COMIRNATY JN.1 10 micrograms/dose Dispersion for Injection

COVID-19 mRNA Vaccine (bretovameran 10 mcg)

What is in this leaflet

What COMIRNATY JN.1 is used for

COMIRNATY JN.1 is a vaccine used for preventing COVID-19 caused by SARS-CoV-2 virus.

COMIRNATY JN.1 10 micrograms/dose Dispersion for Injection is given to children aged 5 to 11 years (i.e. 5 to less than 12 years of age).

How COMIRNATY JN.1 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 JN.1 does not contain the virus to produce immunity, it cannot give your child COVID-19.

Before you use COMIRNATY JN.1

- *When you must not use it*

Do not take COMIRNATY JN.1

If your child is allergic to active substance or any of the other ingredients of this vaccine (listed in section **Product Description**).

Pregnancy and lactation

If your child is pregnant, tell your doctor, nurse or pharmacist before your child receives this vaccine.

No data are available yet regarding the use of COMIRNATY JN.1 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 JN.1 can be used during pregnancy.

No data are available yet regarding the use of COMIRNATY JN.1 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 JN.1 can be used while breast feeding.

Children

COMIRNATY JN.1 10 micrograms/dose Dispersion for Injection should be used only for children 5 to 11 years of age, and it is not recommended for children aged under 5 years.

There is formulation for infants and children aged 6 months to 4 years. For details, please refer to RiMUP of other formulation.

The vaccine is not recommended for infants aged under 6 months.

- *Before you start to use it*

Talk to your doctor before your child is given the vaccine if:

- your child has ever had a severe allergic reaction or breathing problems after any other vaccine injection or after your child was given this vaccine in the past.
- your child is feeling nervous about the vaccination process or has ever fainted following any needle injection.
- your child has a severe illness or infection with high fever. However, your child can have his/her vaccination if your child has a mild fever or upper airway infection like a cold.
- your child has a bleeding problem, your child bruise easily or your child use a medicine to prevent blood-clots.
- your child has a weakened immune system, because of a disease such as HIV infection or a medicine such as corticosteroid that affects your child's 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 **Side Effects**).

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.

COMIRNATY JN.1 10 micrograms/dose Dispersion for Injection

COVID-19 mRNA Vaccine (bretovameran 10 mcg)

The risk of myocarditis and pericarditis seems lower in children ages 5 to 11 years compared with ages 12 to 17 years. Most cases of myocarditis and pericarditis recover. Some cases required intensive care support and fatal cases have been seen. Following vaccination, you and your child 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 JN.1 may not fully protect all those who receive it and it is not known how long you will be protected.

The efficacy of COMIRNATY JN.1 may be lower in people who are immuno-compromised. If your child is immunocompromised, he/she may receive additional doses of COMIRNATY JN.1. In these cases, your child should continue to maintain physical precautions to help prevent COVID-19. In addition, your child's close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your child's doctor.

- *Taking other medicines*

Tell your doctor if is using, has recently used or might use any other medicines or has recently received any other vaccine, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use COMIRNATY JN.1

- *How much to use*

COMIRNATY JN.1 is given as an injection of 0.3 mL into a muscle of your child's upper arm.

Your child will receive 1 injection, regardless whether he/she has received a COVID-19 vaccine before.

If your child was previously vaccinated with a COVID-19 vaccine, he/she should not receive a dose of Comirnaty JN.1 until at least 3 months after the most recent dose

If your child is immuno-compromised, he or she may receive additional doses of COMIRNATY JN.1.

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

- *When to use it*

Use as directed by your doctor.

- *How long to use it*

Use as directed by your doctor.

- *If you forget to use it*

If your child missed a 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 your child or anyone else may have taken too much of this vaccine. Do this even if there are no signs of discomfort or poisoning. Your child 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*

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 temporarily affect your child's ability to use machines or undertake activities such as cycling. Wait until these effects have worn off before resuming activities that require your child's full attention.

Side Effects

Like all medicines, COMIRNATY JN.1 can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if your child experiences 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
- diarrhoea

COMIRNATY JN.1 10 micrograms/dose Dispersion for Injection

COVID-19 mRNA Vaccine (bretovameran 10 mcg)

Common side effects: may affect up to 1 in 10 people
- nausea, vomiting
- injection site redness ('very common' in 5 to 11 years of age)
- enlarged lymph nodes (more frequently observed after a booster dose)

Uncommon side effects: may affect up to 1 in 100 people
- feeling unwell, feeling weak or lack of energy/sleepy
- arm pain
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- decrease 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)

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 JN.1

- *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.

Stored 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.

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 (previously frozen) vial

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 expiry date at 2°C to 8°C.

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.

Once thawed, the vaccine should not be re-frozen.

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.

- *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.

COMIRNATY JN.1 10 micrograms/dose Dispersion for Injection

COVID-19 mRNA Vaccine (bretovameran 10 mcg)

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 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a blue flip-off plastic cap with aluminium seal.

  Pack size: 10 vials

- *Ingredients*

  - Active ingredient
    Bretovameran - 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
    -Trometamol
    -Trometamol hydrochloride
    -Sucrose
    -Water for injections

- *MAL number:*

  COMIRNATY JN.1 10 micrograms/dose Dispersion for Injection-
  MAL22016037AZ

Batch Release Site:
Pfizer Manufacturing Belgium NV,
Rijksweg 12, Puurs-Sint-Amands,
2870, Belgium

Batch Release Site:
BioNTech Manufacturing GmbH,
Kupferbergterrasse 17-19, 55116
Mainz, Germany

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
25/09/2025

Serial Number
NPRA(R3/01)14012025/0343

PLD-COMIRNATY-0925