PAA214010
038

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

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▼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

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 (hypoaesthesia)
- 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 below and include batch/Lot number if available. By reporting side effects you can help provide more information on the safety of this medicine.

- **België/Belgique/Belgien**
  Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten, Afdeling Vigilantie,
  Galileelaan 5/03, 1210 BRUSSEL,
  Postbus 97, 1000 BRUSSEL, Madou
  Website: www.eenbijwerkingmelden.be
  e-mail: adr@fagg.be
  Agence fédérale des médicaments et des produits de santé, Division Vigilance,
  Avenue Galilée 5/03, 1210 BRUXELLES,
  Boîte Postale 97, 1000 BRUXELLES, Madou
  Site internet: www.notifieruneffetindesirable.be
  e-mail: adr@afmps.be
- **България**
  Изпълнителна агенция по лекарствата, ул. „Дамян Груев" № 8, 1303 София, Тел.: +359 2 8903417
  уебсайт: www.bda.bg
- **Česká republika**
  Státní ústav pro kontrolu léčiv, Šrobárova 48,
  100 41 Praha 10,
  Webové stránky: www.sukl.cz/nahlasit-nezadouci-ucinek
- **Danmark**
  Lægemiddelstyrelsen, Axel Heides Gade 1,
  DK-2300 København S,
  Websted: www.meldenbivirkning.dk
- **Deutschland**
  Bundesinstitut für Impfstoffe und biomedizinische Arzneimittel, Paul-Ehrlich-Institut,
  Paul-Ehrlich-Str. 51-59, 63225 Langen, Tel: +49 6103 77 0,
  Fax: +49 6103 77 1234, Website: www.pei.de
- **Eesti**
  Ravimiamet, Koduleht: www.ravimiamet.ee
- **Ελλάδα**
  Εθνικός Οργανισμός Φαρμάκων,
  Μεσογείων 284, GR-15562 Χολαργός, Αθήνα,
  Τηλ: + 30 21 32040380/337,
  Φαξ: + 30 21 06549585,
  Ιστότοπος: http://www.eof.gr
- **España**
  Sistema Español de Farmacovigilancia de Medicamentos de Uso Humano: www.notificaRAM.es
- **France**
  Agence nationale de sécurité du médicament et des produits de santé (ANSM) et réseau des Centres Régionaux de Pharmacovigilance
  Site internet: https://signalement.social-sante.gouv.fr/
- **Hrvatska**
  Agencija za lijekove i medicinske proizvode (HALMED)
  Internetska stranica: www.halmed.hr ili potražite HALMED aplikaciju putem Google Play ili Apple App Store trgovine
- **Ireland**
  HPRA Pharmacovigilance, Website: www.hpra.ie
- **Ísland**
  til Lyfjastofnunar, www.lyfjastofnun.is
- **Italia**
  Agenzia Italiana del Farmaco, Sito web:
  https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse
- **Κύπρος**
  Φαρμακευτικές Υπηρεσίες, Υπουργείο Υγείας, CY-1475
  Λευκωσία, Τηλ: +357 22608607, Φαξ: + 357 22608669,
  Ιστότοπος: www.moh.gov.cy/phs
- **Latvija**
  Zāļu valsts aģentūra, Jersikas iela 15, Rīga, LV 1003,
  Tīmekļa vietne: www.zva.gov.lv
- **Lietuva**
  Valstybinė vaistų kontrolės tarnyba prie Lietuvos Respublikos sveikatos apsaugos ministerijos
  Tel.: 8 800 73568
  El. paštas: NepageidaujamaR@vvkt.lt
  Pranešimo forma pildymui internetu:
  https://vapris.vvkt.lt/vvkt-web/public/nrv
  Pranešimo forma skelbiama
  https://www.vvkt.lt/index.php?4004286486
- **Luxembourg/Luxemburg**
  Centre Régional de Pharmacovigilance de Nancy ou Division de la pharmacie et des médicaments de la Direction de la santé
  Site internet : www.guichet.lu/pharmacovigilance
- **Magyarország**
  Nemzeti Népegészségügyi és Gyógyszerészeti Központ
  Postafiók 450, H-1372 Budapest
  Honlap: www.ogyei.gov.hu
  elektronikus bejelentő form: https://mellekhatas.ogyei.gov.hu/
  e-mail: adr.box@ogyei.gov.hu
- **Malta**
  ADR Reporting Website:
  www.medicinesauthority.gov.mt/adrportal
- **Nederland**
  Nederlands Bijwerkingen Centrum Lareb
  Website: www.lareb.nl
- **Norge**
  Statens legemiddelverk
  Nettside: www.legemiddelverket.no/pasientmelding
- **Österreich**
  Bundesamt für Sicherheit im Gesundheitswesen,
  Traisengasse 5, 1200 WIEN, ÖSTERREICH
  Fax: + 43 (0) 50 555 36207,
  Website: http://www.basg.gv.at/
- **Polska**
  Departament Monitorowania Niepożądanych Działań Produktów Leczniczych Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Al. Jerozolimskie 181C, PL-02 222 Warszawa
  Tel.: + 48 22 49 21 301, Faks: + 48 22 49 21 309
  Strona internetowa: https://smz.ezdrowie.gov.pl
- **Portugal**
  Sitio da internet:
  http://www.infarmed.pt/web/infarmed/submissaoram (preferencialmente) ou através dos seguintes contactos:
  Direção de Gestão do Risco de Medicamentos Parque da Saúde de Lisboa, Av. Brasil 53, 1749-004 Lisboa
  Tel: +351 21 798 73 73
  Linha do Medicamento: 800222444 (gratuita)
  e-mail: farmacovigilancia@infarmed.pt
- **România**
  Agenția Națională a Medicamentului și a Dispozitivelor Medicale din România Str. Aviator Sănătescu nr. 48, sector 1 București 011478- RO
  e-mail: adr@anm.ro, Website: www.anm.ro
- **Slovenija**
  Javna agencija Republike Slovenije za zdravila in medicinske pripomočke, Sektor za farmakovigilanco, Nacionalni center za farmakovigilanco, Slovenčeva ulica 22, SI-1000 Ljubljana
  Tel: +386 (0)8 2000 500, Faks: +386 (0)8 2000 510
  e-pošta: h-farmakovigilanca@jazmp.si
  spletna stran: www.jazmp.si
- **Slovenská republika**
  Štátny ústav pre kontrolu liečiv, Sekcia klinického skúšania liekov a farmakovigilancie, Kvetná 11,
  SK-825 08 Bratislava,
  Tel: + 421 2 507 01 206
  e-mail: neziaduce.ucinky@sukl.sk
  Tlačivo na hlásenie podozrenia na nežiaduci účinok lieku je na webovej stránke www.sukl.sk v časti Bezpečnosť liekov/ Hlásenie podozrení na nežiaduce účinky liekov, Formulár na elektronické podávanie hlásení:
  https://portal.sukl.sk/eskadra/
- **Suomi/Finland**
  www-sivusto: www.fimea.fi, Lääkealan turvallisuus- ja kehittämiskeskus Fimea, Lääkkeiden haittavaikutusrekisteri, PL 55, 00034 FIMEA
  webbplats: www.fimea.fi,
  Säkerhets- och utvecklingscentret för läkemedelsområdet Fimea, Biverkningsregistret, PB 55, 00034 FIMEA
- **Sverige**
  Läkemedelsverket, Box 26, 751 03 Uppsala
  Webbplats: www.lakemedelsverket.se
- **United Kingdom (Northern Ireland)**
  Yellow Card Scheme
  Website: https://coronavirus-yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store

