

## Package leaflet: Information for the user

### Comirnaty Omicron XBB.1.5 30 micrograms/dose dispersion for injection Adults and adolescents from 12 years COVID-19 mRNA Vaccine (nucleoside modified) 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 you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you receive this vaccine because it contains important information for you.**

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

#### What is in this leaflet

1. What Comirnaty Omicron XBB.1.5 is and what it is used for
2. What you need to know before you receive Comirnaty Omicron XBB.1.5
3. How Comirnaty Omicron XBB.1.5 is given
4. Possible side effects
5. How to store Comirnaty Omicron XBB.1.5
6. Contents of the pack and other information

#### 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 30 micrograms/dose dispersion for injection is given to adults and adolescents from 12 years of age and older.

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 you COVID-19.

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

#### 2. What you need to know before you receive Comirnaty Omicron XBB.1.5

##### Comirnaty Omicron XBB.1.5 should not be given

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

##### Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given the vaccine if:

- you have ever had a severe allergic reaction or breathing problems after any other vaccine injection or after you were given this vaccine in the past.

- you are feeling nervous about the vaccination process or have ever fainted following any needle injection.
- you have a severe illness or infection with high fever. However, you can have your vaccination if you have a mild fever or upper airway infection like a cold.
- you have a bleeding problem, you bruise easily or you use a medicine to prevent blood-clots.
- you have a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your 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 you will be protected.

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

### **Children**

Comirnaty Omicron XBB.1.5 30 micrograms/dose dispersion for injection is not recommended for children aged under 12 years.

There are paediatric formulations available for infants aged 6 months and above and children below 12 years of age. 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 doctor or pharmacist if you are using, have recently used or might use any other medicines or have recently received any other vaccine.

### **Pregnancy and breast-feeding**

If you are pregnant or think you may be pregnant, tell your doctor, nurse or pharmacist before you receive 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 ability to drive or use machines. Wait until these effects have worn off before you drive or use machines.

### **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 upper arm.

You will receive 1 injection, regardless whether you have received a COVID-19 vaccine before.

If you were previously vaccinated with a COVID-19 vaccine, you should not receive a dose of Comirnaty Omicron XBB.1.5 until at least 3 months after the most recent dose.

If you are immunocompromised, you 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 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
- chills
- joint pain
- diarrhoea
- fever

Some of these side effects were slightly more frequent in adolescents 12 to 15 years than in adults.

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

- injection site redness
- nausea
- vomiting
- enlarged lymph nodes (more frequently observed after a booster dose)

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

- feeling unwell
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- feeling weak or lack of energy/sleepy
- 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 you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#) and include batch/Lot number if available. 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.

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

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 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 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.

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 is called raxtozinameran.
  - A single dose vial contains 1 dose of 0.3 mL with 30 micrograms raxtozinameran each.
  - A multidose vial contains 6 doses of 0.3 mL with 30 micrograms raxtozinameran each.
- 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 white to off-white dispersion (pH: 6.9 - 7.9) provided in either:

- A single dose vial of 1 dose in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal; or
- A multidose vial of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a grey flip-off plastic cap with aluminium seal.

Single dose vial pack size: 10 vials

Multidose vial pack sizes: 10 vials or 195 vials

Not all pack sizes may be marketed.

