Package leaflet: Information for the user

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

▼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 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 your child gets 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 is and what it is used for

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

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

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

Comirnaty 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 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 Comirnaty 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 have 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. 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 may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of Comirnaty, even after a third dose, may be lower in people who are immunocompromised. 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 3 micrograms/dose concentrate for dispersion for injection is not recommended for children aged 5 years to 11 years. There is a paediatric presentation available for children 5 years to 11 years. For details, please refer to the Package Leaflet for Comirnaty 10 micrograms/dose concentrate for dispersion for injection.

Comirnaty is not recommended for infants aged under 6 months.

Other medicines and Comirnaty
Tell your 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 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 Comirnaty 30 micrograms/dose concentrate for dispersion for injection, Comirnaty 30 micrograms/dose dispersion for injection or Comirnaty 10 micrograms/dose concentrate for dispersion for injection.

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

3. How Comirnaty is given

Comirnaty is given after dilution as an injection of 0.2 mL into a muscle of the thigh in infants from 6 to less than 12 months of age. In infants and children 1 year of age or older, Comirnaty is given after dilution as an injection of 0.2 mL into a muscle of the thigh or into a muscle of the upper arm.

Your child will receive 3 injections.

It is recommended to receive the second dose of the same vaccine 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose to complete the vaccination course.

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

If you have any further questions on the use of Comirnaty, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty 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)

Uncommon side effects: may affect up to 1 in 100 people
- enlarged lymph nodes (more frequently observed after the booster dose)
- 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 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 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

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 contains

- The active substance is COVID-19 mRNA Vaccine called tozinameran. After dilution, the vial contains 10 doses of 0.2 mL with 3 micrograms tozinameran 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 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 sizes: 10 vials

Not all pack sizes may be marketed.

Marketing Authorisation Holder
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55131 Mainz
Germany
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Pfizer Manufacturing Belgium NV
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2870 Puurs
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For any information about this medicine, please contact: Medical Information, Pfizer Ltd, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS. Telephone 01304 616161.

This leaflet was last revised in 03/2023.

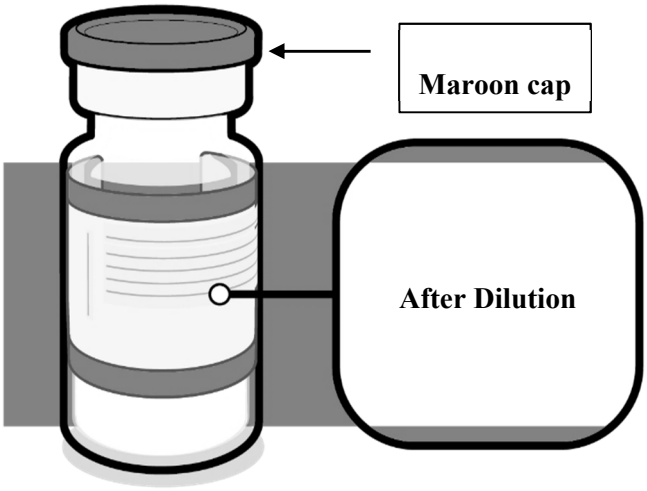
Ref: bCY/3mcg 3_0

The following information is intended for healthcare professionals only:
Administer Comirnaty intramuscularly after dilution as a course of 3 doses (0.2 mL each); the second dose of the same vaccine administered 3 weeks after the first dose followed by a third dose at least 8 weeks after the second dose to complete the vaccination course.

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 3 micrograms/dose should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

<table>
<tr><th colspan="2">VIAL VERIFICATION OF COMIRNATY 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)</th></tr>
<tr><td> 

3 mcg</td><td>

Verify that the vial has a maroon plastic cap.
If the vial has a purple plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 30 micrograms/dose concentrate for dispersion for injection.
If the vial has a grey plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 30 micrograms/dose dispersion for injection, Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection, or Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection.
If the vial has an orange plastic cap, please make reference to the Summary of Product Characteristics for Comirnaty 10 micrograms/dose concentrate for dispersion for injection or Comirnaty Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection.

