

| <u>MA (EU) number</u> | <u>(Invented) name</u>          | <u>Strength</u> | <u>Pharmaceutical Form</u>               | <u>Route of Administration</u> | <u>Immediate Packaging</u>                   | <u>Content (concentration)</u> | <u>Pack size</u>                     |
|-----------------------|---------------------------------|-----------------|--|--------------------------------|--|--------------------------------|--------------------------------------|
| EU/1/20/1528/018      | COMIRNATY<br>Omicron<br>XBB.1.5 | --10            | Dispersion for injection                 | Intramuscular use              | vial (glass)                                 | 0.48 ml (1 dose)               | 10 single dose vials<br>(10 doses)   |
| EU/1/20/1528/019      | COMIRNATY<br>Omicron<br>XBB.1.5 | --10            | Dispersion for injection                 | Intramuscular use              | vial (glass)                                 | 2.25 ml<br>(6 doses)           | 10 multidose vials<br>(60 doses)     |
| EU/1/20/1528/020      | COMIRNATY<br>Omicron<br>XBB.1.5 | --10            | Dispersion for injection                 | Intramuscular use              | vial (glass)                                 | 2.25 ml<br>(6 doses)           | 195 multidose vials<br>(1170 doses)  |
| EU/1/20/1528/021      | COMIRNATY<br>Omicron<br>XBB.1.5 | --11            | Concentrate for dispersion for injection | Intramuscular use              | vial (glass)                                 | 1.3 ml<br>(10 doses)           | 10 multidose vials<br>(100 doses)    |
| EU/1/20/1528/022      | COMIRNATY<br>Omicron<br>XBB.1.5 | --12            | Dispersion for injection                 | Intramuscular use              | vial (glass)                                 | 0.48 ml (1 dose)               | 10 single dose vials<br>(10 doses)   |
| EU/1/20/1528/023      | COMIRNATY<br>Omicron<br>XBB.1.5 | --12            | Dispersion for injection                 | Intramuscular use              | vial (glass)                                 | 2.25 ml<br>(6 doses)           | 10 multidose vials<br>(60 doses)     |
| EU/1/20/1528/024      | COMIRNATY<br>Omicron<br>XBB.1.5 | --13            | Concentrate for dispersion for injection | Intramuscular use              | vial (glass)                                 | 0.4 ml<br>(10 doses)           | 10 multidose vials<br>(100 doses)    |
| EU/1/20/1528/025      | COMIRNATY<br>Omicron<br>XBB.1.5 | --10            | Dispersion for injection                 | Intramuscular use              | pre-filled syringe (cyclic-olefin copolymer) | 0.432 ml<br>(1 dose)           | 10 pre-filled syringes<br>(10 doses) |
| EU/1/20/1528/026      | COMIRNATY<br>Omicron<br>XBB.1.5 | --14            | Concentrate for dispersion for injection | Intramuscular use              | vial (glass)                                 | 0.48 ml<br>(3 doses)           | 10 multidose vials<br>(30 doses)     |
| EU/1/20/1528/027      | COMIRNATY<br>Omicron<br>XBB.1.5 | --10            | Dispersion for injection                 | Intramuscular use              | pre-filled syringe (glass)                   | 0.418 ml<br>(1 dose)           | 10 pre-filled syringes<br>(10 doses) |
| EU/1/20/1528/028      | COMIRNATY<br>JN.1               | --15            | Dispersion for injection                 | Intramuscular use              | vial (glass)                                 | 0.48 ml (1 dose)               | 10 single dose vials<br>(10 doses)   |

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| EU/1/20/1528/029 | COMIRNATY<br>JN.1 | --15 | Dispersion for injection                 | Intramuscular use | vial (glass)                                 | 2.25 ml<br>(6 doses) | 10 multidose vials<br>(60 doses)     |
| EU/1/20/1528/030 | COMIRNATY<br>JN.1 | --15 | Dispersion for injection                 | Intramuscular use | pre-filled syringe (glass)                   | 0.418 ml<br>(1 dose) | 10 pre-filled syringes<br>(10 doses) |
| EU/1/20/1528/031 | COMIRNATY<br>JN.1 | --15 | Dispersion for injection                 | Intramuscular use | pre-filled syringe (cyclic-olefin copolymer) | 0.432 ml<br>(1 dose) | 10 pre-filled syringes<br>(10 doses) |
| EU/1/20/1528/032 | COMIRNATY<br>JN.1 | --16 | Dispersion for injection                 | Intramuscular use | vial (glass)                                 | 0.48 ml (1 dose)     | 10 single dose vials<br>(10 doses)   |
| EU/1/20/1528/033 | COMIRNATY<br>JN.1 | --16 | Dispersion for injection                 | Intramuscular use | vial (glass)                                 | 2.25 ml<br>(6 doses) | 10 multidose vials<br>(60 doses)     |
| EU/1/20/1528/034 | COMIRNATY<br>JN.1 | --17 | Concentrate for dispersion for injection | Intramuscular use | vial (glass)                                 | 1.3 ml<br>(10 doses) | 10 multidose vials<br>(100 doses)    |
| EU/1/20/1528/035 | COMIRNATY<br>JN.1 | --18 | Concentrate for dispersion for injection | Intramuscular use | vial (glass)                                 | 0.48 ml<br>(3 doses) | 10 multidose vials<br>(30 doses)     |
| EU/1/20/1528/036 | COMIRNATY<br>JN.1 | --19 | Concentrate for dispersion for injection | Intramuscular use | vial (glass)                                 | 0.4 ml<br>(10 doses) | 10 multidose vials<br>(100 doses)    |
| EU/1/20/1528/037 | COMIRNATY<br>KP.2 | --20 | Dispersion for injection                 | Intramuscular use | vial (glass)                                 | 0.48 ml (1 dose)     | 10 single dose vials<br>(10 doses)   |
| EU/1/20/1528/038 | COMIRNATY<br>KP.2 | --20 | Dispersion for injection                 | Intramuscular use | vial (glass)                                 | 2.25 ml<br>(6 doses) | 10 multidose vials<br>(60 doses)     |
| EU/1/20/1528/039 | COMIRNATY<br>KP.2 | --20 | Dispersion for injection                 | Intramuscular use | pre-filled syringe (glass)                   | 0.418 ml<br>(1 dose) | 10 pre-filled syringes<br>(10 doses) |
| EU/1/20/1528/040 | COMIRNATY<br>KP.2 | --21 | Dispersion for injection                 | Intramuscular use | vial (glass)                                 | 0.48 ml (1 dose)     | 10 single dose vials<br>(10 doses)   |