### **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  
2870 Puurs  
Belgium

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

**België/Belgique/Belgien**  
**Luxembourg/Luxemburg**  
Pfizer S.A./N.V.  
Tél/Tel: +32 (0)2 554 62 11

**Lietuva**  
Pfizer Luxembourg SARL filialas Lietuvoje  
Tel. +370 52 51 4000

**България**  
Пфайзер Люксембург САРЛ, Клон  
България  
Тел: +359 2 970 4333

**Magyarország**  
Pfizer Kft  
Tel: +36 1 488 3700

**Česká republika**  
Pfizer, spol. s r.o.  
Tel: +420 283 004 111

**Malta**  
Vivian Corporation Ltd.  
Tel: +35621 344610

**Danmark**  
Pfizer ApS  
Tlf: +45 44 201 100

**Norge**  
Pfizer AS  
Tlf: +47 67 526 100

**Deutschland**  
BioNTech Manufacturing GmbH  
Tel: +49 6131 90840

**Nederland**  
Pfizer BV  
Tel: +31 (0)10 406 43 01

**Eesti**  
Pfizer Luxembourg SARL Eesti filiaal  
Tel: +372 666 7500

**Österreich**  
Pfizer Corporation Austria Ges.m.b.H  
Tel: +43 (0)1 521 15-0

**Ελλάδα**  
Pfizer Ελλάς Α.Ε.  
Τηλ.: +30 210 6785 800

**Polska**  
Pfizer Polska Sp. z o.o.  
Tel.: +48 22 335 61 00

**España**  
Pfizer, S.L.  
Tel: +34914909900

**Portugal**  
Laboratórios Pfizer, Lda.  
Tel: +351 21 423 5500

**France**  
Pfizer  
Tél +33 1 58 07 34 40

**România**  
Pfizer Romania S.R.L  
Tel: +40 (0) 21 207 28 00

**Hrvatska**

Pfizer Croatia d.o.o.  
Tel: +385 1 3908 777

**Ireland**

Pfizer Healthcare Ireland  
Tel: 1800 633 363 (toll free)  
+44 (0)1304 616161

**Ísland**

Icepharma hf  
Simi: +354 540 8000

**Italia**

Pfizer S.r.l.  
Tel: +39 06 33 18 21

**Κύπρος**

Pfizer Ελλάς A.E. (Cyprus Branch)  
Τηλ: +357 22 817690

**Latvija**

Pfizer Luxembourg SARL filiāle Latvijā  
Tel.: +371 670 35 775

**Slovenija**

Pfizer Luxembourg SARL  
Pfizer, podružnica za svetovanje s področja  
farmacevtske dejavnosti, Ljubljana  
Tel.: +386 (0) 1 52 11 400

**Slovenská republika**

Pfizer Luxembourg SARL,  
organizačná zložka  
Tel: +421 2 3355 5500

**Suomi/Finland**

Pfizer Oy  
Puh/Tel: +358 (0)9 430 040

**Sverige**

Pfizer AB  
Tel: +46 (0)8 550 520 00

**United Kingdom (Northern Ireland)**

Pfizer Limited  
Tel: +44 (0) 1304 616161

**This leaflet was last revised in**

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



URL: [www.comirnatyglobal.com](http://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.

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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.

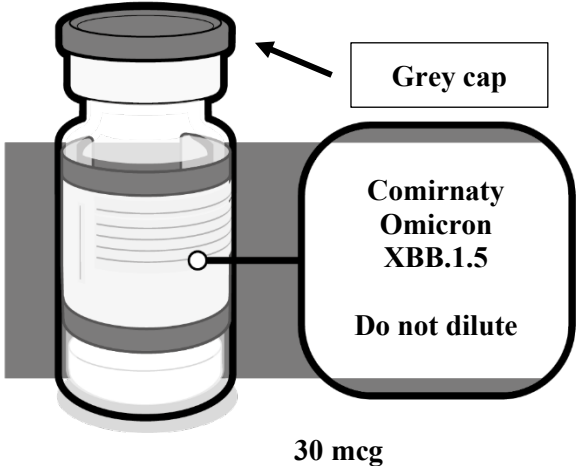
Additional doses may be given to individuals who are severely immunocompromised.

## 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.

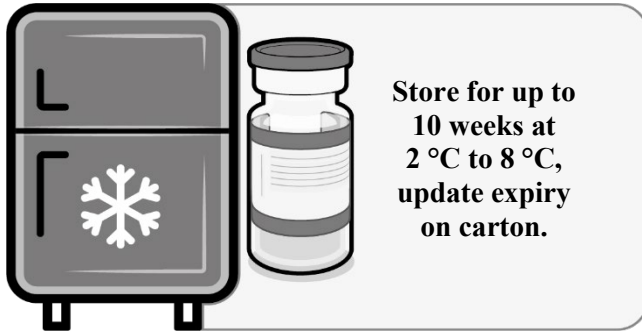
## Handling instructions

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

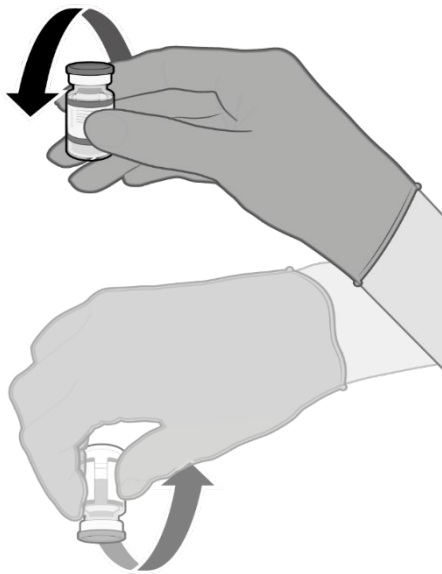
<b>INSTRUCTIONS APPLICABLE TO BOTH SINGLE DOSE AND MULTIDOSE VIALS</b>	
<b>VIAL VERIFICATION OF COMIRNATYOMICRON XBB.1.5 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)</b>	
 <p>The diagram shows a glass vial with a grey plastic cap. A callout box labeled 'Grey cap' points to the cap. Another callout box labeled 'Comirnaty Omicron XBB.1.5' and 'Do not dilute' points to the vial's label. Below the vial, the text '30 mcg' is displayed.</p>	<ul style="list-style-type: none"><li>• <b>Verify that the vial has a grey plastic cap and the product name is Comirnaty Omicron XBB.1.5 30 micrograms/dose dispersion for injection.</b></li><li>• Check whether the vial is a single dose vial or a multidose vial and follow the applicable handling instructions below.</li><li>• If the vial has another product name on the label, please make reference to the Summary of Product Characteristics for that formulation.</li></ul>



