     |            |             |              |   |                |                  |        |      | Exercise tolerance<br>decreased (n/a - Not<br>Recovered/Not<br>Resolved - ),  |   |              |
|                     |            |             |              |   |                |                  |        |      | Myocarditis (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),   |   |              |
|                     |            |             |              |   |                |                  |        |      | Palpitations (n/a -<br>Not Recovered/Not  |   |              |
| J-EC-<br>0013192474 | 08/08/2022 | Spontaneous | Professional | Not available   | 12-17<br>Years | Not<br>Specified | Male   | No   | Resolved - )<br>Syncope (n/a -<br>Unknown - )   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -                        | Not reported |
| -EC-<br>013192776   | 08/08/2022 | Spontaneous | Professional | Konno, A Cardiac MRI performed for<br>myocarditis after COVID-19<br>vaccination: A report of 3 pediatric<br>cases. The 58th Annual Meeting of<br>Japanese Society of Pediatric<br>Cardiology and Cardiac. 2022;58th | 12-17<br>Years | Not<br>Specified | Male   |      | Blood creatine<br>phosphokinase MB<br>increased (6d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),  | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a]) | Not reported |
|                     |            |             |              |   |                |                  |        |      | Blood creatine<br>phosphokinase<br>increased (6d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),   |   |              |
|                     |            |             |              |   |                |                  |        |      | Blood pressure<br>increased (6d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),  |   |              |
|                     |            |             |              |   |                |                  |        |      | C-reactive protein<br>increased (5d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),  |   |              |
|                     |            |             |              |   |                |                  |        |      | Chest discomfort (6d -<br>Recovered/Resolved - Caused/Prolonged<br>Hospitalisation),  |   |              |
|                     |            |             |              |   |                |                  |        |      | Chest pain (6d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),   |   |              |
|                     |            |             |              |   |                |                  |        |      | Electrocardiogram ST segment elevation (6d -  |   |              |
|                     |            |             |              |   |                |                  |        |      | Recovered/Resolved - Caused/Prolonged Hospitalisation, Other Medically Important Condition),  |   |              |
|                     |            |             |              |   |                |                  |        |      | Electrocardiogram T<br>wave inversion (6d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),    |   |              |
|                     |            |             |              |   |                |                  |        |      | Fibrin D dimer<br>increased (6d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),  |   |              |
|                     |            |             |              |   |                |                  |        |      | Heart rate increased<br>(6d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),  |   |              |
|                     |            |             |              |   |                |                  |        |      | Myocardial necrosis<br>marker increased<br>(n/a - Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition), |   |              |
|                     |            |             |              |   |                |                  |        |      | Myocarditis (6d -<br>Recovered/Resolved -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),                              |   |              |
|                     |            |             |              |   |                |                  |        |      | Pain in extremity (7d<br>-<br>Recovered/Resolved<br>- Caused/Prolonged  |   |              |
|                     |            |             |              |   |                |                  |        |      | Hospitalisation),   |   |              |

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|-----------------------|------------|-------------|----------------------------|-------------------------------------|---------------|----------------|------------------|--------|------|--|--|--------------|------------|
| EU-EC-<br>10013193018 | 08/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No   | Hospitalisation), Troponin I increased (6d - Recovered/Resolved - Caused/Prolonged Hospitalisation) Abnormal behaviour (n/a - Recovering/Resolving - Other Medically Important Condition), | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular                   | Not reported | Ī          |
|                       |            |             |                            |                                     |               |                |                  |        |      | Feeling hot (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),  | use])  |              |            |
|                       |            |             |                            |                                     |               |                |                  |        |      | Headache (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   |  |              |            |
|                       |            |             |                            |                                     |               |                |                  |        |      | Hemiparesis (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),  |  |              |            |
|                       |            |             |                            |                                     |               |                |                  |        |      | Hypophagia (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   |  |              |            |
|                       |            |             |                            |                                     |               |                |                  |        |      | Lethargy (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important Condition)   |  |              |            |
| EU-EC-<br>10013193546 | 08/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No   | Abdominal pain<br>lower (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),  | [TOZINAMERAN] (S -   | Not reported | <u>I</u>   |
|                       |            |             |                            |                                     |               |                |                  |        |      | Diarrhoea (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),  | use])  |              |            |
|                       |            |             |                            |                                     |               |                |                  |        |      | Haematuria (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   |  |              |            |
|                       |            |             |                            |                                     |               |                |                  |        |      | Myocarditis (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),  |  |              |            |
|                       |            |             |                            |                                     |               |                |                  |        |      | Nausea (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   |  |              |            |