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

Manufacturer

BioNTech Manufacturing GmbH
Kupferbergterrasse 17 - 19
55116 Mainz
Germany

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

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

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Danmark
Pfizer ApS, Tlf: +45 44 201 100

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BioNTech Manufacturing GmbH, Tel: +49 6131 90840

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

Ελλάδα
Pfizer Ελλάς A.E., Τηλ.: +30 210 6785 800

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

France
Pfizer, Tél +33 1 58 07 34 40

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

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

Magyarország
Pfizer Kft, Tel: +36 1 488 3700

Malta
Vivian Corporation Ltd., Tel: +35621 344610

Norge
Pfizer AS, Tlf: +47 67 526 100

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

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

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

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

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

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 08/2023.

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:

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.

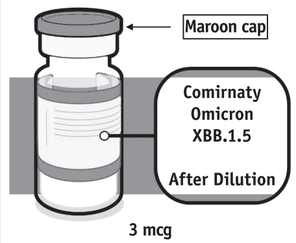
If the child has completed a COVID-19 primary vaccination course or has a history of prior SARS-CoV-2 infection, administer Comirnaty Omicron XBB.1.5 intramuscularly after dilution a single dose of 0.2 mL. If the individual was previously vaccinated with a COVID-19 vaccine, the individual should receive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

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



3 mcg

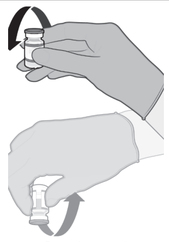
- **Verify that the vial has a maroon plastic cap and the product name is Comirnaty Omicron XBB.1.5 3 micrograms/dose concentrate for dispersion for injection.**
- If the vial has another product name on the label, please make reference to the Summary of Product Characteristics for that formulation.

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


Store for up to 10 weeks at 2 °C to 8 °C.

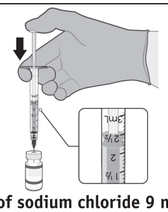
- If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 10-vial pack may take 2 hours to thaw. Ensure vials are completely thawed prior to use.
- Upon moving vials to 2 °C to 8 °C storage, update the expiry 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)

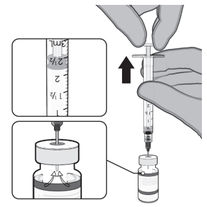

Gently × 10

- 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.

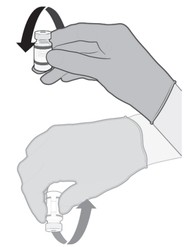
DILUTION OF COMIRNATY OMICRON XBB.1.5 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)


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

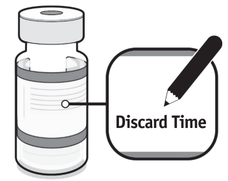
- The thawed vaccine must be diluted in its original vial with 2.2 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.


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

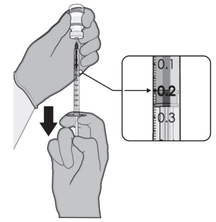
- Gently invert the diluted dispersion 10 times. Do not shake.
- The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.



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.