

Package leaflet: Information for the user

Comirnaty Omicron XBB.1.5 10 micrograms/dose dispersion for injection Children 5 to 11 years COVID-19 mRNA Vaccine raxtozinameran

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects your child may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before your child receives this vaccine because it contains important information for your child.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor, pharmacist or nurse.
- If your child gets any side effects, talk to your child's doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Comirnaty Omicron XBB.1.5 is and what it is used for

Comirnaty Omicron XBB.1.5 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2.

Comirnaty Omicron XBB.1.5 10 micrograms/dose dispersion for injection is given to children from 5 to 11 years of age.

The vaccine causes the immune system (the body's natural defences) to produce antibodies and blood cells that work against the virus, so giving protection against COVID-19.

As Comirnaty Omicron XBB.1.5 does not contain the virus to produce immunity, it cannot give your child COVID-19.

The use of this vaccine should be in accordance with official recommendations.

2. What you need to know before your child receives Comirnaty Omicron XBB.1.5

Comirnaty Omicron XBB.1.5 should not be given

- if your child is allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your child's doctor, pharmacist or nurse before your child is given the vaccine if your child:

- has ever had a severe allergic reaction or breathing problems after any other vaccine injection or after having been given this vaccine in the past.
- is feeling nervous about the vaccination process or has ever fainted following any needle injection.

- has a severe illness or infection with high fever. However, your child can have the vaccination if he/she has a mild fever or upper airway infection like a cold.
- has a bleeding problem, bruises easily or uses a medicine to prevent blood-clots.
- has a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects the immune system.

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Comirnaty (see section 4). These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males. The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen. Following vaccination, you should be alert to signs of myocarditis and pericarditis, such as breathlessness, palpitations and chest pain, and seek immediate medical attention should these occur.

As with any vaccine, Comirnaty Omicron XBB.1.5 may not fully protect all those who receive it and it is not known how long your child will be protected.

The efficacy of Comirnaty Omicron XBB.1.5 may be lower in people who are immunocompromised. If your child is immunocompromised, he/she may receive additional doses of Comirnaty Omicron XBB.1.5. In these cases, your child should continue to maintain physical precautions to help prevent COVID-19. In addition, your child's close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your child's doctor.

Children

Comirnaty Omicron XBB.1.5 10 micrograms/dose dispersion for injection is not recommended for children aged under 5 years.

There are paediatric formulations available for infants and children aged 6 months to 4 years. For details, please refer to the Package Leaflet for other formulations.

The vaccine is not recommended for infants aged under 6 months.

Other medicines and Comirnaty Omicron XBB.1.5

Tell your child's doctor or pharmacist if your child is using, has recently used or might use any other medicines or has recently received any other vaccine.

Pregnancy and breast-feeding

If your child is pregnant, tell your child's doctor, nurse or pharmacist before your child receives this vaccine.

No data are available yet regarding the use of Comirnaty Omicron XBB.1.5 during pregnancy. However, a large amount of information from pregnant women vaccinated with the initially approved Comirnaty vaccine during the second and third trimester have not shown negative effects on the pregnancy or the newborn baby. While information on effects on pregnancy or the newborn baby after vaccination during the first trimester is limited, no change to the risk for miscarriage has been seen. Comirnaty Omicron XBB.1.5 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty Omicron XBB.1.5 during breast-feeding. However, no effects on the breastfed newborn/infant are anticipated. Data from women who were breast-feeding after vaccination with the initially approved Comirnaty vaccine have not shown a risk for adverse effects in breastfed newborns/infants. Comirnaty Omicron XBB.1.5 can be used while breast-feeding.

Driving and using machines

Some of the effects of vaccination mentioned in section 4 (Possible side effects) may temporarily affect your child's ability to use machines or undertake activities such as cycling. Wait until these effects have worn off before resuming activities that require your child's full attention.

3. How Comirnaty Omicron XBB.1.5 is given

Comirnaty Omicron XBB.1.5 is given as an injection of 0.3 mL into a muscle of your child's upper arm.

Your child will receive 1 injection, regardless whether he/she has received a COVID-19 vaccine before.

If your child was previously vaccinated with a COVID-19 vaccine, he/she should not receive a dose of Comirnaty Omicron XBB.1.5 until at least 3 months after the most recent dose.

If your child is immunocompromised, he/she may receive additional doses of Comirnaty Omicron XBB.1.5.