**HANDLING PRIOR TO USE OF COMIRNATY OMICRON XBB.1.5  
30 MICROGRAMS/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)**

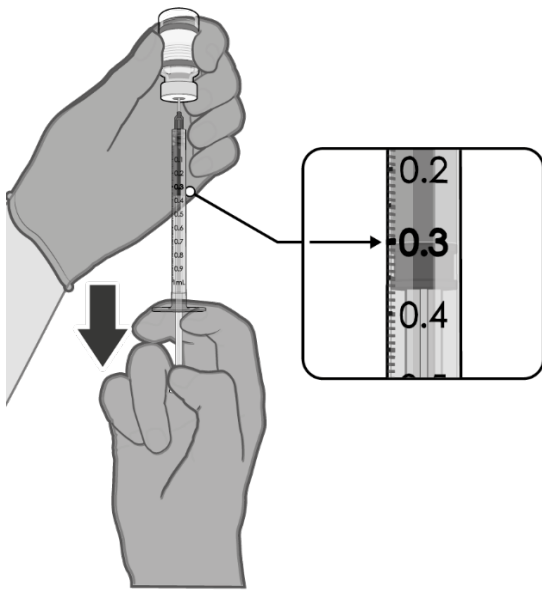


- If the single or multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw. Ensure vials are completely thawed prior to use.
  - Single dose vials: A 10-vial pack of single dose vials may take 2 hours to thaw.
  - Multidose vials: 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.



- 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 white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discoloration are present.

**PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY OMICRON XBB.1.5  
30 MICROGRAMS/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)**



**0.3 mL vaccine**

Single dose vials

- Withdraw a single 0.3 mL dose of vaccine.
- Discard vial and any excess volume.

Multidose vials

- 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.

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.

## 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 (nucleoside modified) 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

1. What Comirnaty Omicron XBB.1.5 is and what it is used for
2. What you need to know before your child receives Comirnaty Omicron XBB.1.5
3. How Comirnaty Omicron XBB.1.5 is given
4. Possible side effects
5. How to store Comirnaty Omicron XBB.1.5
6. Contents of the pack and other information

#### 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
- chills
- joint pain
- diarrhoea
- fever

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

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

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

- feeling unwell
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- feeling weak or lack of energy/sleepy
- 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. You can also report side effects directly via the national reporting system listed in [Appendix V](#) and include batch/Lot number if available. 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.

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

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 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 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.

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 discoloration.

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.
  - A single dose vial contains 1 dose of 0.3 mL with 10 micrograms of raxtozinameran per dose.
  - 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 either:

- A single dose vial of 1 dose in a 2 mL clear vial (type I glass), with a rubber stopper and a blue flip-off plastic cap with aluminium seal; or
- 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.

Single dose vial pack size: 10 vials

Multidose vial pack size: 10 vials

Not all pack sizes may be marketed.