|                       |            |             |                            |                                     |               |                |                  |        |      | Pyrexia (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important Condition)  |  |              |            |
| EU-EC-<br>10013193626 | 08/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No   | Pneumonia (7d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use]) | Not reported | <u>I</u>   |
|                       |            |             |                            |                                     |               |                |                  |        |      | Pulmonary<br>tuberculosis (7d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important Condition)   |  |              |            |
| EU-EC-<br>10013194125 | 08/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male   | No   | Syncope (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)  | [TOZINAMERAN] (S -<br>COVID-19   | Not reported | ľ          |
| EU-EC-<br>10013194288 | 08/08/2022 | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No   | Syncope (1d -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19  | Not reported | Ī          |
| EU-EC-<br>10013194355 | 08/08/2022 | Spontaneous |                            | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Male   | No   | Pyrexia (n/a -<br>Recovering/Resolving - ),<br>Vomiting (n/a -<br>Recovering/Resolving   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d - n/a                          | Not reported | ŀ          |
| EU-EC-<br>10013194403 | 08/08/2022 | Spontaneous | Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female | No   | Vaccination site rash<br>(n/a -<br>Recovering/Resolving - )  | immunisation - Drug<br>withdrawn - [1d - n/a   | Not reported | Ī          |
| EU-EC-                | 08/08/2022 | Spontaneous | Non                        | European                            | Not available | 12-17          | Adolescent       | Male   | No   | Pyrexia (n/a -   | - Intramuscular use])<br>COMIRNATY   | Not reported | <u>I</u> ) |

| 0.11.2022             | 15.25      |             |                                   |                                     |               | Ku             | n Line Li        | sung R           | eport |  |  |                       |
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| 10013194409           |            |             | Healthcare<br>Professional        |                                     |               | Years          |                  |                  |       | Recovering/Resolving   | [TOZINAMERAN] (S -<br>COVID-19   |                       |
|                       |            |             |                                   |                                     |               |                |                  |                  |       | Vomiting (n/a -<br>Recovering/Resolving - )  | immunisation - Drug<br>withdrawn - [1d - n/a<br>- Intramuscular use])  |                       |
| EU-EC-<br>10013173337 | 05/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male             | No    | Chest pain (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not  | Not reported I        |
|                       |            |             |                                   | / wed                               |               |                |                  |                  |       | Diarrhoea (n/a -<br>Recovering/Resolving   | applicable - [1d - n/a<br>- n/a])  |                       |
|                       |            |             |                                   |                                     |               |                |                  |                  |       | Gastroenteritis (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation),  |  |                       |
|                       |            |             |                                   |                                     |               |                |                  |                  |       | Myocarditis (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),                          |  |                       |
|                       |            |             |                                   |                                     |               |                |                  |                  |       | Oropharyngeal pain<br>(n/a -<br>Recovering/Resolving<br>-),  |  |                       |
|                       |            |             |                                   |                                     |               |                |                  |                  |       | Pyrexia (3d -<br>Recovered/Resolved<br>-),   |  |                       |
|                       |            |             |                                   |                                     |               |                |                  |                  |       | Vomiting (n/a -<br>Recovering/Resolving  |  |                       |
| EU-EC-<br>10013173444 | 05/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male             | No    | Leukopenia (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use]) | Not reported I        |
| EU-EC-<br>10013173601 | 05/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male             | No    | - Other Medically  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use]) | Not reported I        |
| EU-EC-<br>10013173667 | 05/08/2022 | Spontaneous | Healthcare<br>Professional        |                                     | Not available | 12-17<br>Years |                  | Not<br>Specified | No    | Arthralgia (n/a -<br>Unknown - ),  | COMIRNATY<br>[TOZINAMERAN] (S -  | Not reported <u>I</u> |
|                       |            |             |                                   | Area                                |               |                |                  |                  |       | Asthenia (n/a -<br>Unknown - ),<br>Chest pain (n/a -<br>Unknown - ),<br>Headache (n/a -<br>Unknown - ),<br>Injection site<br>reaction (n/a -<br>Unknown - ), | COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use])   |                       |
|                       |            |             |                                   |                                     |               |                |                  |                  |       | Myalgia (n/a -<br>Unknown - ),<br>Pyrexia (24h -<br>Recovered/Resolved   |  |                       |
| EU-EC-<br>10013174474 | 05/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female           | No    | Pericarditis (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a  | Not reported I        |
|                       |            |             |                                   |                                     |               |                |                  |                  |       | Pleuritic pain (n/a -<br>Recovering/Resolving<br>- )   | - n/a])  |                       |
| EU-EC-<br>10013174813 | 05/08/2022 | Spontaneous | Healthcare                        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female           | No    | Hyperthyroidism (n/a -<br>Recovering/Resolving - Other Medically<br>Important<br>Condition),   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular                       | Not reported I        |
|                       |            |             |                                   |                                     |               |                |                  |                  |       | Irritability (n/a -<br>Recovering/Resolving<br>- ),  | use])  |                       |
|                       |            |             |                                   |                                     |               |                |                  |                  |       | Palpitations (n/a -<br>Recovering/Resolving<br>- ),  |  |                       |
