

Package leaflet: Information for the user

Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection Adults and adolescents from 12 years COVID-19 mRNA Vaccine (nucleoside modified) 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® Original/Omicron BA.4-5 is and what it is used for
2. What you need to know before you receive Comirnaty® Original/Omicron BA.4-5
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4. Possible side effects
5. How to store Comirnaty® Original/Omicron BA.4-5
6. Contents of the pack and other information

1. What Comirnaty® Original/Omicron BA.4-5 is and what it is used for

Comirnaty® Original/Omicron BA.4-5 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2. It is given to adults and adolescents from 12 years of age and older.

Comirnaty® Original/Omicron BA.4-5 is only for individuals who have previously received at least a primary vaccination course against COVID-19.

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® Original/Omicron BA.4-5 does not contain the virus to produce immunity, it cannot give you COVID-19.

2. What you need to know before you receive Comirnaty® Original/Omicron BA.4-5

Comirnaty® Original/Omicron BA.4-5 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 Comirnaty® or Comirnaty® Original/Omicron BA.4-5 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. 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[®] Original/Omicron BA.4-5 may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of Comirnaty[®] Original/Omicron BA.4-5 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[®] Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection is not recommended for children aged under 12 years.

There is a paediatric presentation available for children 5 to 11 years of age. For details, please refer to the Package Leaflet for Comirnaty[®] Original/Omicron BA.4-5 (5/5 micrograms)/dose concentrate for dispersion for injection.

Other medicines and Comirnaty[®] Original/Omicron BA.4-5

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[®] Original/Omicron BA.4-5 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[®] Original/Omicron BA.4-5 can be used during pregnancy.

No data are available yet regarding the use of Comirnaty[®] Original/Omicron BA.4-5 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[®] Original/Omicron BA.4-5 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® Original/Omicron BA.4-5 is given

Comirnaty® Original/Omicron BA.4-5 is given as an injection of 0.3 mL into a muscle of your upper arm.

Comirnaty® Original/Omicron BA.4-5 may be given at least 3 months after the most recent dose of a COVID-19 vaccine.

Comirnaty® Original/Omicron BA.4-5 is only indicated for individuals who have previously received at least a primary vaccination course against COVID-19.

Please check with your healthcare provider regarding eligibility for and timing of the booster dose.

For details on the primary vaccination course in individuals 12 years of age and older, please see the Package Leaflet for Comirnaty® 30 micrograms/dose dispersion for injection or Comirnaty® 30 micrograms/dose concentrate for dispersion for injection.

If you have any further questions on the use of Comirnaty® Original/Omicron BA.4-5, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Comirnaty® Original/Omicron BA.4-5 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

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 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 (hypoaesthesia)
- 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 to FDA Philippines via online reporting through the FDA Philippines website at <https://www.fda.gov.ph/pharmacovigilance/> and include batch/lot number if available. By reporting side effects, you can help provide more information on the safety of this medicine.

In addition, you can report side effects to Pfizer, Inc. at the contact information provided below.

<i>Reporting Link dedicated for Pfizer-BioNTech/Comirnaty® COVID-19 mRNA Vaccine</i>	<i>Alternate reporting via email and fax</i>	<i>Contact numbers</i>
https://www.pfizersafetyreporting.com/#/en	<i>Email:</i> PHL.AEReporting@pfizer.com <i>Fax:</i> 1 800 1110 1520 (Toll Free)	+63 9178108146 +63 2 8451 9288 +63 2 8415 9200 ext 19288

5. How to store Comirnaty® Original/Omicron BA.4-5

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® Original/Omicron BA.4-5 contains

- The active substances of COVID-19 mRNA Vaccine are tozinameran and famtozinameran.
 - A single dose vial contains 1 dose of 0.3 mL with 15 micrograms of tozinameran (Original) and 15 micrograms of famtozinameran (Omicron BA.4-5) per dose.
 - A multidose vial contains 6 doses of 0.3 mL with 15 micrograms of tozinameran (Original) and 15 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
 - trometamol
 - trometamol hydrochloride
 - sucrose
 - water for injections

What Comirnaty® Original/Omicron BA.4-5 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 sizes: 10 vials.

Multidose vials pack sizes: 10 vials.

Not all pack sizes may be marketed.



Pfizer Inc., New York, NY 10017

BIONTECH

BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

For any information about this medicine, please contact the Emergency Use Authorization (EUA) Holder:

Pfizer, Inc.

19F - 20F, 8 Rockwell Bldg., Hidalgo Drive
Rockwell Center, Poblacion, Makati City 1210
Metro Manila, Philippines

Fax number: 1 800 1110 1520 (Toll Free)

Contact numbers: +63 9175171575, +63 2 8451 9288, +63 2 8415 9200 ext 19288

Please submit your medical information inquiries to <https://pmiform.com/CONS/PH> or for healthcare professionals please visit www.pfizermedicalinformation.ph.

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



URL: www.comirnatyglobal.com

The following information is intended for healthcare professionals only:

The dose of Comirnaty® Original/Omicron BA.4-5 is 0.3 mL given intramuscularly.

There should be an interval of at least 3 months between administration of Comirnaty® Original/Omicron BA.4-5 and the last prior dose of a COVID-19 vaccine.

Comirnaty® Original/Omicron BA.4-5 is only indicated for individuals who have previously received at least a primary vaccination course against COVID-19.