### **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  
2870 Puurs  
Belgium

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

**België/Belgique/Belgien**  
**Luxembourg/Luxemburg**  
Pfizer S.A./N.V.  
Tél/Tel: +32 (0)2 554 62 11

**Lietuva**  
Pfizer Luxembourg SARL filialas Lietuvoje  
Tel. +370 52 51 4000

**България**  
Пфайзер Люксембург САРЛ, Клон  
България  
Тел: +359 2 970 4333

**Magyarország**  
Pfizer Kft  
Tel: +36 1 488 3700

**Česká republika**  
Pfizer, spol. s r.o.  
Tel: +420 283 004 111

**Malta**  
Vivian Corporation Ltd.  
Tel: +35621 344610

**Danmark**  
Pfizer ApS  
Tlf: +45 44 201 100

**Norge**  
Pfizer AS  
Tlf: +47 67 526 100

**Deutschland**  
BioNTech Manufacturing GmbH  
Tel: +49 6131 90840

**Nederland**  
Pfizer BV  
Tel: +31 (0)10 406 43 01

**Eesti**  
Pfizer Luxembourg SARL Eesti filiaal  
Tel: +372 666 7500

**Österreich**  
Pfizer Corporation Austria Ges.m.b.H  
Tel: +43 (0)1 521 15-0

**Ελλάδα**  
Pfizer Ελλάς Α.Ε.  
Τηλ.: +30 210 6785 800

**Polska**  
Pfizer Polska Sp. z o.o.  
Tel.: +48 22 335 61 00

**España**  
Pfizer, S.L.  
Tel: +34914909900

**Portugal**  
Laboratórios Pfizer, Lda.  
Tel: +351 21 423 5500

**France**  
Pfizer  
Tél +33 1 58 07 34 40

**România**  
Pfizer Romania S.R.L  
Tel: +40 (0) 21 207 28 00



**Hrvatska**

Pfizer Croatia d.o.o.  
Tel: +385 1 3908 777

**Ireland**

Pfizer Healthcare Ireland  
Tel: 1800 633 363 (toll free)  
+44 (0)1304 616161

**Ísland**

Icepharma hf  
Simi: +354 540 8000

**Italia**

Pfizer S.r.l.  
Tel: +39 06 33 18 21

**Κύπρος**

Pfizer Ελλάς A.E. (Cyprus Branch)  
Τηλ: +357 22 817690

**Latvija**

Pfizer Luxembourg SARL filiāle Latvijā  
Tel.: +371 670 35 775

**Slovenija**

Pfizer Luxembourg SARL  
Pfizer, podružnica za svetovanje s področja  
farmacevtske dejavnosti, Ljubljana  
Tel.: +386 (0) 1 52 11 400

**Slovenská republika**

Pfizer Luxembourg SARL,  
organizačná zložka  
Tel: +421 2 3355 5500

**Suomi/Finland**

Pfizer Oy  
Puh/Tel: +358 (0)9 430 040

**Sverige**

Pfizer AB  
Tel: +46 (0)8 550 520 00

**United Kingdom (Northern Ireland)**

Pfizer Limited  
Tel: +44 (0) 1304 616161

**This leaflet was last revised in**

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



URL: [www.comirnatyglobal.com](http://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.

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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.

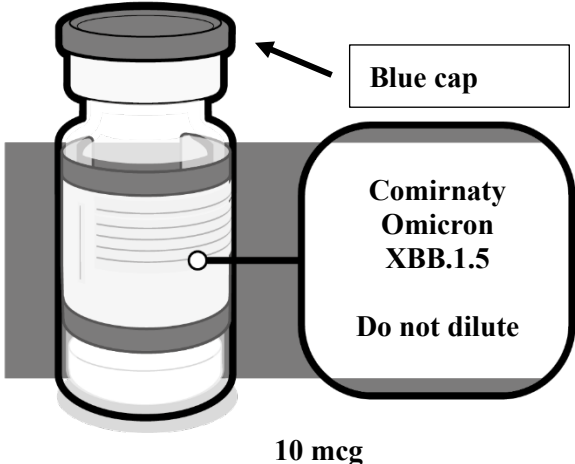
Additional doses may be given to individuals who are severely immunocompromised.

### Traceability

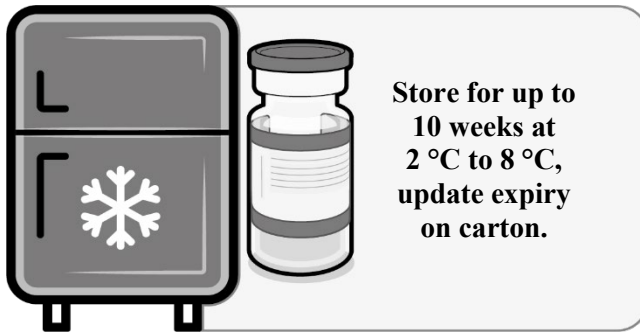
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

### Handling instructions

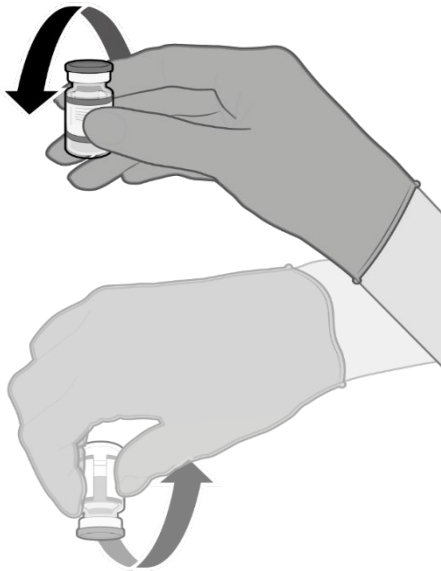
Comirnaty Omicron XBB.1.5 should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

<b>INSTRUCTIONS APPLICABLE TO BOTH SINGLE DOSE AND MULTIDOSE VIALS</b>	
<b>VIAL VERIFICATION OF COMIRNATY OMICRON XBB.1.5 10 MICROGRAMS/DOSE DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)</b>	
	<ul style="list-style-type: none"><li>• <b>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.</b></li><li>• Check whether the vial is a single dose vial or a multidose vial and follow the applicable handling instructions below.</li><li>• If the vial has another product name on the label, please make reference to the Summary of Product Characteristics for that formulation.</li></ul>

**HANDLING PRIOR TO USE OF COMIRNATY OMICRON XBB.1.5  
10 MICROGRAMS/DOSE DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)**