|                       |            |             |                                   |                                     |               |                |                  |                  |       | Temperature<br>intolerance (n/a -<br>Recovering/Resolving<br>- )   |  |                       |
| EU-EC-<br>10013175131 | 05/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female           | No    | Syncope (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use]) | Not reported I        |
| EU-EC-<br>10013175279 | 05/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available |                | Not<br>Specified | Male             | No    | Myocarditis (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - Intramuscular                         | Not reported I        |

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| EU-EC-<br>10013175631 | 05/08/2022 | Spontaneous |                            | European                            | Not available  | 12-17<br>Years | Not<br>Specified | Male   | No | Basal ganglia<br>haemorrhage (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use]) | Not reported  |
| EU-EC-<br>10013175643 | 05/08/2022 | Spontaneous |                            | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Not<br>Specified | Male   | No | Fatigue (2d -<br>Recovered/Resolved - ),<br>Headache (2d -<br>Recovered/Resolved - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                  | Not reported  |
|                       |            |             |                            |                                     |  |                |                  |        |    | Injection site<br>reaction (2d -<br>Recovered/Resolved<br>-),  |  |   |
|                       |            |             |                            |                                     |  |                |                  |        |    | Myalgia (2d -<br>Recovered/Resolved<br>- )   |  |   |
| EU-EC-<br>10013175723 | 05/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available  | 12-17<br>Years | Not<br>Specified | Male   | No | Chills (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),<br>Dizziness (n/a -   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])     | Not reported  |
|                       |            |             |                            |                                     |  |                |                  |        |    | Recovering/Resolving - Other Medically Important Condition)  |  |   |
| EU-EC-<br>10013175829 | 05/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Sanada, H Two Cases of Pericarditis<br>Following COVID-19 Vaccination, The<br>58th Annual Meeting of Japanese<br>Society of Pediatric Cardiology and<br>Cardiac, 2022;58th |                | Not<br>Specified | Male   | No | Headache (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),<br>Malaise (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation), | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                  | Not reported  |
|                       |            |             |                            |                                     |  |                |                  |        |    | Myocardial necrosis<br>marker increased<br>(n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important                              |  |   |
|                       |            |             |                            |                                     |  |                |                  |        |    | Condition), Orthostatic intolerance (n/a - Not Recovered/Not Resolved - ),   |  |   |
|                       |            |             |                            |                                     |  |                |                  |        |    | Pericardial effusion<br>(n/a - Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),                                     |  |   |
|                       |            |             |                            |                                     |  |                |                  |        |    | Pericarditis (n/a -<br>Not Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),                                    |  |   |
|                       |            |             |                            |                                     |  |                |                  |        |    | Troponin I increased<br>(n/a - Unknown - )   |  |   |
| EU-EC-<br>10013176337 | 05/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available  | 12-17<br>Years | Not<br>Specified | Female | No | Psychogenic seizure<br>(n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use]) | Not reported  |
| EU-EC-<br>10013176725 | 05/08/2022 | Spontaneous | Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available  | 12-17<br>Years | Not<br>Specified | Male   | No | Syncope (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use]) | Not reported  |
| EU-EC-<br>10013177443 | 05/08/2022 | Spontaneous | Healthcare<br>Professional |                                     | Not available  | 12-17<br>Years | Not<br>Specified | Female | No | Syncope (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a3mL - Intramuscular use])                      | Not reported  |
| EU-EC-<br>10013177984 | 05/08/2022 | Spontaneous |                            | Non<br>European<br>Economic<br>Area | Not available  | 12-17<br>Years | Not<br>Specified | Male   | No | COVID-19 (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),   | TOZINAMERAN<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a                            | [BECLOMETASONE DIPROPIONATE] (C - n/a - n/a - [n/a - n/a - n/a]), [DEXMETHYLPHENIDATE, DEXMETHYLPHENIDATE |
|                       |            |             |                            |                                     |  |                |                  |        |    | Vaccination failure<br>(n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)  |  | HYDROCHLORIDE] (C - n/a - n/a - [n/a - n/a - n/a - n/a])  |
| EU-EC-<br>10013178126 | 05/08/2022 | Spontaneous |                            | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Female | No | Amenorrhoea (n/a -<br>Not Recovered/Not<br>Resolved - ),   | COMIRNATY 30<br>MICROGRAMS/DOSE<br>DISPERSION FOR<br>INJECTION COVID-  | Not reported  |

| .11.2022            | 15.25      |  |                                |                                     |  | Ru             | n Line L         | isting R   | eport |   |   |  |
|---------------------|------------|--|--------------------------------|-------------------------------------|--|----------------|------------------|--|-------|---|---|--|
|                     |            |  |                                |                                     |  |                |                  |  |       | Recovered/Not<br>Resolved - ),<br>Menstruation<br>irregular (n/a - Not<br>Recovered/Not<br>Resolved - )                             | MODIFIED)<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation -<br>Unknown - [n/a - n/a<br>- n/a])                          |  |
| .0013178412         |            | Spontaneous  | Professional                   | Non<br>European<br>Economic<br>Area | Not available  | Years          | Not<br>Specified | Female   | No    | Psychogenic seizure<br>(n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)                                    | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use])  | Not reported   |
| U-EC-<br>0013179112 | 05/08/2022 | Spontaneous  | Healthcare<br>Professional     | Non<br>European<br>Economic<br>Area | Not available  |                | Not<br>Specified | Female   | No    | Decreased appetite (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation), Dizziness (n/a - Recovering/Resolving           | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])      | Not reported   |
|                     |            |  |                                |                                     |  |                |                  |  |       | Caused/Prolonged Hospitalisation), Nausea (n/a - Recovering/Resolving - Caused/Prolonged Hospitalisation),                          |   |  |
