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# COMIRNATY® Concentrate for Dispersion for Injection

BNT162b2 COVID-19 mRNA Vaccine (30 mcg)

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| | |
|---|---|
| PLD Title | : BNT162b2 COVID-19 mRNA Vaccine (COMIRNATY) |
| PLD Date | : 8 January 2021 |
| Country | : Malaysia |
| Reference Document | : Malaysia CLD dated 28 December 2020; EU PIL dated 21 December 2020 |
| Reason for change | : PfLEET Number- 2020-0066822 (D): New PLD creation |

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**What is in this leaflet**



**What COMIRNATY 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 18 years of age and older.

**How COMIRNATY works**

The vaccine causes the immune system (the body's natural defenses) 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.

**Before you use COMIRNATY**

- *When you must not use it*

**Do not take COMIRNATY**

If you are allergic to BNT162b2 COVID-19 mRNA Vaccine or any of the other ingredients of COMIRNATY.

*Pregnancy and lactation*

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.

*Children and adolescents*

COMIRNATY is not recommended for children aged under 18 years as limited safety and efficacy data are available.

- *Before you start to use it*

Talk to your doctor before taking COMIRNATY 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 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.

As with any vaccine, the 2-dose vaccination course of COMIRNATY may not fully protect all those who receive it and it is not known how long you will be protected.

- *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. No interaction studies between COMIRNATY and other drugs have been performed.

*COMIRNATY contains potassium and sodium*

This vaccine contains less than 1 mmol potassium (39 mg) per dose, that is to say essentially 'potassium-free'.

This vaccine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'.

**How to use COMIRNATY**

- *How much to use*

COMIRNATY is given after dilution as an injection of 0.3 mL into a muscle of your upper arm. You will receive 2 injections, given at least 21 days apart.

After the first dose of COMIRNATY, you should receive a second dose of the same vaccine after 21 days to complete the vaccination course.

There are no data available on the interchangeability of COMIRNATY with other COVID-19 vaccines to complete the vaccination course. Individuals who have received 1 dose of COMIRNATY should receive a

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second dose of COMIRNATY to complete the vaccination course.

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

- *If you forget to use it*

If you missed the second dose, consult your doctor or pharmacist if you are unsure about what you should do.

- *If you use too much (overdose)*

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this vaccine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

**While you are using it**

- *Things you must do*

The use of this vaccine should be in accordance with official recommendations.

Tell all the doctors, dentists and pharmacists treating you that you are taking COMIRNATY.

- *Things you must not do*

Concomitant administration of COMIRNATY with other vaccines has not been studied therefore, do not take any new medicines after receiving COMIRNATY without consulting your doctor.

- *Things to be careful of*

*Driving and using machines*
Some of the effects of vaccination mentioned in section **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.

**Side Effects**

Like all medicines, COMIRNATY can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this vaccine.

Very common side effects: may affect more than 1 in 10 people
- injection site: pain, swelling
- tiredness
- headache
- muscle pain
- joint pain
- chills, fever

Common side effects: may affect up to 1 in 100 people
- injection site redness
- nausea

Uncommon side effects: may affect up to 1 in 1000 people
- enlarged lymph nodes
- feeling unwell
- pain in limb
- insomnia
- injection site itching

Rare side effects: may affect up to 1 in 10,000 people
- temporary one sided facial drooping

Not known (cannot be estimated from the available data)
- severe allergic reaction.

If you experience any of these side effects that would not go away, tell your doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

**Storage and Disposal of COMIRNATY**

- *Storage*

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.

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After thawing, the vaccine should be diluted and used immediately. However, in-use stability data have demonstrated that once removed from freezer, the undiluted vaccine can be stored for up to 5 days at 2 °C to 8 °C, or up to 2 hours at temperatures up to 30 °C, prior to use.

After dilution, store the vaccine at 2 °C to 30 °C and use within 6 hours. Discard any unused vaccine.

Once removed from the freezer and diluted, the vials should be marked with the new discard date and time. Once thawed, the vaccine cannot be re-frozen.

Do not use this vaccine if you notice particulates in the dilution or discolouration.

- *Disposal*

This vaccine should not be disposed of via wastewater or household waste. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**Product Description**

- *What it looks like*

The vaccine is a white to off-white dispersion (pH: 6.9 - 7.9) provided in a multidose vial of 5 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a flip-off plastic cap with aluminium seal.

Pack size: 195 vials

- *Ingredients*
  - Active ingredient
    BNT162b2 COVID-19 mRNA Vaccine (nucleoside modified)
  - Inactive ingredients
    - ((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
    - Potassium chloride
    - Potassium dihydrogen phosphate
    - Sodium chloride
    - Disodium phosphate dihydrate
    - Sucrose
    - Water for injections

- *MAL number:*

COMIRNATY Concentrate for Dispersion for injection
MAL*********

**Manufacturer and Batch Release Site:**
Pfizer Manufacturing Belgium NV,
Rijksweg 12, Puurs, 2870, Belgium

**Product Registration Holder**
Pfizer (Malaysia) Sdn. Bhd.
Level 10 & 11
Wisma Averis, Tower 2
Avenue 5, Bangsar South
No. 8, Jalan Kerinchi
59200 Kuala Lumpur, Malaysia

