Package leaflet: Information for the user

COMIRNATY, COVID-19 mRNA Vaccine (nucleoside modified), 30 micrograms/dose Dispersion for Injection

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 is and what it is used for
2. What you need to know before you receive COMIRNATY
3. How COMIRNATY is given
4. Possible side effects
5. How to store COMIRNATY
6. Contents of the pack and other information

1. What COMIRNATY is and what it is used for

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

COMIRNATY is given to adults and adolescents from 5 years of age and older.

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 you COVID-19.

2. What you need to know before you receive COMIRNATY

COMIRNATY 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 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 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. 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 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:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

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.

Children
COMIRNATY is not recommended for children aged under 5 years.

Other medicines and COMIRNATY
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.

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 is given

COMIRNATY (For 12 Years of Age and Older) (Vials with Grey 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.

A booster dose of COMIRNATY may be given after the second dose.

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
- injection site: pain, 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
- 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 or itching
- feeling weak or lack of energy/sleep
- decreased appetite
- 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

Not known (cannot be estimated from the available data)
- severe allergic reaction
- inflammation of the heart muscle (myocarditis) or inflammation of the lining outside the heart (pericarditis) which can result in breathlessness, palpitations or chest pain
- 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

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 12 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 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.
- The vial contains 6 doses of 0.3 mL with 30 micrograms mRNA 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
  - Tromethamine (Tris base)
  - Tris (hydroxymethyl) aminoethane hydrochloride (Tris HCl)
  - Sucrose
  - Water for injection

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 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:

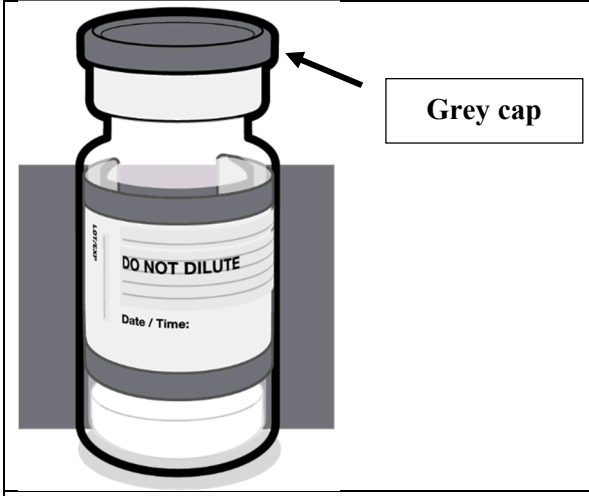
Administer COMIRNATY (For 12 Years of Age and Older) (Vials with Grey Cap) intramuscularly as a primary series of 2 doses (0.3 mL each) 3 weeks apart.

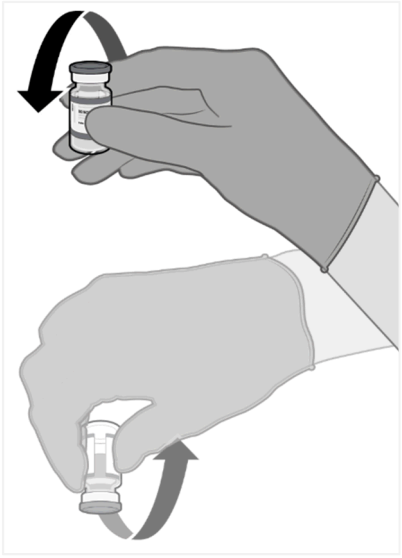
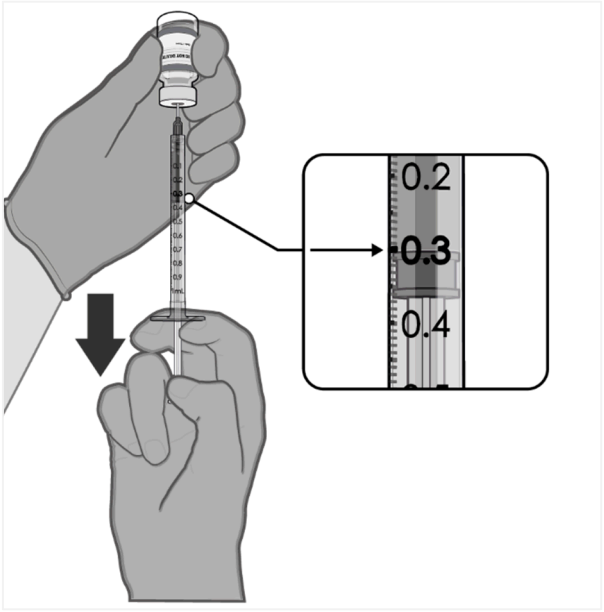
A booster dose of COMIRNATY may be given after the second dose.

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

<table>
<tr><th colspan="2">COMIRNATY (Do Not Dilute) (For Age 12 Years and Older)</th></tr>
<tr><td colspan="2">VIAL VERIFICATION</td></tr>
<tr><td> 
</td><td>• Verify that the vial has a grey plastic cap. If the vial has an orange plastic cap, refer to the handling instructions for COMIRNATY (For Age 5 Years to <12 Years) (Vials with Orange Cap).</td></tr>
<tr><td colspan="2">HANDLING PRIOR TO USE</td></tr>
<tr><td> 
</td><td>• 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 6 hours to thaw. Ensure vials are completely thawed prior to use.
• 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 for immediate use.</td></tr>
</table>

<table>
<tr><th colspan="2">COMIRNATY (Do Not Dilute) (For Age 12 Years and Older)</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 white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discoloration are present.</td></tr>
<tr><th colspan="2">PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY</th></tr>
<tr><td> 

0.3 mL vaccine</td><td>• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
• Withdraw 0.3 mL of COMIRNATY.

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.
• Discard any unused vaccine 12 hours after first puncture. Record the appropriate date/time on the vial.</td></tr>
</table>

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

COM30-SIN-0822/PIL/0
Date of Last Revision: August 2022