|                     |            |  |                                |                                     |  |                |                  |  |       | Vomiting (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation)   |   |  |
| J-EC-<br>0013180849 | 05/08/2022 | Spontaneous  |                                | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Female   | No    | Hypomenorrhoea<br>(n/a - Not<br>Recovered/Not<br>Resolved - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -                                   | [KETOPROFENE] (C -<br>Migraine - n/a - [n/a -<br>n/a - Oral use]),<br>[KETOPROFEN] (C -                                |
|                     |            |  |                                |                                     |  |                |                  |  |       | Migraine (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)                                       | 1{DF} -<br>Intramuscular use])  | Migraine - n/a - [n/a -<br>n/a - Oral use]),<br>[PARACETAMOL] (C -<br>Migraine - n/a - [n/a -<br>n/a - Oral use])      |
| J-EC-<br>0013180967 | 05/08/2022 | Spontaneous  | Healthcare<br>Professional     |                                     | Not available  | 12-17<br>Years | Adolescent       | Female   | No    | Condition aggravated<br>(78d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation),                                     | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} -                        | ENBREL [ETANERCEPT]<br>(C - Juvenile idiopathic<br>arthritis - Not applicable -<br>[n/a - 25mg -<br>Subcutaneous use]) |
|                     |            |  |                                |                                     |  |                |                  |  |       | Rheumatoid arthritis<br>(78d -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation)                                      | Intramuscular use])   |  |
| J-EC-<br>0013181202 | 05/08/2022 | Spontaneous  | Healthcare<br>Professional     | European<br>Economic<br>Area        | Not available  | 12-17<br>Years | Adolescent       | Female   | No    | Deafness (26d -<br>Recovered/Resolved - ),<br>Headache (26d -<br>Recovered/Resolved - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d -<br>1{DF} -<br>Intramuscular use]) | Not reported   |
|                     |            |  |                                |                                     |  |                |                  |  |       | Hypotension (26d -<br>Recovered/Resolved<br>-),   | Intumuscular usejj  |  |
|                     |            |  |                                |                                     |  |                |                  |  |       | Paraesthesia (26d -<br>Recovered/Resolved - ),<br>Vision blurred (26d -   |   |  |
| U-EC-               | 05/08/2022 | Spontaneous  | Healthcare                     | Non                                 | Not available  | 12-17          | Not              | Male   | No    | Recovered/Resolved - ) Cardiac dysfunction  | COMIRNATY   | [FLUTICASONE   |
| 0013182065          | 03,00,2022 | 5/08/2022 Spontaneous Healthcare Professional European Economic Area | Professional European Economic | European<br>Economic                | Total deliberation of the second of the seco | Years          | Not<br>Specified | Male   | No    | (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition),    | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use])               | PROPIONATE, SALMETEROL XINAFOATE] (C - Asthma - n/a - [n/a - n/a - Inhalation use]),  [FLUTICASONE PROPIONATE] (C -    |
|                     |            |  |                                |                                     |  |                |                  | Chest discomfort<br>(n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation), |       | Asthma - n/a - [n/a - n/a - Inhalation use]),  [MONTELUKAST, MONTELUKAST SODIUM] (C - Asthma, Rhinitis allergic - n/a - [n/a - n/a  |   |  |
|                     |            |  |                                |                                     |  |                |                  |  |       | Chest pain (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),                                       |   | - Oral use]),  [OLOPATADINE HYDROCHLORIDE] (C - Asthma, Rhinitis allergic - n/a - [n/a - n/a - Oral                    |
|                     |            |  |                                |                                     |  |                |                  |  |       | Dyspnoea (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged  |   | use])  |
|                     |            |  |                                |                                     |  |                |                  |  |       | Hospitalisation),<br>Malaise (n/a -<br>Unknown - ),   |   |  |
|                     |            |  |                                |                                     |  |                |                  |  |       | Myocarditis (n/a -<br>Recovering/Resolving<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important<br>Condition), |   |  |
|                     |            |  |                                |                                     |  |                |                  |  |       | Palpitations (n/a -   |   |  |

|                     |            |             |                                   |                              |               |                |                  |                  |   | Pyrexia (n/a - Not<br>Recovered/Not<br>Resolved -  |  |              |
|---------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|------------------|---|--|--|--------------|
|                     |            |             |                                   |                              |               |                |                  |                  |   | Caused/Prolonged<br>Hospitalisation)   |  |              |
| I-EC-<br>013182682  | 05/08/2022 | Spontaneous | Healthcare<br>Professional        | Economic                     | Not available | 12-17<br>Years | Not<br>Specified | Female           | No  | Asthenia (9d -<br>Recovered/Resolved<br>-),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19  | Not reported |
|                     |            |             |                                   | Area                         |               |                |                  |                  |   | COVID-19 (3d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),                    | immunisation - Not<br>applicable - [1d - n/a<br>- Intramuscular use])                    |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Cough (9d -<br>Recovered/Resolved<br>-),   |  |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Nasopharyngitis (9d  |  |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | -<br>Recovered/Resolved<br>-),   |  |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Vaccination failure<br>(3d -<br>Recovered/Resolved<br>- Other Medically<br>Important Condition)          |  |              |
| J-EC-<br>013163908  | 04/08/2022 | Spontaneous | Non<br>Healthcare                 | European<br>Economic         | Not available |                | Not<br>Specified | Male             | No  | Dyspnoea (n/a -<br>Unknown - ),  | COMIRNATY [TOZINAMERAN] (S -   | Not reported |
|                     |            |             | Professional                      |                              |               |                |                  |                  |   | Fatigue (n/a -<br>Unknown - ),   | COVID-19<br>immunisation - Not<br>applicable - [n/a -                                    |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Headache (n/a -<br>Unknown - ),  | 1{DF} -<br>Intramuscular use])   |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Oropharyngeal pain<br>(n/a - Unknown - ),  |  |              |
|                     |            |             |                                   |                              |               |                |                  |                  | Pyrexia (n/a -<br>Unknown - ),<br>Vaccination site pain |  |  |              |