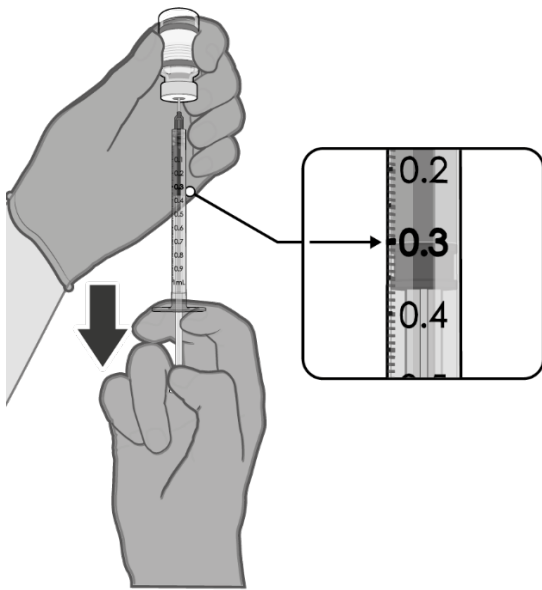


- If the single or multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw. Ensure vials are completely thawed prior to use.
  - Single dose vials: A 10-vial pack of single dose vials may take 2 hours to thaw.
  - Multidose vials: 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.



- 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 discoloration are present.

**PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY OMICRON XBB.1.5  
10 MICROGRAMS/DOSE DISPERSION FOR INJECTION (CHILDREN 5 TO 11 YEARS)**



**0.3 mL vaccine**

Single dose vials

- Withdraw a single 0.3 mL dose of vaccine.
- Discard vial and any excess volume.

Multidose vials

- 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.

## Package leaflet: Information for the user

### Comirnaty Omicron XBB.1.5 3 micrograms/dose concentrate for dispersion for injection Infants and children 6 months to 4 years COVID-19 mRNA Vaccine (nucleoside modified) 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

1. What Comirnaty Omicron XBB.1.5 is and what it is used for
2. What you need to know before your child receives Comirnaty Omicron XBB.1.5
3. How Comirnaty Omicron XBB.1.5 is given
4. Possible side effects
5. How to store Comirnaty Omicron XBB.1.5
6. Contents of the pack and other information

#### 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 3 micrograms/dose concentrate for dispersion for injection is given to infants and children from 6 months to 4 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 may be lower in people who are immunocompromised. If your child is immunocompromised, he/she may receive additional doses of Comirnaty. 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 3 micrograms/dose concentrate for dispersion for injection is not recommended for children aged 5 years to 11 years.

There are paediatric formulations available for children 5 to 11 years of age. 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**

Comirnaty Omicron XBB.1.5 3 micrograms/dose concentrate for dispersion for injection is not intended for individuals older than 5 years of age.

For details for use in individuals older than 5 years of age, please refer to the Package Leaflet for those formulations.

### **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**

If your infant is from 6 months to less than 12 months of age, he/she will be given Comirnaty Omicron XBB.1.5 after dilution as an injection of 0.2 mL into a muscle of the thigh. If your infant or child is 1 year of age or older, he/she will be given Comirnaty Omicron XBB.1.5 after dilution as an injection of 0.2 mL into a muscle of the thigh or into a muscle of the upper arm.

If your child has not completed a COVID-19 primary vaccination course or has not been infected by COVID-19 in the past, your child will receive a maximum of 3 injections (the total number of doses required as primary course). It is recommended to receive the second dose 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose to complete the primary course.

If your child has previously completed a COVID-19 primary vaccination course or has had COVID-19, your child will receive 1 injection. If your child was previously vaccinated with a COVID-19 vaccine, your child should not receive a dose of Comirnaty Omicron XBB.1.5 until at least 3 months after the most recent dose.

If your child turns 5 years old between their doses in the primary course, he/she should complete the primary course at the same 3 micrograms dose level.

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

#### Interchangeability

Your child may receive either Comirnaty, Comirnaty Original/Omicron BA.4-5, or Comirnaty Omicron XBB.1.5 (or a combination) for the primary course. Your child should not receive more than the total number of doses needed as primary course. Your child should only be administered the primary course once.

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

- irritability (6 months to < 2 years)
- injection site: pain/tenderness, swelling
- tiredness
- headache
- drowsiness (6 months to < 2 years)
- muscle pain
- chills
- joint pain
- diarrhoea
- fever

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

- nausea
- vomiting
- injection site redness ('very common' in 6 months to 11 years)
- enlarged lymph nodes (more frequently observed after a booster dose)

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

- feeling unwell
- arm pain
- insomnia
- injection site itching

- allergic reactions such as rash ('common' for 6 months to < 2 years) or itching
- feeling weak or lack of energy/sleepy
- decreased appetite ('very common' for 6 months to < 2 years)
- 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. You can also report side effects directly via [the national reporting system listed in Appendix V](#) and include batch/Lot number if available. 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.