</td></tr>
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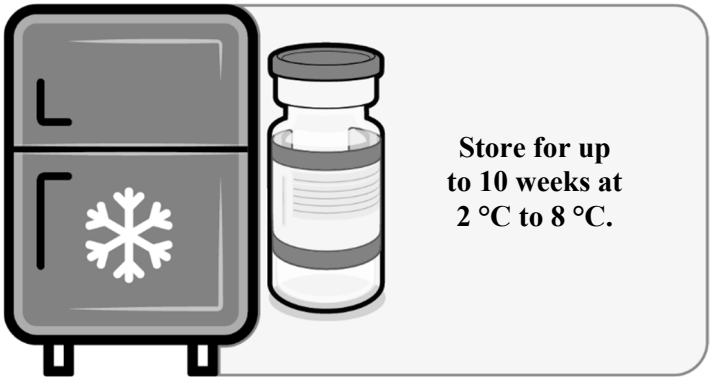
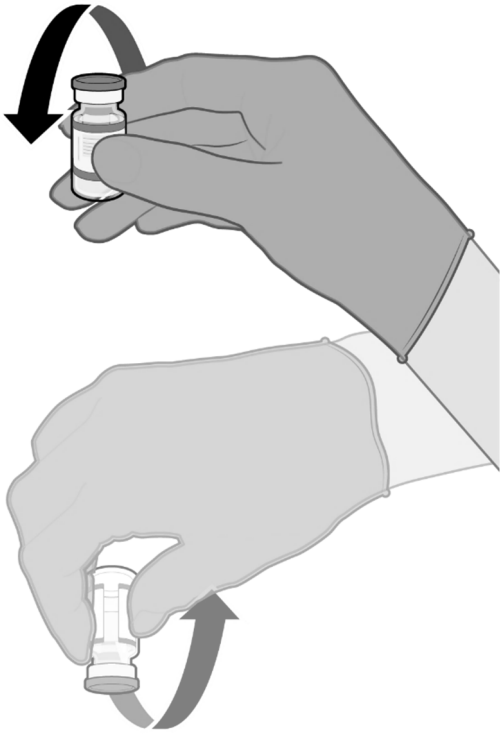
HANDLING PRIOR TO USE OF COMIRNATY 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)



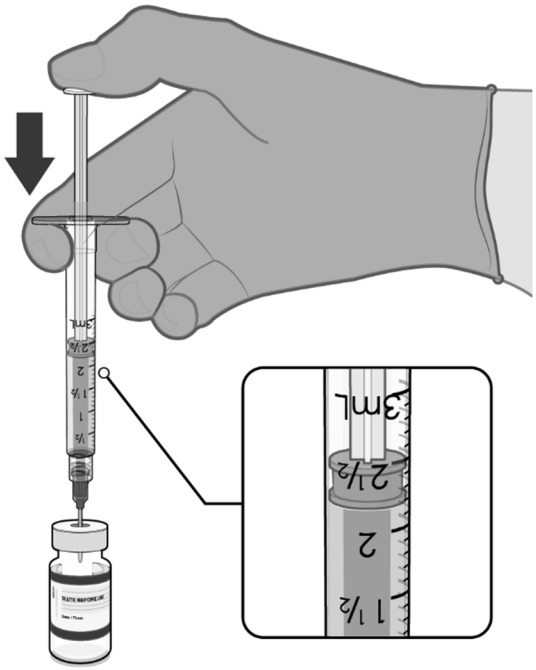
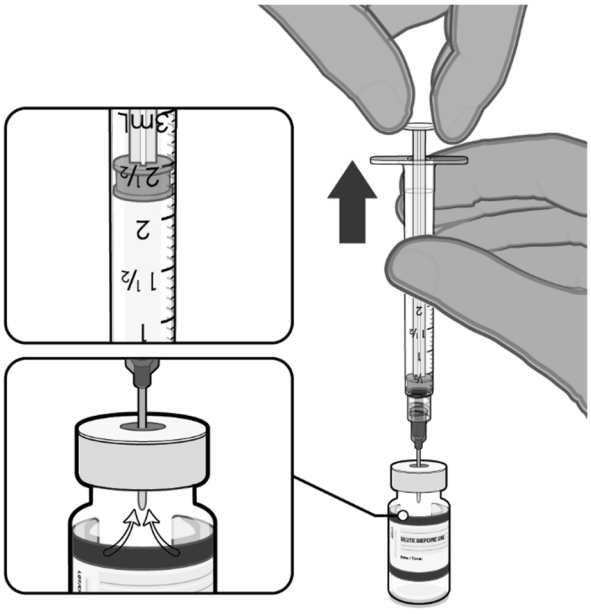
- If the multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 10 vial pack may take 2 hours to thaw. Ensure vials are completely thawed prior to use.
- Upon moving vials to 2 °C to 8 °C storage, update the expiry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