| J-EC-               | 04/08/2022 | Spontaneous | Healthcare                        | European                     | Not available | 12-17          | Adolescent       | Female           | No  | (n/a - Unknown - )<br>Conversion disorder  | COMIRNATY  | Not reported |
| 0013164288          |            |             | Professional                      | Economic<br>Area             |               | Years          |                  |                  |   | (n/a -<br>Recovering/Resolving<br>- ),   | [TOZINAMERAN] (S -<br>Immunisation - n/a -<br>[n/a - n/a - n/a])                         |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Disturbance in<br>attention (n/a -<br>Recovered/Resolved<br>-),  |  |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Fatigue (n/a -<br>Recovered/Resolved<br>-),  |  |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Hallucination,<br>auditory (n/a -<br>Recovered/Resolved -<br>Other Medically<br>Important<br>Condition), |  |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Headache (n/a -<br>Recovered/Resolved  |  |              |
| J-EC-<br>0013164635 | 04/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Female           | No  | COVID-19 (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),                                 | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [n/a - n/a<br>- Intramuscular use])       | Not reported |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Vaccination failure<br>(n/a - Unknown -<br>Other Medically<br>Important Condition)                       |  |              |
| J-EC-<br>0013164960 | 04/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Not<br>Specified | No  | Loss of<br>consciousness (n/a -<br>Unknown - Other<br>Medically Important<br>Condition),                 | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a - | Not reported |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Pyrexia (24h -<br>Recovered/Resolved<br>-),  | n/a - Intramuscular<br>use])   |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Vaccination site pain  |  |              |
| J-EC-<br>0013165235 | 04/08/2022 | Spontaneous | Healthcare<br>Professional        | Non                          | Not available |                | Not<br>Specified | Male             | No  | (n/a - Unknown - )<br>Neoplasm malignant<br>(n/a - Unknown -   | COMIRNATY<br>[TOZINAMERAN] (S -  | Not reported |
| 015105255           |            |             | FIOLESSIONAL                      | Economic<br>Area             |               | lears          | Specified        |                  |   | Other Medically Important Condition),  | COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>10ug - n/a])                    |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Product administered to patient of inappropriate age   | 10ug - 11/a]/  |              |
| J-EC-<br>0013165295 | 04/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available |                | Not<br>Specified | Male             | No  | (n/a - Unknown - )<br>Headache (n/a -<br>Unknown - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19  | Not reported |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Herpes dermatitis<br>(n/a - Not<br>Recovered/Not<br>Resolved - ),  | immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                                  |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Pain in extremity<br>(n/a - Unknown - ),   |  |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Pruritus (n/a -<br>Unknown - ),  |  |              |
|                     |            |             |                                   |                              |               |                |                  |                  |   | Rash (n/a - Not  |  |              |

| 1.11.2022             | 15.25      |             |                                   |                                     |               | Κι             | ın Line L        | isting R | eport |   |  |   |          |
|-----------------------|------------|-------------|-----------------------------------|-------------------------------------|---------------|----------------|------------------|----------|-------|---|--|---|----------|
|                       |            |             |                                   |                                     |               |                |                  |          |       | Resolved - ),   |  |   |          |
|                       |            |             |                                   |                                     |               |                |                  |          |       | Rash (n/a - Unknown<br>- )  |  |   |          |
| EU-EC-<br>10013165302 | 04/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Dysphagia (3d -<br>Recovered/Resolved<br>- )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                     | Not reported  | <u>I</u> |
| EU-EC-<br>10013165358 | 04/08/2022 | Spontaneous | Healthcare                        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Fatigue (n/a -<br>Unknown - ),<br>Pyrexia (12h -<br>Recovered/Resolved<br>- )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -                                   | Not reported  | <u>I</u> |
| EU-EC-<br>10013165380 | 04/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Headache (n/a - Not<br>Recovered/Not<br>Resolved - ),<br>Vaccination site<br>erythema (n/a - Not<br>Recovered/Not   | n/a - n/a])  COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - n/a - n/a])                       | Not reported  | Ī        |
| EU-EC-<br>10013167212 | 04/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No    | Resolved - ) Administration site pain (2d - Recovered/Resolved - ), Body temperature increased (2d - Recovered/Resolved - ), Headache (2d - Recovered/Resolved - )  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use]) | Not reported  | <u>I</u> |
| EU-EC-<br>10013167259 | 04/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Epilepsy (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),<br>Pyrexia (n/a -<br>Recovered/Resolved<br>- ),<br>Seizure (n/a -<br>Recovered/Resolved<br>- Caused/Prolonged<br>Hospitalisation,<br>Other Medically<br>Important Condition)   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - Intramuscular<br>use])   | Not reported  | Ī        |
| EU-EC-<br>10013168209 | 04/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No    | Heavy menstrual<br>bleeding (n/a - Not<br>Recovered/Not<br>Resolved - ),<br>Polymenorrhoea (n/a   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use]) | Not reported  | <u>I</u> |
| EU-EC-<br>10013168245 | 04/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional |                                     | Not available | 12-17<br>Years | Adolescent       | Female   | No    | Heavy menstrual<br>bleeding (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),<br>Polymenorrhoea (n/a<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} -<br>Intramuscular use])  | Not reported  | Ī        |
| EU-EC-<br>10013168364 | 04/08/2022 | Spontaneous | Healthcare                        | European<br>Economic<br>Area        | Not available | 12-17<br>Years | Adolescent       | Female   | No    | Acne (n/a -<br>Recovering/Resolving - ),  Dysmenorrhoea (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),  Menometrorrhagia<br>(n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition),  Menstruation<br>irregular (n/a - Not<br>Recovered/Not<br>Resolved - Other | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [25d -<br>1{DF} -<br>Intramuscular use]) | Not reported  | Ŀ        |
| EU-EC-<br>10013168865 | 04/08/2022 | Spontaneous |                                   | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Medically Important<br>Condition) COVID-19 (n/a -<br>Unknown - Other<br>Medically Important<br>Condition), Drug ineffective (n/a -<br>Unknown - Other<br>Medically Important  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                    | ENBREL [ETANERCEPT]<br>(C - Juvenile idiopathic<br>arthritis - n/a - [n/a -<br>50mg - Subcutaneous<br>use]) | Ī        |