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 2 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 3 micrograms raxtozinameran each.
- 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 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 a maroon 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  
2870 Puurs  
Belgium

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

**België/Belgique/Belgien**  
**Luxembourg/Luxemburg**  
Pfizer S.A./N.V.  
Tél/Tel: +32 (0)2 554 62 11

**Lietuva**  
Pfizer Luxembourg SARL filialas Lietuvoje  
Tel: +370 52 51 4000

**България**  
Пфайзер Люксембург САРЛ, Клон  
България  
Тел: +359 2 970 4333

**Magyarország**  
Pfizer Kft  
Tel: +36 1 488 3700

**Česká republika**  
Pfizer, spol. S r.o.  
Tel: +420 283 004 111

**Malta**  
Vivian Corporation Ltd.  
Tel: +35621 344610

**Danmark**  
Pfizer ApS  
Tlf: +45 44 201 100

**Norge**  
Pfizer AS  
Tlf: +47 67 526 100

**Deutschland**  
BioNTech Manufacturing GmbH  
Tel: +49 6131 90840

**Nederland**  
Pfizer BV  
Tel: +31 (0)10 406 43 01

**Eesti**  
Pfizer Luxembourg SARL Eesti filiaal  
Tel: +372 666 7500

**Österreich**  
Pfizer Corporation Austria Ges.m.b.H  
Tel: +43 (0)1 521 15-0

**Ελλάδα**  
Pfizer Ελλάς Α.Ε.  
Τηλ.: +30 210 6785 800

**Polska**  
Pfizer Polska Sp. Z o.o.  
Tel.: +48 22 335 61 00

**España**  
Pfizer, S.L.  
Tel: +34914909900

**Portugal**  
Laboratórios Pfizer, Lda.  
Tel: +351 21 423 5500

**France**  
Pfizer  
Tél +33 1 58 07 34 40

**România**  
Pfizer Romania S.R.L  
Tel: +40 (0) 21 207 28 00

**Hrvatska**

Pfizer Croatia d.o.o.  
Tel: +385 1 3908 777

**Ireland**

Pfizer Healthcare Ireland  
Tel: 1800 633 363 (toll free)  
+44 (0)1304 616161

**Ísland**

Icepharma hf  
Simi: +354 540 8000

**Italia**

Pfizer S.r.l.  
Tel: +39 06 33 18 21

**Κύπρος**

Pfizer Ελλάς A.E. (Cyprus Branch)  
Τηλ: +357 22 817690

**Latvija**

Pfizer Luxembourg SARL filiāle Latvijā  
Tel.: +371 670 35 775

**Slovenija**

Pfizer Luxembourg SARL  
Pfizer, podružnica za svetovanje s področja  
farmacevtske dejavnosti, Ljubljana  
Tel.: +386 (0) 1 52 11 400

**Slovenská republika**

Pfizer Luxembourg SARL,  
organizačná zložka  
Tel: +421 2 3355 5500

**Suomi/Finland**

Pfizer Oy  
Puh/Tel: +358 (0)9 430 040

**Sverige**

Pfizer AB  
Tel: +46 (0)8 550 520 00

**United Kingdom (Northern Ireland)**

Pfizer Limited  
Tel: +44 (0) 1304 616161

**This leaflet was last revised in**

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



URL: [www.comirnatyglobal.com](http://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.

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**The following information is intended for healthcare professionals only:**

If the child has not completed a COVID-19 primary vaccination course or does not have a history of prior SARS-CoV-2 infection, administer Comirnaty Omicron XBB.1.5 intramuscularly after dilution as a primary course of maximum 3 doses (the total number of doses required as primary course) (0.2 mL each); the second dose administered 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose to complete the primary course.

If the child has completed a COVID-19 primary vaccination course or has a history of prior SARS-CoV-2 infection, administer Comirnaty Omicron XBB.1.5 intramuscularly after dilution a single dose of 0.2 mL. If the individual was previously vaccinated with a COVID-19 vaccine, the individual should receive a dose of Comirnaty Omicron XBB.1.5 at least 3 months after the most recent dose.

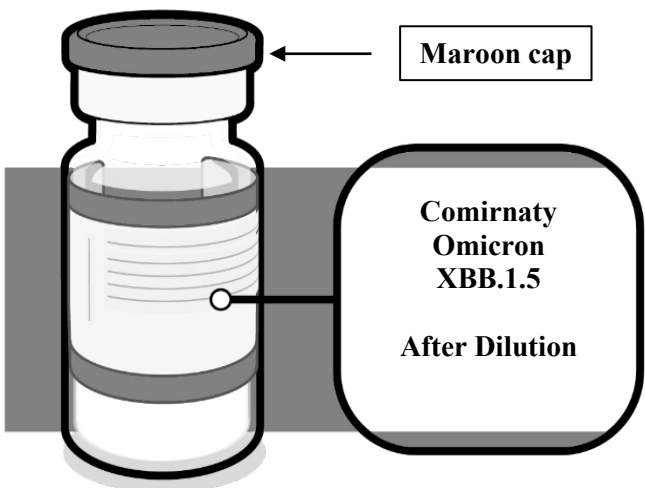
Additional doses may be given to individuals who are severely immunocompromised.

