Package leaflet: Information for the user

COMIRNATY Original/Omicron BA.4-5 5/5 micrograms per dose Dispersion for Injection
(also called COMIRNATY (Bivalent) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue 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 5/5 micrograms per dose Dispersion for Injection, COVID-19 mRNA Vaccine (nucleoside modified) is called COMIRNATY (Bivalent) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue Cap).

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

COMIRNATY (Bivalent) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue Cap) is given to children from 5 years to <12 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 children 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) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue Cap) is given as an injection of 0.3 mL into a muscle of your upper arm.

You will receive 2 injections.

It is recommended to receive the second dose of the same vaccine 3 weeks after the first dose to complete the primary vaccination course.

Booster dose
A booster dose of COMIRNATY (Bivalent) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue Cap) may be given at least 3 months after the second dose.

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) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue 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 first puncture.

Thawed vials can be handled in room light conditions.

After first puncture, 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 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) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue Cap) contains

- The active substances of COVID-19 mRNA Vaccine are called tozinameran/famtozinameran.
- The vial contains 1 doses of 0.3 mL with 5 micrograms of tozinameran (Original) and 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 clear to slightly opalescent suspension (pH: 6.9 - 7.9) provided in a single dose 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 single dose 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.

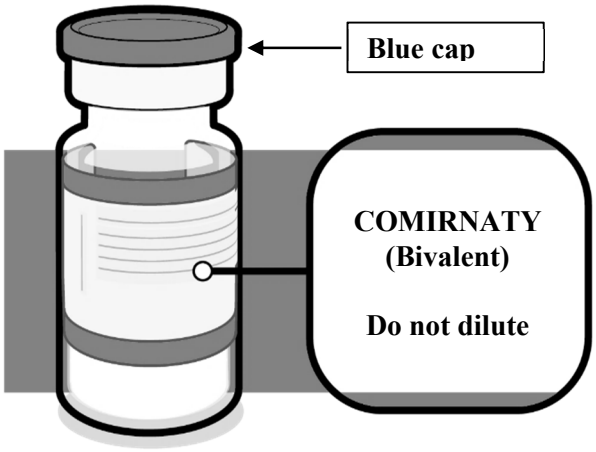
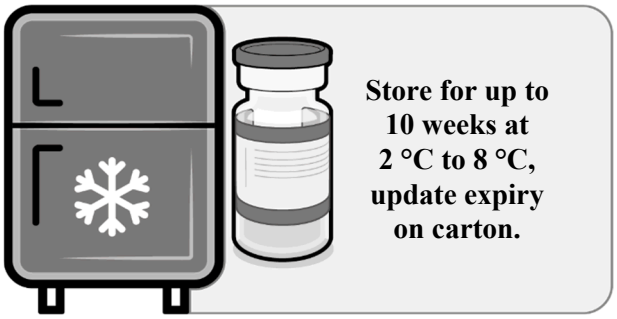
The following information is intended for healthcare professionals only:

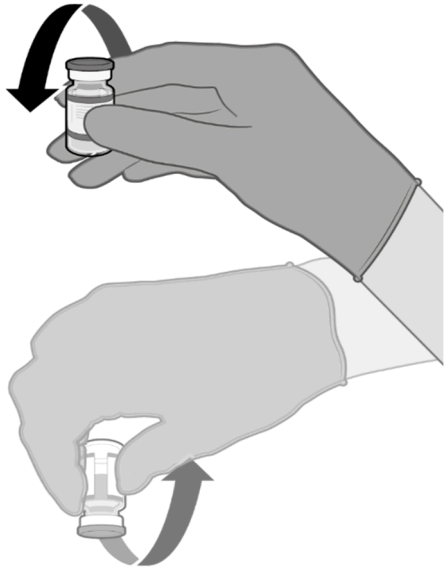
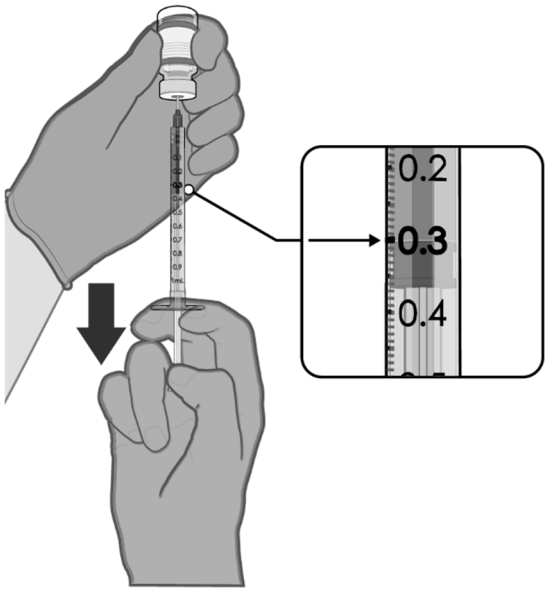
A dose of COMIRNATY (Bivalent) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue Cap) may be given to individuals from 5 years to <12 years of age.

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) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue Cap)	
VIAL VERIFICATION	
 **5/5 mcg**	• **Verify that the vial has a blue cap and a blue border around the label and the product name is COMIRNATY (Original/Omicron BA.4-5) 5/5 micrograms per dose dispersion for injection.** • If the vial has a grey, purple, orange, or maroon plastic cap, refer to the handling instructions for that formulation.
HANDLING PRIOR TO USE	
	• If the single dose 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 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.

<table>
<tr><th colspan="2">COMIRNATY (Bivalent) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue Cap)</th></tr>
<tr><td> 
Gently × 10</td><td>• Gently mix by inverting vials 10 times prior to use. Do not shake.
• Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
• After mixing, the vaccine should present as a clear to slightly opalescent dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.</td></tr>
<tr><th colspan="2">PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY (Bivalent) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue Cap)</th></tr>
<tr><td> 

0.3 mL vaccine</td><td>• Withdraw a single 0.3 mL dose of COMIRNATY (Bivalent) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue Cap).
• Discard vial and any excess volume.</td></tr>
</table>

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

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