| EU-EC-<br>10013169672 | 04/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female   | No    | Condition) Headache (n/a - Not Recovered/Not Resolved - Other Medically Important Condition)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                    | Not reported  | <u>I</u> |
| EU-EC-<br>10013169730 | 04/08/2022 | Spontaneous | Healthcare<br>Professional        | Non<br>European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Male     | No    | Arthralgia (n/a -<br>Recovered/Resolved<br>- ),<br>Headache (n/a -  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not   | Not reported  | Ī        |

| 00.11.2022            | 10.20      |             |                                   |                              |               | 110            | III LIIIC L      | isting it | сроп |   |   |              |          |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|-----------|------|---|---|--------------|----------|
|                       |            |             |                                   |                              |               |                |                  |           |      | Recovered/Resolved  | applicable - [1d - n/a<br>- n/a])   |              |          |
|                       |            |             |                                   |                              |               |                |                  |           |      | Intussusception (n/a  |   |              |          |
|                       |            |             |                                   |                              |               |                |                  |           |      | Recovered/Resolved - Other Medically Important Condition),  |   |              |          |
|                       |            |             |                                   |                              |               |                |                  |           |      | Lethargy (n/a -<br>Recovered/Resolved<br>- ),   |   |              |          |
|                       |            |             |                                   |                              |               |                |                  |           |      | Loss of<br>consciousness (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),  |   |              |          |
|                       |            |             |                                   |                              |               |                |                  |           |      | Myalgia (n/a -<br>Recovered/Resolved<br>-),   |   |              |          |
|                       |            |             |                                   |                              |               |                |                  |           |      | Pyrexia (n/a -<br>Recovered/Resolved<br>- ),  |   |              |          |
|                       |            |             |                                   |                              |               |                |                  |           |      | Vaccination site<br>reaction (n/a -<br>Recovered/Resolved<br>-)   |   |              |          |
| EU-EC-<br>10013170450 | 04/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female    | No   | Menstruation<br>irregular (n/a -<br>Unknown - )   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - n/a - n/a])            | Not reported | <u>I</u> |
| EU-EC-<br>10013171053 |            | Spontaneous |                                   | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Female    | No   | Syncope (n/a -<br>Recovered/Resolved<br>- )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>n/a - n/a - [n/a -<br>1{DF} -<br>Intramuscular use])             | Not reported | <u>I</u> |
| EU-EC-<br>10013171791 | 04/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Female    | No   | Vomiting (n/a -<br>Recovering/Resolving<br>- )  | COMIRNATY   |              | <u>I</u> |
| EU-EC-<br>10013171818 |            | Spontaneous |                                   | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Female    | No   | Fatigue (n/a -<br>Unknown - ),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19   | Not reported | D        |
|                       |            |             |                                   | Aica                         |               |                |                  |           |      | Malaise (n/a -<br>Unknown - ),  | immunisation - Not<br>applicable - [1d -<br>1{DF} - n/a])   |              |          |
|                       |            |             |                                   |                              |               |                |                  |           |      | Oropharyngeal pain<br>(n/a - Unknown - )  |   |              | Ļ        |
| EU-EC-<br>10013152349 | 03/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available | 12-17<br>Years | Specified        | Male      | No   | Breakthrough COVID-19 (10d - Recovered/Resolved - ), Cough (n/a - Recovered/Resolved - ), Dyspnoea (n/a - Recovered/Resolved - ), Headache (n/a - Recovered/Resolved - ), | COMTRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - In/a3mL - Intramuscular use]) | Not reported | <u>I</u> |
|                       |            |             |                                   |                              |               |                |                  |           |      | Hyperpyrexia (3d -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),   |   |              |          |
|                       |            |             |                                   |                              |               |                |                  |           |      | Oropharyngeal pain<br>(n/a -<br>Recovered/Resolved<br>-)  |   |              | L        |
| EU-EC-<br>10013154438 |            | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Female    | No   | Chronic fatigue<br>syndrome (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation),  | COMIRNATY<br>[TOZINAMERAN] (S -<br>Immunisation - n/a -<br>[n/a - n/a - n/a])                       | Not reported | <u>I</u> |
|                       |            |             |                                   |                              |               |                |                  |           |      | Tremor (n/a - Not<br>Recovered/Not<br>Resolved -<br>Caused/Prolonged<br>Hospitalisation)  |   |              |          |
| EU-EC-<br>10013154741 | 03/08/2022 | Spontaneous | Healthcare                        | European<br>Economic         | Not available | 12-17<br>Years | Not<br>Specified | Male      | No   | Dysphagia (n/a -<br>Recovered/Resolved  | COMIRNATY<br>[TOZINAMERAN] (S -   | Not reported | <u>I</u> |
|                       |            |             | Professional                      | Area                         |               |                |                  |           |      | - ),  Dyspnoea (n/a - Recovered/Resolved - ),   | COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                                |              |          |
|                       |            |             |                                   |                              |               |                |                  |           |      | Myalgia (n/a -<br>Recovered/Resolved<br>-),   |   |              |          |
|                       |            |             |                                   |                              |               |                |                  |           |      | Rash erythematous<br>(2wk -<br>Recovered/Resolved<br>-)   |   |              |          |
| EU-EC-<br>10013154744 | 03/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female    | No   | Erythema (n/a -<br>Unknown - ),<br>Pain in extremity  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not                                   | Not reported | <u>I</u> |