If you have any further questions on the use of Comirnaty Omicron XBB.1.5, ask your child's doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty Omicron XBB.1.5 can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people

- injection site: pain, swelling
- tiredness, headache
- muscle pain, joint pain
- chills, fever
- diarrhoea

Common side effects: may affect up to 1 in 10 people

- nausea
- vomiting ('very common' in pregnant women 18 years of age and older and in immunocompromised individuals 5 to 18 years of age)
- injection site redness ('very common' in 5 to 11 years of age and in immunocompromised individuals 5 years of age and older)
- enlarged lymph nodes (more frequently observed after a booster dose)

Uncommon side effects: may affect up to 1 in 100 people

- feeling unwell, feeling weak or lack of energy/sleepy
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- decreased appetite
- dizziness
- excessive sweating, night sweats

Rare side effects: may affect up to 1 in 1 000 people

- temporary one sided facial drooping
- allergic reactions such as hives or swelling of the face

Very rare side effects: may affect up to 1 in 10 000 people

- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain

Not known (cannot be estimated from the available data)

- severe allergic reaction
- extensive swelling of the vaccinated limb
- swelling of the face (swelling of the face may occur in patients who have had facial dermatological fillers)
- a skin reaction that causes red spots or patches on the skin, that may look like a target or “bulls-eye” with a dark red centre surrounded by paler red rings (erythema multiforme)
- unusual feeling in the skin, such as tingling or a crawling feeling (paraesthesia)
- decreased feeling or sensitivity, especially in the skin (hypoesthesia)
- heavy menstrual bleeding (most cases appeared to be non-serious and temporary in nature)

Reporting of side effects

If your child gets any side effects, talk to your child’s doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

If you are concerned about a side-effect it can be reported directly via the Coronavirus Yellow Card reporting site <https://coronavirus-yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Comirnaty Omicron XBB.1.5

Keep this medicine out of the sight and reach of children.

The following information about storage, expiry and use and handling is intended for healthcare professionals.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C.

Store in the original package in order to protect from light.

The vaccine will be received frozen at -90 °C to -60 °C. Frozen vaccine can be stored either at -90 °C to -60 °C or 2 °C to 8 °C upon receipt.

Multidose vials: 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 6 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Thawed (previously frozen) vials: 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 expiry 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.

Opened vials: After first puncture, 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 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 (nucleoside modified) is called raxtozinameran.
A multidose vial contains 6 doses of 0.3 mL with 10 micrograms of raxtozinameran per dose.
- The other ingredients are:
 - ((4-hydroxybutyl)azanediyl)bis(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 clear to slightly opalescent dispersion (pH: 6.9 - 7.9) provided in a multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a blue flip-off plastic cap with aluminium seal.

Pack size: 10 vials

Marketing Authorisation Holder

BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz
Germany
Phone: +49 6131 9084-0
Fax: +49 6131 9084-2121
service@biontech.de

Manufacturers

BioNTech Manufacturing GmbH
Kupferbergterrasse 17 - 19
55116 Mainz
Germany

Pfizer Manufacturing Belgium NV
Rijksweg 12
Puurs-Sint-Amands, 2870
Belgium

For any information about this medicine, please contact: Medical Information, Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS. Telephone 01304 616161.

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The following information is intended for healthcare professionals only:

Administer Comirnaty Omicron XBB.1.5 intramuscularly as a single dose of 0.3 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 prior to use

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

- **Verify** that the vial has a **blue plastic cap** and the product **name is Comirnaty Omicron XBB.1.5 (10 micrograms)/dose dispersion for injection** (children 5 to 11 years).
- If the vial has another product name on the label, please make reference to the Summary of Product Characteristics for that formulation.
- If the 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. Ensure vials are completely thawed prior to use. A 10-vial pack of multidose vials may take 6 hours to thaw.
- 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.

Preparation of 0.3 mL doses

- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a clear to slightly opalescent dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
- Check whether the vial is a multidose vial and follow the applicable handling instructions below:
 - Multidose vials contain 6 doses of 0.3 mL each.
 - Using aseptic technique, cleanse the vial stopper with a single use antiseptic swab.
 - Withdraw 0.3 mL of Comirnaty Omicron XBB.1.5 for children aged 5 to 11 years.

Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead-volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

- Each dose must contain 0.3 mL of vaccine.

- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Record the appropriate date/time on the vial. Discard any unused vaccine 12 hours after first puncture.

Disposal

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