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|------------------|-------------------|------------------|--|----------------------|--------------|----------------------|-------------------------------------|
| EU/1/20/1528/041 | COMIRNATY<br>KP.2 | -- <sup>21</sup> | Dispersion for<br>injection                    | Intramuscular<br>use | vial (glass) | 2.25 ml<br>(6 doses) | 10 multidose<br>vials<br>(60 doses) |
| EU/1/20/1528/042 | COMIRNATY<br>KP.2 | -- <sup>22</sup> | Concentrate for<br>dispersion for<br>injection | Intramuscular<br>use | vial (glass) | 0.48 ml<br>(3 doses) | 10 multidose<br>vials<br>(30 doses) |

--<sup>10</sup>: COMIRNATY Omicron XBB.1.5 30 micrograms/dose dispersion for injection (EU/1/20/1528/018-020, EU/1/20/1528/025, EU/1/20/1528/027):

1 dose (0.3 mL) contains 30 micrograms of raxtozinameran, COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).

Raxtozinameran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron XBB.1.5).

--<sup>11</sup>: COMIRNATY Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection (EU/1/20/1528/021):

After dilution, 1 dose (0.2 mL) contains 10 micrograms of raxtozinameran, COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).

Raxtozinameran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron XBB.1.5).

--<sup>12</sup>: COMIRNATY Omicron XBB.1.5 10 micrograms/dose dispersion for injection (EU/1/20/1528/022-023):

1 dose (0.3 mL) contains 10 micrograms of raxtozinameran, COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).

Raxtozinameran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron XBB.1.5).

--<sup>13</sup>: COMIRNATY Omicron XBB.1.5 3 micrograms/dose concentrate for dispersion for injection (EU/1/20/1528/024):

After dilution, 1 dose (0.2 mL) contains 3 micrograms of raxtozinameran, COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).

Raxtozinameran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron XBB.1.5).

--<sup>14</sup>: COMIRNATY Omicron XBB.1.5 3 micrograms/dose concentrate for dispersion for injection (EU/1/20/1528/026):

After dilution, 1 dose (0.3 mL) contains 3 micrograms of raxtozinameran, COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).

Raxtozinameran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron XBB.1.5).

--<sup>15</sup>: COMIRNATY JN.1 30 micrograms/dose dispersion for injection (EU/1/20/1528/028-031):

1 dose (0.3 mL) contains 30 micrograms of bretovameran, COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).

Bretovameran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron JN.1).

--16: COMIRNATY JN.1 10 micrograms/dose dispersion for injection (EU/1/20/1528/032-033):

1 dose (0.3 mL) contains 10 micrograms of bretovameran, COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).

Bretovameran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron JN.1).

--17: COMIRNATY JN.1 10 micrograms/dose concentrate for dispersion for injection (EU/1/20/1528/034):

After dilution, 1 dose (0.2 mL) contains 10 micrograms of bretovameran, COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).

Bretovameran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron JN.1).

--18: COMIRNATY JN.1 3 micrograms/dose concentrate for dispersion for injection (EU/1/20/1528/035):

After dilution, 1 dose (0.3 mL) contains 3 micrograms of bretovameran, COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).

Bretovameran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron JN.1).

--19: COMIRNATY JN.1 3 micrograms/dose concentrate for dispersion for injection (EU/1/20/1528/036):

After dilution, 1 dose (0.2 mL) contains 3 micrograms of bretovameran, COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).

Bretovameran is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron JN.1).

--20: COMIRNATY KP.2 30 micrograms/dose dispersion for injection (EU/1/20/1528/037-039):

1 dose (0.3 mL) contains 30 micrograms mRNA encoding KP.2, COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).

The mRNA encoding KP.2 is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron KP.2).

--21: COMIRNATY KP.2 10 micrograms/dose dispersion for injection (EU/1/20/1528/040-041):

1 dose (0.3 mL) contains 10 micrograms mRNA encoding KP.2, COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).

The mRNA encoding KP.2 is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron KP.2).

--22: COMIRNATY KP.2 3 micrograms/dose concentrate for dispersion for injection (EU/1/20/1528/042):

After dilution, 1 dose (0.3 mL) contains 3 micrograms mRNA encoding KP.2, COVID-19 mRNA Vaccine (nucleoside modified, embedded in lipid nanoparticles).

The mRNA encoding KP.2 is a single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 (Omicron KP.2).