|                       |            |             |                                   |                              |               |                |                  |           |      | (n/a - Unknown - )  |   |              | I        |

| J.11.2022<br>         |            | I           | I                                 | I                            | I             |                | ın ∟ine ∟<br>∣   |        | (epoi |   | applicable - [1d - n/a  | l            | ı          |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|--------|-------|---|---|--------------|------------|
|                       | 03/08/2022 | Spontaneous |                                   | European                     | Not available | 12-17          | Not              | Male   | No    | Cardiovascular  | - n/a])<br>COMIRNATY  | Not reported | <u>I</u>   |
| 10013154747           |            |             | Healthcare<br>Professional        | Economic<br>Area             |               | Years          | Specified        |        |       | disorder (n/a -<br>Unknown - ),<br>Dizziness (n/a - Not<br>Recovered/Not            | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])   |              |            |
|                       |            |             |                                   |                              |               |                |                  |        |       | Resolved - ),<br>Headache (n/a -  |   |              |            |
| EU-EC-                | 03/08/2022 | Spontaneous |                                   | European                     | Not available | 12-17          | Adolescent       | Male   | No    | Unknown - ) Urticaria (n/a - Not  | COMIRNATY   | Not reported | <u>I</u>   |
| 10013155355           |            |             | Healthcare<br>Professional        | Economic<br>Area             |               | Years          |                  |        |       | Recovered/Not<br>Resolved - )   | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - n/a -<br>[n/a - 2{DF} - n/a])              | ·            |            |
| EU-EC-<br>10013156240 | 03/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No    | Pain (n/a - Unknown<br>-)   | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a - 1{DF} -        | Not reported | <u>I</u>   |
| EU-EC-<br>10013156243 | 03/08/2022 | Spontaneous | Non<br>Healthcare                 | European<br>Economic         | Not available | 12-17<br>Years | Not<br>Specified | Female | No    | Fatigue (n/a -<br>Recovering/Resolving  | Intramuscular use]) COMIRNATY [TOZINAMERAN] (S -  | Not reported | 1          |
| 10013130243           |            |             | Professional                      |                              |               | rears          | эрестеч          |        |       | - ),  Headache (n/a - Recovering/Resolving  | COVID-19<br>immunisation - Not<br>applicable - [n/a -                                       |              |            |
|                       |            |             |                                   |                              |               |                |                  |        |       | - ),<br>Pain (n/a -<br>Recovering/Resolving   | Intramuscular use])   |              |            |
| EU-EC-<br>10013157248 | 03/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No    | Blood<br>immunoglobulin E<br>increased (n/a - Not<br>Recovered/Not<br>Resolved - ), | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -    | Not reported | Ī          |
|                       |            |             |                                   |                              |               |                |                  |        |       | Dizziness (n/a -<br>Recovering/Resolving<br>- ),                                    | n/a - n/a])   |              |            |
|                       |            |             |                                   |                              |               |                |                  |        |       | Eosinophil count increased (n/a - Recovering/Resolving - ),                         |   |              |            |
|                       |            |             |                                   |                              |               |                |                  |        |       | Palpitations (n/a -<br>Recovering/Resolving<br>- )                                  |   |              |            |
| EU-EC-<br>10013157664 | 03/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Male   | No    | Body temperature increased (2d - Recovering/Resolving - ),                          | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -                | Not reported | 1          |
|                       |            |             |                                   |                              |               |                |                  |        |       | Headache (n/a -<br>Recovering/Resolving   | 1{DF} -   |              |            |
| EU-EC-<br>10013157783 | 03/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic         | Not available | 12-17<br>Years | Not<br>Specified | Female | No    | Abdominal pain (n/a<br>-<br>Recovered/Resolved                                      | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19   | Not reported | 10         |
|                       |            |             | Professional                      | Aled                         |               |                |                  |        |       | With Sequelae - ),  Flatulence (n/a - Recovered/Resolved                            | immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                                     |              |            |
|                       | 03/08/2022 | Spontaneous |                                   | European                     | Not available |                | Not              | Male   | Yes   | With Sequelae - ) Eczema nummular   | COMIRNATY   | Not reported | 10         |
| 10013157848           |            |             | Healthcare<br>Professional        | Economic<br>Area             |               | Years          | Specified        |        |       | (n/a - Not<br>Recovered/Not<br>Resolved - ),<br>Parapsoriasis (n/a -                | [TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])  |              |            |
|                       |            |             |                                   |                              |               |                |                  |        |       | Not Recovered/Not<br>Resolved - )   |   |              |            |
| EU-EC-<br>10013157954 | 03/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No    | Headache (4d - Not<br>Recovered/Not<br>Resolved - )                                 | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a | Not reported | 10         |
| EU-EC-<br>10013158600 | 03/08/2022 | Spontaneous | Healthcare                        | European<br>Economic         | Not available | 12-17<br>Years | Not<br>Specified | Male   | No    | Arthralgia (n/a -<br>Unknown - ),   | - n/a])<br>COMIRNATY<br>[TOZINAMERAN] (S -  | Not reported | I.         |
|                       |            |             | Professional                      | Area                         |               |                |                  |        |       | Dyspnoea (n/a -<br>Unknown - ),   | COVID-19<br>immunisation - Not<br>applicable - [1d - n/a                                    |              |            |
|                       |            |             |                                   |                              |               |                |                  |        |       | Fatigue (n/a -<br>Unknown - ),  | - n/a])   |              |            |
|                       |            |             |                                   |                              |               |                |                  |        |       | Headache (n/a -<br>Unknown - ),   |   |              |            |