Traceability

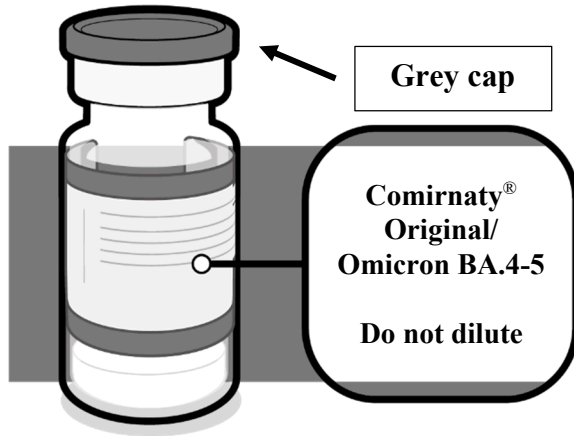
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Handling instructions

Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

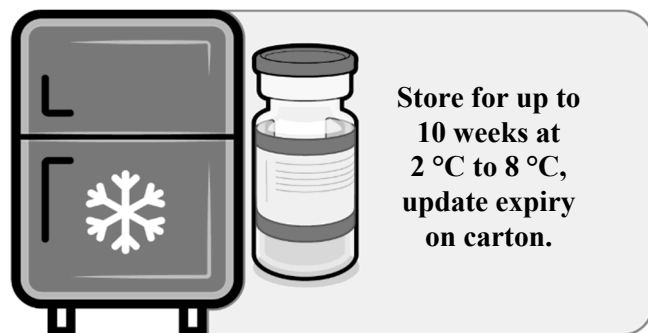
INSTRUCTIONS APPLICABLE TO BOTH SINGLE DOSE AND MULTIDOSE VIALS

**VIAL VERIFICATION OF COMIRNATY® ORIGINAL/OMICRON BA.4-5
(15/15 MICROGRAMS)/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)**

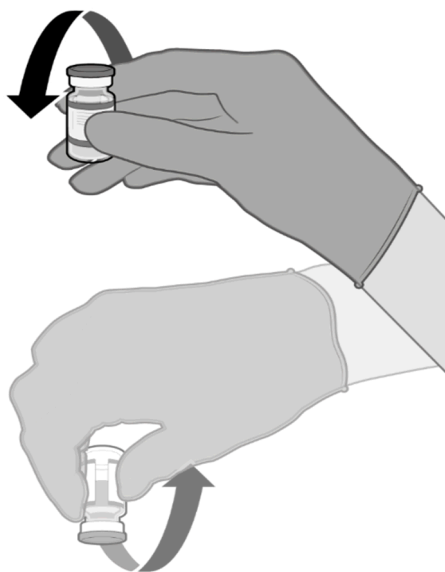


- Verify that the vial has a grey plastic cap and a grey border around the label and the product name is Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection.
- Check whether the vial is a single dose vial or a multidose vial and follow the applicable handling instructions below.
- If the vial has a grey plastic cap and a grey border and the product name is Comirnaty® 30 micrograms/dose dispersion for injection, please make reference to the Product Information for this formulation.
- If the vial has a purple plastic cap, please make reference to the Product Information for Comirnaty® 30 micrograms/dose concentrate for dispersion for injection.
- If the vial has an orange plastic cap, please make reference to the Product Information 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.
- If the vial has a maroon plastic cap, please make reference to the Product Information for Comirnaty® 3 micrograms/dose concentrate for dispersion for injection.

**HANDLING PRIOR TO USE OF COMIRNATY® ORIGINAL/OMICRON BA.4-5
(15/15 MICROGRAMS)/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)**



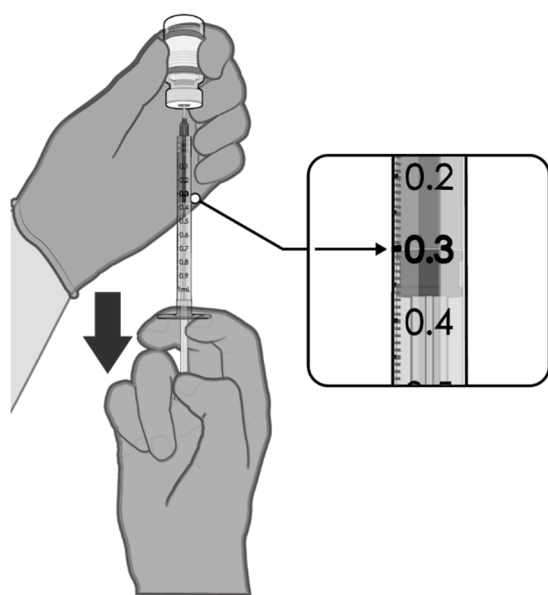
- If the single or multidose vial is stored frozen it must be thawed prior to use. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw. Ensure vials are completely thawed prior to use.
 - Single dose vials: A 10-vial pack of single dose vials may take 2 hours to thaw.
 - Multidose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

- 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 discolouration are present.

**PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY[®]
ORIGINAL/OMICRON BA.4-5 (15/15 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[®] Original/Omicron BA.4-5.

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.

Philippines EUA Product information for vaccine recipients
(Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose
formulation) revision number: **4.0**
Philippines EUA Product information for vaccine recipients
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