### Traceability

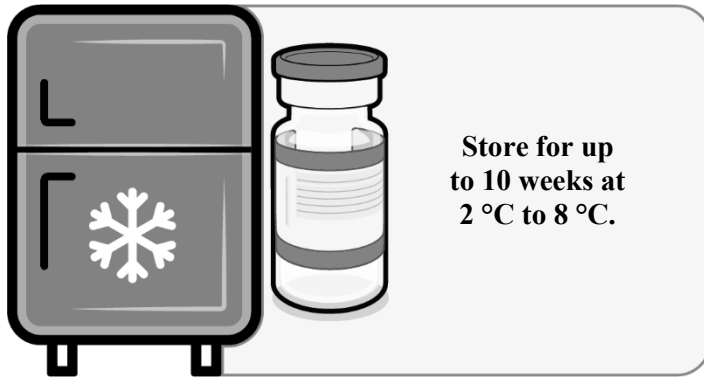
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

### 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.

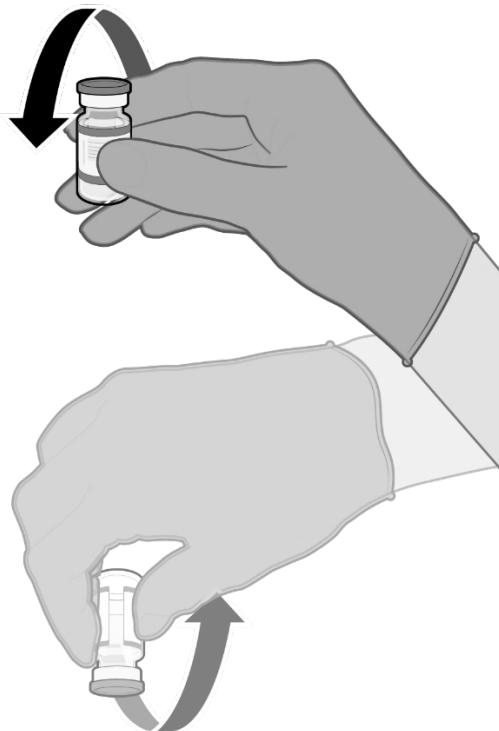
<b>VIAL VERIFICATION OF COMIRNATY OMICRON XBB.1.5 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)</b>	
 <p>3 mcg</p>	<ul style="list-style-type: none"><li>• <b>Verify that the vial has a maroon plastic cap and the product name is Comirnaty Omicron XBB.1.5 3 micrograms/dose concentrate for dispersion for injection.</b></li><li>• If the vial has another product name on the label, please make reference to the Summary of Product Characteristics for that formulation.</li></ul>

**HANDLING PRIOR TO USE OF COMIRNATY OMICRON XBB.1.5  
3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION  
(INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)**



- 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 2 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.

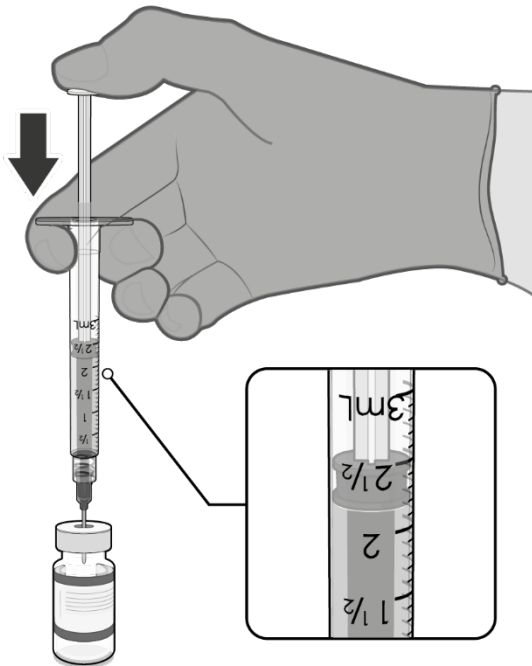
**MIXING PRIOR TO DILUTION OF COMIRNATY OMICRON XBB.1.5  
3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION  
(INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)**



**Gently × 10**

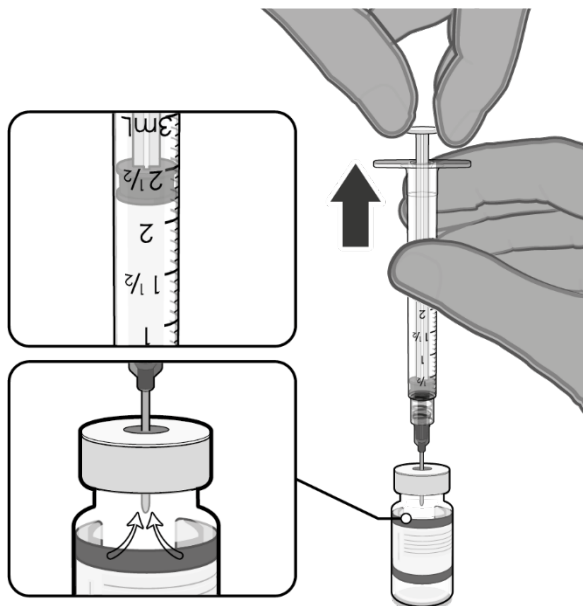
- Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.
- Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.