|                       |            |             |                                   |                              |               |                |                  |        |       | Nausea (n/a -<br>Unknown - )  |   |              |            |
| EU-EC-<br>10013158942 | 03/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No    | Amenorrhoea (n/a -<br>Not Recovered/Not<br>Resolved - )                             | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [n/a -                | Not reported | <u>I</u> ! |
| EU-EC-<br>10013158948 | 03/08/2022 | Spontaneous | Healthcare                        | European<br>Economic         | Not available | 12-17<br>Years | Not<br>Specified | Male   | No    | COVID-19 (n/a -<br>Unknown - ),   | n/a - n/a])  COMIRNATY  [TOZINAMERAN] (S -  | Not reported | 10         |
|                       |            |             | Professional                      | Area                         |               |                |                  |        |       | Chills (n/a -<br>Recovering/Resolving<br>- ),                                       | COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                         |              |            |
|                       |            |             |                                   |                              |               |                |                  |        |       | Dizziness (n/a -<br>Recovering/Resolving<br>- ),                                    |   |              |            |
|                       |            |             |                                   |                              |               |                |                  |        |       | Headache (n/a - Not<br>Recovered/Not<br>Resolved - ),                               |   |              |            |

| .11.2022              | 13.23      |             |                                   |                              |               |                | ın Line L<br>    |        | (eport   | I   |  |              |
|-----------------------|------------|-------------|-----------------------------------|------------------------------|---------------|----------------|------------------|--------|--|---|--|--------------|
|                       |            |             |                                   |                              |               |                |                  |        |  | Pyrexia (n/a -<br>Recovering/Resolving<br> -)   |  |              |
| U-EC-<br>0013159052   | 03/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Female | No   | Amenorrhoea (n/a -<br>Not Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use]) | Not reported |
| U-EC-<br>0013159073   | 03/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Male   | No   | Chest discomfort<br>(n/a -<br>Recovered/Resolved - ),<br>Dyspnoea (n/a -<br>Recovered/Resolved -<br>Other Medically<br>Important<br>Condition),<br>Tachycardia (n/a - | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [n/a -<br>1{DF} -<br>Intramuscular use]) | Not reported |
| U-EC-<br>0013159096   | 03/08/2022 | Spontaneous |                                   | European<br>Economic         | Not available | 12-17<br>Years | Adolescent       | Female | No   | Recovered/Resolved - Other Medically Important Condition)  Dysmenorrhoea (n/a - Not Recovered/Not   | COMIRNATY [TOZINAMERAN] (S -   | Not reported |
| 3013133030            |            |             | Professional                      |                              |               | rears          |                  |        |  | Resolved - Other<br>Medically Important<br>Condition),<br>Gastrointestinal<br>disorder (n/a - Not<br>Recovered/Not<br>Resolved - ),                                   | COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} -<br>Intramuscular use])                                     |              |
|                       |            |             |                                   |                              |               |                |                  |        |  | Nausea (n/a - Not<br>Recovered/Not<br>Resolved - )  |  |              |
| :U-EC-<br>.0013159217 | 03/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Female | No   | Heavy menstrual bleeding (n/a - Recovered/Resolved - Other Medically Important Condition),  Menstruation irregular (n/a - Not Pagesyperd/Met.                         | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} -<br>Intramuscular use])  | Not reported |
|                       |            |             |                                   |                              |               |                |                  |        | Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition) |   |  |              |
| EU-EC-<br>10013159316 | 03/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Female | No   | Amenorrhoea (n/a -<br>Recovering/Resolving<br>- Other Medically<br>Important<br>Condition),<br>Heavy menstrual  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Drug<br>withdrawn - [1d -<br>1{DF} -<br>Intramuscular use])  | Not reported |
|                       |            |             |                                   |                              |               |                |                  |        |  | bleeding (n/a -<br>Recovered/Resolved<br>- Other Medically<br>Important<br>Condition),<br>Iron deficiency   |  |              |
|                       |            |             |                                   |                              |               |                |                  |        |  | anaemia (n/a - Not<br>Recovered/Not<br>Resolved - Other<br>Medically Important<br>Condition)  |  |              |
| :U-EC-<br>0013159332  | 03/08/2022 | Spontaneous | Healthcare<br>Professional        | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No   | Antinuclear antibody<br>(n/a - Unknown - ),<br>COVID-19 (n/a - Not<br>Recovered/Not<br>Resolved - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d - n/a<br>- n/a])                     | Not reported |
| 0013159391            | 03/08/2022 | Spontaneous |                                   | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Female | No   | Menstruation delayed<br>(n/a -<br>Recovered/Resolved<br>-)  | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>1{DF} -<br>Intramuscular use]) | Not reported |
| U-EC-<br>0013159503   | 03/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Female | No   | Influenza like illness<br>(n/a -<br>Recovered/Resolved<br>- ),<br>Injection site<br>erythema (n/a -   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [1d -<br>1{DF} -<br>Intramuscular use])  | Not reported |
|                       |            |             |                                   |                              |               |                |                  |        |  | Recovered/Resolved<br>-),<br>Pain (n/a -<br>Recovered/Resolved  | intumoscular usejj   |              |
| U-EC-<br>0013159504   | 03/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available | 12-17<br>Years | Adolescent       | Male   | No   | - ) Injection site swelling (n/a - Recovered/Resolved - ), Skin reaction (n/a - Recovered/Resolved  | COMIRNATY [TOZINAMERAN] (S - COVID-19 immunisation - Not applicable - [1d - 1{DF} - Intramuscular use])                    | Not reported |
| EU-EC-<br>0013159581  | 03/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic<br>Area | Not available | 12-17<br>Years | Not<br>Specified | Female | No   | leavy menstrual<br>bleeding (n/a -<br>Unknown - )   | COMIRNATY<br>[TOZINAMERAN] (S -<br>COVID-19<br>immunisation - Not<br>applicable - [n/a -<br>n/a - n/a])                    | Not reported |
| U-EC-<br>10013159592  | 03/08/2022 | Spontaneous | Non<br>Healthcare<br>Professional | European<br>Economic         | Not available | 12-17<br>Years | Not<br>Specified | Female | No   | Chills (n/a -<br>Unknown - ),   | COMIRNATY [TOZINAMERAN] (S - COVID-19  | Not reported |

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