

When stored frozen at -90 °C to -60 °C, 10-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 4 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Once removed from the freezer, the unopened vial may be stored and transported refrigerated at 2 °C to 8 °C for up to 10 weeks; not exceeding the printed expiry date (EXP). The outer carton should be marked with the new discard date at 2 °C to 8 °C. Once thawed, the vaccine cannot be re-frozen.

Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8 °C and 30 °C.

Thawed vials can be handled in room light conditions.

After dilution, store the vaccine at 2 °C to 30 °C and use within 12 hours, which includes up to 6 hours transportation time. Discard any unused vaccine.

Do not use this vaccine if you notice particulates in the dilution or discolouration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Comirnaty Omicron XBB.1.5 contains

- The active substance of COVID-19 mRNA Vaccine is called raxtozinameran. After dilution, the vial contains 10 doses of 0.2 mL with 10 micrograms raxtozinameran each.
- The other ingredients are:
 - (4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
 - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
 - 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)
 - cholesterol
 - trometamol
 - trometamol hydrochloride
 - sucrose
 - water for injections

What Comirnaty Omicron XBB.1.5 looks like and contents of the pack

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in a multidose vial of 10 doses in a 2 mL clear vial (type I glass), with a rubber stopper and an orange flip-off plastic cap with aluminium seal.

Pack sizes: 10 vials or 195 vials

Not all pack sizes may be marketed.

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Scan the code with a mobile device to get the package leaflet in different languages.



URL: www.comirnatyglobal.com

Detailed information on this medicine is available on the European Medicines Agency website: <http://www.ema.europa.eu>.

This package leaflet is available in all EU/EEA languages on the European Medicines Agency website.

The following information is intended for healthcare professionals only:

Administer Comirnaty Omicron XBB.1.5 intramuscularly after dilution as a single dose of 0.2 mL regardless of prior COVID-19 vaccination status.

For individuals who have previously been vaccinated with a COVID-19 vaccine, Comirnaty Omicron XBB.1.5 should be administered at least 3 months after the most recent dose of a COVID-19 vaccine.

Additional doses may be given to individuals who are severely immunocompromised.

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions

Comirnaty Omicron XBB.1.5 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

VIAL VERIFICATION OF COMIRNATY OMICRON XBB.1.5 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)	
<p>Orange cap</p> <p>Comirnaty Omicron XBB.1.5 After Dilution</p> <p>10 mcg</p>	<ul style="list-style-type: none"> Verify that the vial has an orange plastic cap and the product name is Comirnaty Omicron XBB.1.5 10 micrograms/dose concentrate for dispersion for injection. If the vial has another product name on the label, please make reference to the Summary of Product Characteristics for that formulation.
HANDLING PRIOR TO USE OF COMIRNATY OMICRON XBB.1.5 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)	
<p>Store for up to 10 weeks at 2 °C to 8 °C.</p>	<ul style="list-style-type: none"> If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 10-vial pack may take 4 hours to thaw. Ensure vials are completely thawed prior to use. Upon moving vials to 2 °C to 8 °C storage, update the expiry date on the carton. Unopened vials can be stored for up to 10 weeks at 2 °C to 8 °C; not exceeding the printed expiry date (EXP). Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C. Prior to use, the unopened vial can be stored for up to 12 hours at temperatures up to 30 °C. Thawed vials can be handled in room light conditions.
MIXING PRIOR TO DILUTION OF COMIRNATY OMICRON XBB.1.5 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)	
<p>Gently × 10</p>	<ul style="list-style-type: none"> Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake. Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.
DILUTION OF COMIRNATY OMICRON XBB.1.5 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)	
<p>1.3 mL of sodium chloride 9 mg/mL (0.9%) solution for injection</p>	<ul style="list-style-type: none"> The thawed vaccine must be diluted in its original vial with 1.3 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.

<p>Pull back plunger to 1.3 mL to remove air from vial.</p>	<ul style="list-style-type: none"> Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.3 mL air into the empty diluent syringe.
<p>Gently × 10</p>	<ul style="list-style-type: none"> Gently invert the diluted dispersion 10 times. Do not shake. The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.
<p>Record appropriate date and time. Use within 12 hours after dilution.</p> <p>Discard Time</p>	<ul style="list-style-type: none"> The diluted vials should be marked with the appropriate date and time. After dilution, store at 2 °C to 30 °C and use within 12 hours. Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.
PREPARATION OF INDIVIDUAL 0.2 mL DOSES OF COMIRNATY OMICRON XBB.1.5 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)	
<p>0.2 mL diluted vaccine</p>	<ul style="list-style-type: none"> After dilution, the vial contains 2.6 mL from which 10 doses of 0.2 mL can be extracted. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. Withdraw 0.2 mL of Comirnaty Omicron XBB.1.5 for children aged 5 to 11 years. <p>Low dead-volume syringes and/or needles should be used in order to extract 10 doses from a single vial. The low dead volume syringe and needle combination should have a dead-volume of no more than 35 microlitres.</p> <p>If standard syringes and needles are used, there may not be sufficient volume to extract ten doses from a single vial.</p> <ul style="list-style-type: none"> Each dose must contain 0.2 mL of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. Discard any unused vaccine within 12 hours after dilution.

Disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.