**Date of Revision**
8/1/2021

**Serial Number**
NPRA XXXXXXXXX

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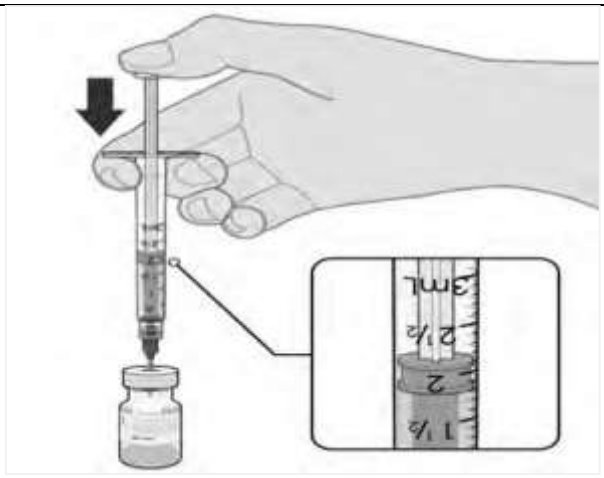
Handling instructions

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

| **THAWING PRIOR TO DILUTION** | |
|---|---|
|  | • The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2°C to 8°C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30°C for immediate use.<br>• Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake.<br>• Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles. |
| **DILUTION** | |
|  | • The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques. |

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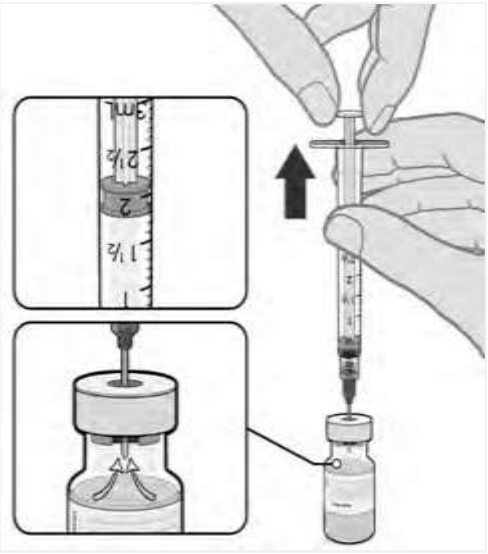
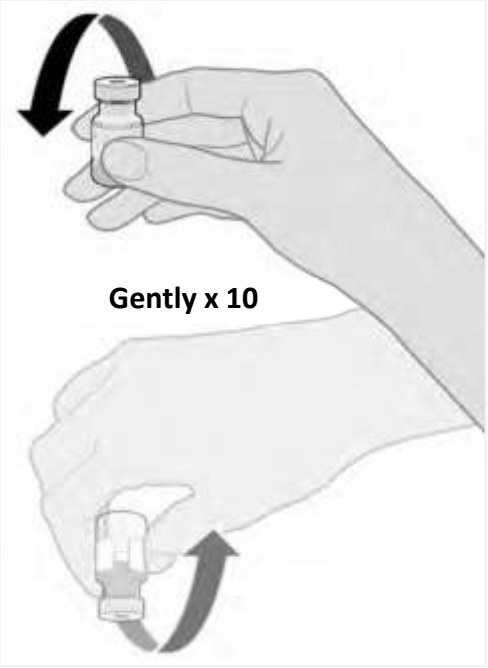
| | |
|---|---|
|  <br>**Pull back plunger to 1.8 mL to remove air from vial** | • Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe. |
|  <br>**Gently x 10** | • Gently invert the diluted dispersion 10 times. Do not shake.<br>• The diluted vaccine should present as an off-white dispersion with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present. |

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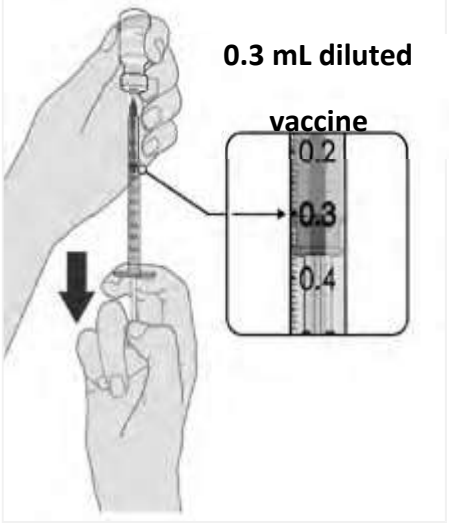
<table>
<tr>
<td> 

<br>Record appropriate date and time.<br>Use within 6 hours after dilution</td>
<td>• The diluted vials should be marked with the appropriate date and time.<br>• Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.</td>
</tr>
<tr>
<td colspan="2">PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY</td>
</tr>
<tr>
<td> 
</td>
<td>• After dilution, the vial contains 2.25 mL corresponding to 5 doses of 0.3 mL. Withdraw the required 0.3 mL dose of diluted vaccine using a sterile needle.<br>• Discard any unused vaccine within 6 hours after dilution.</td>
</tr>
</table>

**PLD-COMIRNATY-1220**