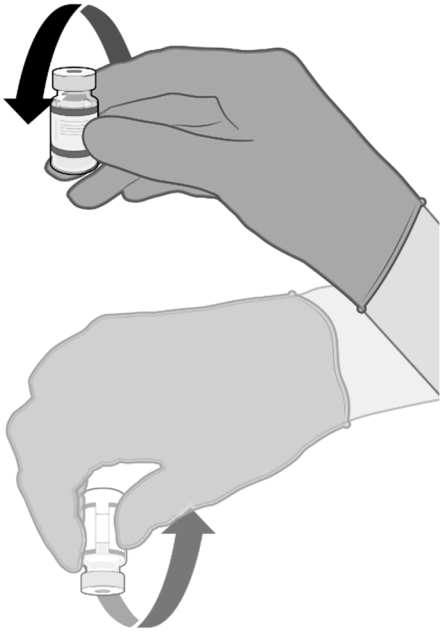
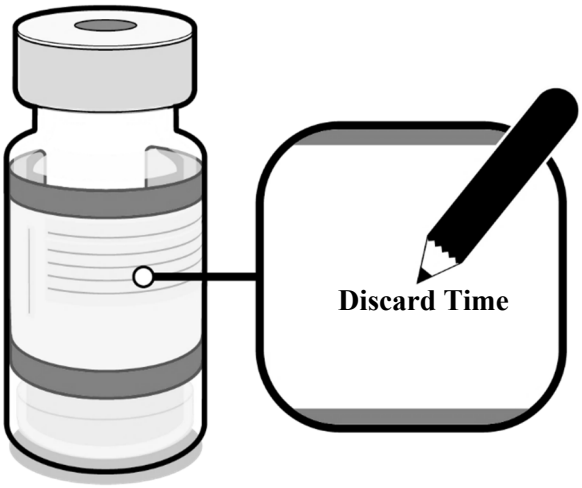
MIXING PRIOR TO DILUTION OF COMIRNATY 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (INFANTS AND CHILDREN 6 MONTHS TO 4 YEARS)



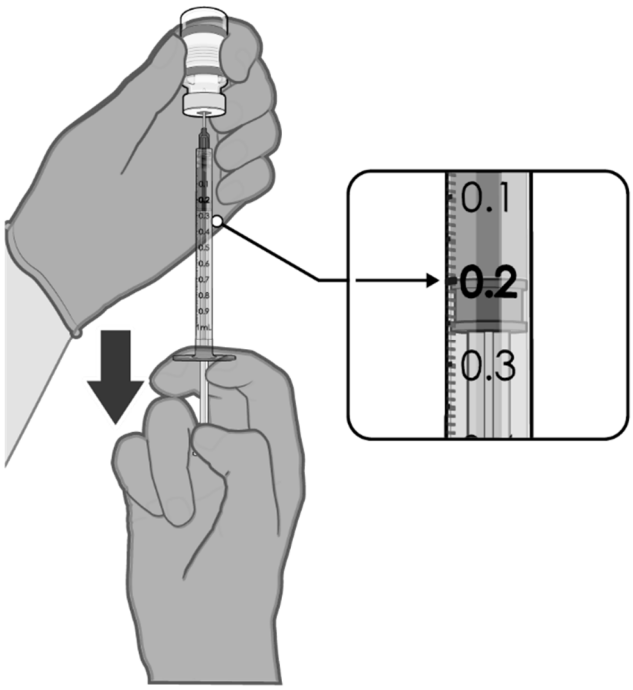
Gently × 10

- 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 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.
 **Discard Time** **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 ºC to 30 ºC 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 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 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.