Package leaflet: Information for the user

COMIRNATY Original/Omicron BA.4-5 1.5/1.5 micrograms per dose Concentrate for Dispersion for Injection
(also called COMIRNATY (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap))
tozinameran/famtozinameran

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 (Bivalent) is and what it is used for

COMIRNATY Original/Omicron BA.4-5 1.5/1.5 micrograms per dose Concentrate for Dispersion for Injection, COVID-19 mRNA Vaccine (nucleoside modified) is called COMIRNATY (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap).

COMIRNATY (Bivalent) is a vaccine used for preventing COVID-19 caused by SARS-CoV-2 virus.

COMIRNATY (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap) is given to infants and children from 6 months to <5 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 (Bivalent) does not contain the virus to produce immunity, it cannot give you COVID-19.

2. What you need to know before you receive COMIRNATY (Bivalent)

COMIRNATY (Bivalent) 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 COMIRNATY or COMIRNATY (Bivalent) in the past.
- you have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart).

- you are feeling nervous about the vaccination process or have ever fainted following any needle injection.
- you have a fever.
- 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.
- you have received another COVID-19 vaccine.

There is a remote chance that COMIRNATY or COMIRNATY (Bivalent) could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of COMIRNATY or COMIRNATY (Bivalent). For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:
- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received COMIRNATY. In most of these people, symptoms began within a few days following receipt of the second dose of COMIRNATY. The risk of myocarditis and pericarditis seems lower in children ages 5 through <12 years compared with ages 12 to 17 years. The chance of having this occur is very low. You should avoid strenuous physical activity for two weeks after vaccination. You should seek medical attention right away if you have any of the following symptoms after receiving COMIRNATY or COMIRNATY (Bivalent):
- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

As with any vaccine, COMIRNATY or COMIRNATY (Bivalent) may not fully protect all those who receive it and it is not known how long you will be protected.

Children
COMIRNATY (Bivalent) is not recommended for infants aged under 6 months.

Other medicines and COMIRNATY (Bivalent)
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 breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before you receive this vaccine.

No data are available yet regarding the use of COMIRNATY (Bivalent) during pregnancy or 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 (Bivalent) is given

Primary vaccination course
COMIRNATY (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap) 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, or into a muscle of the thigh or upper arm in individuals 1 years of age and older.

You 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 primary vaccination course.

If an infant or child starts a primary vaccination course with COMIRNATY (For Age 6 Months to <5 Years) (Vials with Maroon Cap), he/she may complete the series with COMIRNATY (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap).

Individuals who will turn from 4 years to 5 years of age between their doses in the vaccination series should receive their age-appropriate dose at the time of the vaccination and the interval between doses is determined by the individual's age at the start of the vaccination series.

Booster dose
A booster dose of COMIRNATY (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap) may be given at least 3 months after the last prior dose in individuals 6 months through <5 years of age.

If you have any further questions on the use of COMIRNATY (Bivalent), ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, COMIRNATY or COMIRNATY (Bivalent) can cause side effects, although not everybody gets them.

Very common side effects: may affect more than 1 in 10 people
- irritability (individuals 6 months to <2 years of age)
- injection site: pain, tenderness (individuals 6 months to <2 years of age), swelling
- tiredness
- headache
- muscle pain
- chills
- joint pain
- diarrhoea
- increase in body temperature including 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 ('very common' in individuals 6 months to <12 years of age)
- nausea
- vomiting

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 (more frequently observed after the booster dose)
- insomnia
- injection site itching
- allergic reactions such as rash ('common' in individuals 6 months to <2 years of age) or itching
- feeling weak or lack of energy/sleep
- decreased appetite ('very common' in individuals 6 months to <2 years of age)
- dizziness
- excessive sweating
- night sweats ('rare' in individuals 5 years to <12 years of age)

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 tissues under the skin such as 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
- 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)

Reporting of side effects
If you experience a severe allergic reaction, call 995, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **Pfizer Singapore** at the contact information provided below. Please include "Comirnaty Interim Authorization" in the report.