**DILUTION OF COMIRNATY OMICRON XBB.1.5 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)**



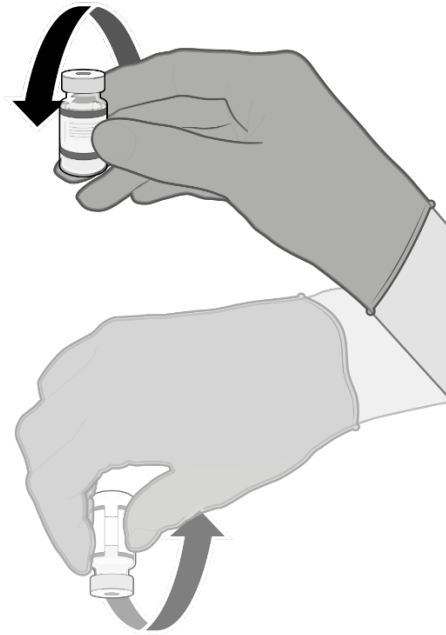
**2.2 mL of sodium chloride 9 mg/mL (0.9%) solution for injection.**

- The thawed vaccine must be diluted in its original vial with 2.2 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.



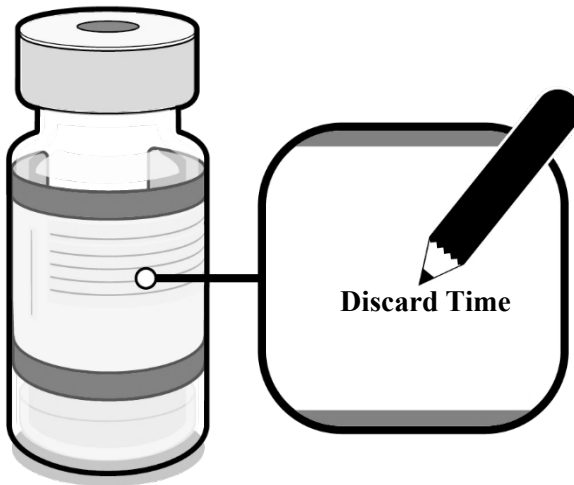
**Pull back plunger to 2.2 mL to remove air from vial.**

- Equalise vial pressure before removing the needle from the vial stopper by withdrawing 2.2 mL air into the empty diluent syringe.



**Gently × 10**

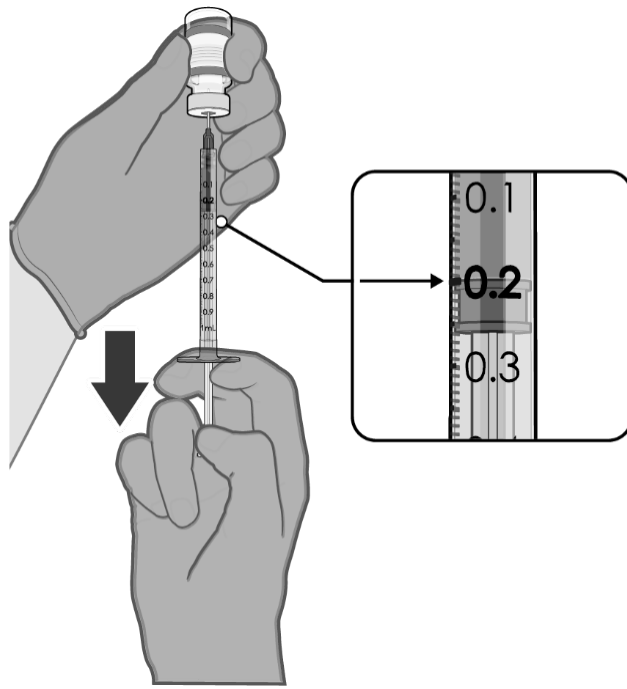
- Gently invert the diluted dispersion 10 times. Do not shake.
- The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.



**Record appropriate date and time.  
Use within 12 hours after dilution.**

- 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  
3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION  
(INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)**



**0.2 mL diluted vaccine**

- 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 infants and children aged 6 months to 4 years.

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.

If standard syringes and needles are used, there may not be sufficient volume to extract ten doses from a single vial.

- 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.