Email	Fax number	Telephone number
SGP.AEReporting@pfizer.com	8001012817 (local toll free)	+65 6403 8888

5. How to store COMIRNATY (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap)

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. The expiry date refers to the last day of that month.

Store in freezer at -90 °C to -60 °C for 18 months.

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, the vaccine can be thawed at either 2 °C to 8 °C or at room temperature (up to 30 °C).

Once removed from the frozen storage, the unopened vial may be stored refrigerated at 2 °C to 8 °C for a single period of up to 10 weeks; not exceeding the 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.

Vaccine may be stored at temperatures between 8 °C to 30 °C for up to 24 hours, including any time at these temperatures following dilution.

Thawed vials can be handled in room light conditions.

After dilution, store and transport the vaccine at 2 °C to 30 °C and use within 12 hours. 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 (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap) contains

- The active substances of COVID-19 mRNA Vaccine are called tozinameran/famtozinameran.
- After dilution, the vial contains 10 doses of 0.2 mL with 1.5 micrograms of tozinameran (Original) and 1.5 micrograms of famtozinameran (Omicron BA.4-5) 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
  - Tromethamine (Tris base)
  - Tris (hydroxymethyl) aminoethane hydrochloride (Tris HCl)
  - Sucrose
  - Water for injection

What COMIRNATY (Bivalent) 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 in a 2 mL clear vial (type I glass), with a rubber stopper and a flip-off plastic cap with aluminium seal, or 2 mL aluminosilicate glass vial with a stopper (bromobutyl rubber) and a flip-off plastic cap with aluminum seal.

Pack size: 10 multidose vials per carton.

Product owner
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz
Germany

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

URL: www.comirnatyglobal.com

Should you have any medical information enquires, you may submit it at https://pmiform.com/HCP/SG.

Alternatively, you may send them to MedicalInformationSingapore@pfizer.com.

7. How can I learn more

- Ask the vaccination provider.
- Visit HSA at https://www.hsa.gov.sg/therapeutic-products/register/special-access-routes/psar-emergency-therapeutic-product.
- Contact your local or state public health department.

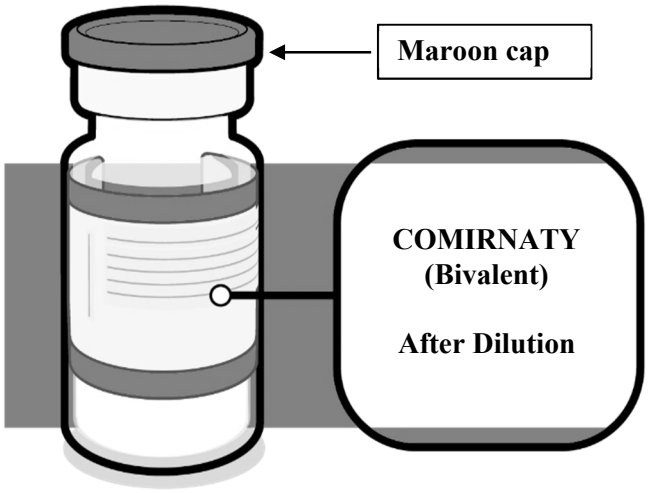
The following information is intended for healthcare professionals only:

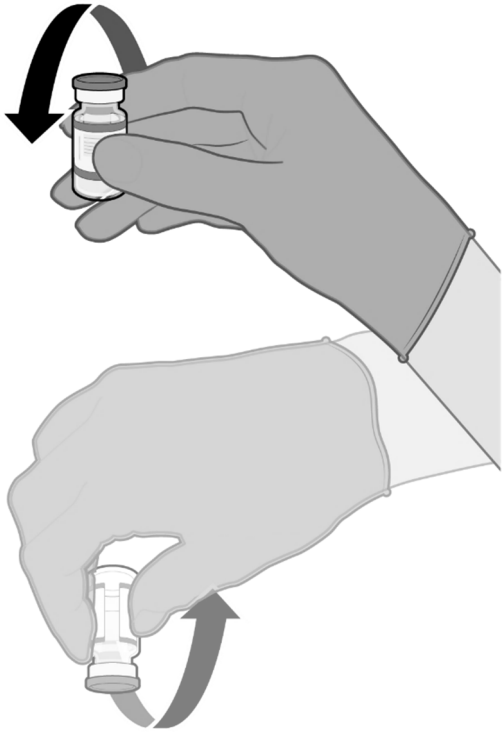
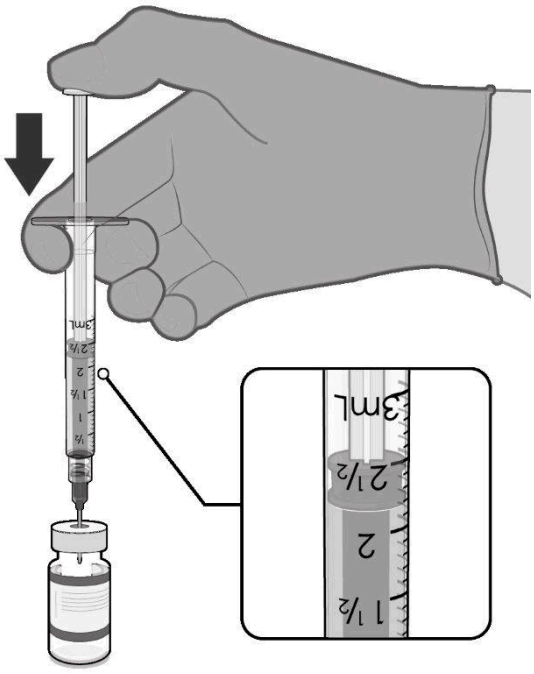
A dose of COMIRNATY (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap) may be given to individuals from 6 months to <5 years of age.

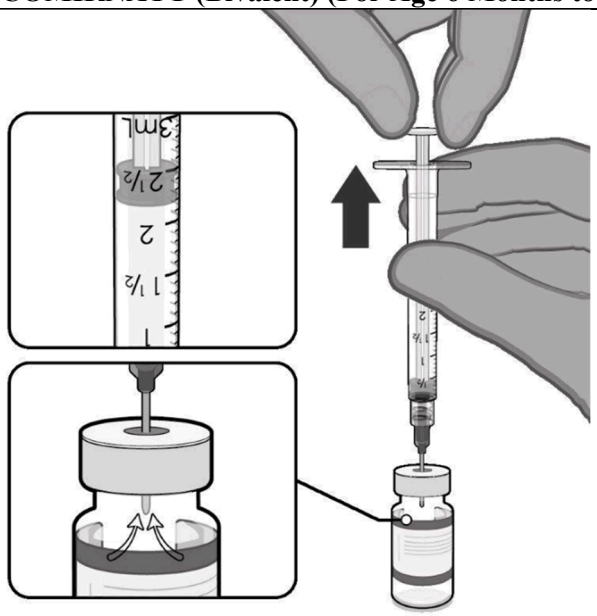
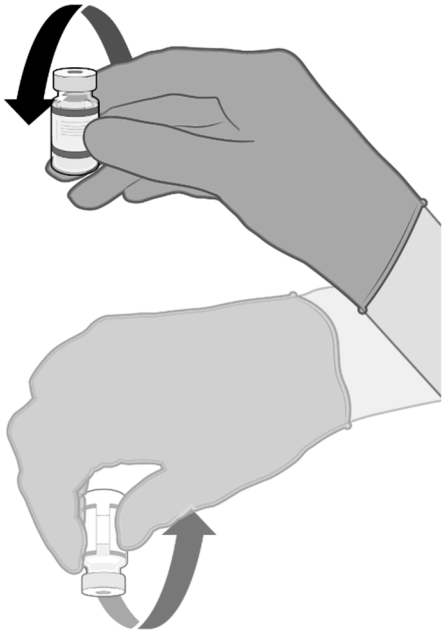
Traceability

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

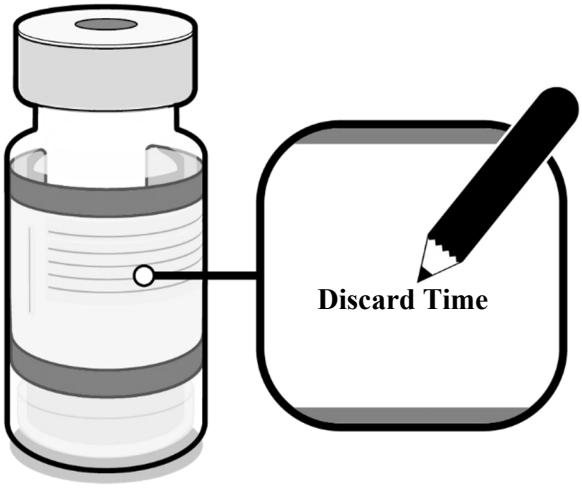
Handling instructions
COMIRNATY (Bivalent) should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

COMIRNATY (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap)	
VIAL VERIFICATION	
 **1.5/1.5 mcg**	• **Verify that the vial has a maroon plastic cap and a maroon border around the label and the product name is COMIRNATY (Original/Omicron BA.4-5) 1.5/1.5 micrograms per dose concentrate for dispersion for injection.** • If the vial has a maroon plastic cap and a maroon border and the product name is COMIRNATY, Concentrate for Dispersion for Injection, 3 micrograms/dose, refer to the handling instructions for COMIRNATY (For Age 6 Months to <5 Years) (Vials with Maroon Cap). • If the vial has a purple, grey, orange or blue plastic cap, refer to the handling instructions for that formulation.
HANDLING PRIOR TO USE	
	• 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. • Unopened vials can be stored for up to 10 weeks at 2 °C to 8 °C; not exceeding the expiry date (EXP). • Alternatively, individual frozen vials may be thawed for 30 minutes at temperatures up to 30 °C for immediate use.

COMIRNATY (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap)	
MIXING PRIOR TO DILUTION	
 **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	
 **2.2 mL of 0.9% sodium chloride 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.

COMIRNATY (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap)	
 **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.

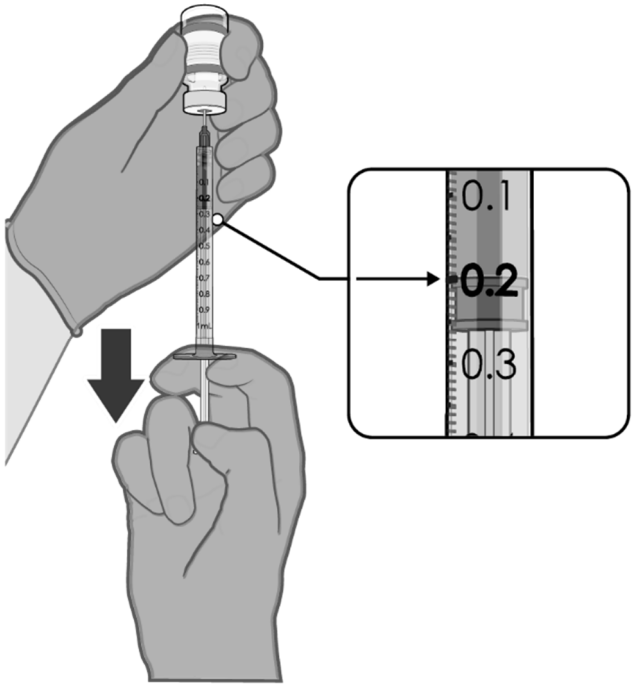
COMIRNATY (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap)



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 (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap)



0.2 mL diluted vaccine

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.2 mL of COMIRNATY (Bivalent) (For Age 6 Months to <5 Years) (Vials with Maroon Cap).

  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.

COMBI03-SIN-0523/PIL/0
Date of last revision: May 2023