Package leaflet: Information for the user

COMIRNATY, COVID-19 mRNA Vaccine (nucleoside-modified), 30 micrograms/dose Dispersion for Injection (Multi-dose Vial) (SIN16396P)
COMIRNATY, COVID-19 mRNA Vaccine (nucleoside-modified), 30 micrograms/dose Dispersion for Injection (Single-dose Vial) (SIN17016P)
COMIRNATY, COVID-19 mRNA Vaccine (nucleoside modified), 30 micrograms/dose Dispersion for Injection in Pre-filled Syringe (SINxxxxxP)
COMIRNATY, COVID-19 mRNA Vaccine (nucleoside-modified), 10 micrograms/dose Dispersion for Injection (Multi-dose Vial) (SIN16397P)
COMIRNATY, COVID-19 mRNA Vaccine (nucleoside-modified), 10 micrograms/dose Dispersion for Injection (Single-dose Vial) (SIN17017P)
COMIRNATY, COVID-19 mRNA Vaccine (nucleoside-modified), 3 micrograms/dose Concentrate for Dispersion for Injection (SIN16616P)

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

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

Available Strengths of COMIRNATY

	Monovalent Presentations
	COMIRNATY (Omicron JN.1)
Age Range of Recipient	**Strength per dose in micrograms**
Infants and children 6 months to <5 years	3 micrograms of bretovameran
Children from 5 to <12 years	10 micrograms of bretovameran
Adults and adolescents 12 years and older	30 micrograms of bretovameran

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 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 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

Sometimes the symptoms of myocarditis and pericarditis may not be specific and could include tiredness, dizziness, nausea and vomiting, abdominal pain, swelling, and cough.

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 infants aged under 6 months.

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.

COMRINATY 30 micrograms may be given at the same time as a flu 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 variant-adapted COMIRNATY 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 is given

Dosing Recommendations

Age Range of Recipient and Strength	**Presentation (Vial Cap and Vial Label Colour or Pre-filled Syringe)**	**Dilution Requirement**	**Site of Administration**	**Dose Schedule[c]**
6 months to <5 years[a] 3 micrograms/dose	Yellow	Must dilute	**Infants from 6 to less than 12 months of age:** muscle of the thigh **Individuals 1 years of age and older:** muscle of the thigh or upper arm	**3 Dose Primary Series:** o Dose 1 and 2: 3 weeks apart o Dose 3: at least 8 weeks after second dose
5 to <12 years[a] 10 micrograms/dose	Blue[b]	Do not dilute	Muscle of your upper arm	**2 Dose Primary Series:** o Dose 2: at least 21 days (preferably 3 weeks) after first dose

Age Range of Recipient and Strength	Presentation (Vial Cap and Vial Label Colour or Pre-filled Syringe)	Dilution Requirement	Site of Administration	Dose Schedule[c]
12 years and older 30 micrograms/dose	Grey[b]	Do not dilute	Muscle of your upper arm	Single dose and in accordance with official recommendations
	Pre-filled syringe	Do not dilute	Muscle of your upper arm	

a. Individuals who will turn from 4 years to 5 years or from 11 years to 12 years of age between their doses in the vaccination series should receive their age-appropriate dose at the time of the vaccination and the interval between doses is determined by the individual's age at the start of the vaccination series.
b. Refers to either the single dose vial presentation for the light blue and light grey caps or the multidose vial presentation for the dark blue and dark grey caps.
c. For individuals less than 12 years of age, the primary series and booster may consist of either COMIRNATY (Original), or a variant-adapted presentation of COMIRNATY, or a combination, but not exceeding the total number of doses recommended for the primary series. The primary series should only be administered once.

A booster may be administered at least 3 months after completion of primary series and in accordance with official recommendations.

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
- 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; 'rare' in individuals 2 to <5 years of age)
- feeling unwell
- arm pain

- 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/sleepy ('rare' in individuals 2 to <5 years of age)
- decreased appetite ('rare' in individuals 2 to <5 years of age; '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
- inflammation of the appendix (appendicitis)

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)
- heavy menstrual bleeding
- blood clot of a vein in the brain (cerebral venous thrombosis)

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.

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.

Vials

Shelf life of frozen vials

The vaccine may 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.

If COMIRNATY is received frozen at -90 °C to -60 °C the frozen vials can continue to be stored at -90 °C to -60 °C according to the table below.

COMIRNATY Variant	**Vaccine Presentation(s) Vial Cap and Vial Label Colour**	**Shelf Life of Unopened Frozen Vials When Stored at -90 °C to -60 °C**
COMIRNATY (Omicron JN.1)	Yellow (3 micrograms)	18 months
	Blue[a] (10 micrograms)	18 months
	Grey[a] (30 micrograms)	18 months

a. Refers to either the single dose vial presentation for the light blue and light grey caps or the multidose vial presentation for the dark blue and dark grey caps.

Thawing frozen vials

- Frozen (-90 °C to -60 °C) vials can be thawed at either 2 °C to 8 °C or at temperatures up to 30 °C (see Handling instructions below for more detailed thawing instructions).
- **Once thawed, the vaccine should not be re-frozen.**

Shelf life of refrigerated vials

- Frozen vials may be transferred to refrigerated storage (2 °C to 8 °C) upon receipt. Once moved to refrigerated storage, unopened vials may be stored for a single period of up to 10 weeks, not exceeding the original expiry date (EXP).
- Upon moving the product to 2 °C to 8 °C storage, the original expiry date on the outer carton should be crossed out and updated expiry date must be written (10 weeks from the date the vials were removed from frozen storage). The vaccine should be used or discarded by the updated expiry date.
- If the vaccine is received refrigerated (2 °C to 8 °C) it should be stored at 2 °C to 8 °C. Check that the expiry date on the outer carton has been updated to reflect the refrigerated expiry date and that the original expiry date has been crossed out.

Storage of thawed, opened (punctured or diluted) vials

- Once a vial has been punctured or diluted (dilution with sodium chloride 9 mg/mL 0.9% solution for injection) chemical and physical in-use stability has been demonstrated for 12 hours at 2 °C to 30 °C.
- From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately after the first puncture of single dose vials and within 12 hours after puncture or dilution of multidose vials. If not used within the recommended duration, in-use storage times and conditions are the responsibility of the user.

Pre-filled syringes

Shelf life of unopened glass pre-filled syringes

8 months when stored at 2 °C to 8 °C.

Verify the storage conditions on the pre-filled syringe label and apply the applicable storage conditions for that presentation.

COMIRNATY glass pre-filled syringes should not be frozen.

Syringes may be stored at temperatures between 8 °C and 30 °C for up to 12 hours.

Store in the original package in order to protect from light.

During use, thawed vials and pre-filled syringes can be handled in room light conditions. Avoid exposure to direct sunlight and ultraviolet light.

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

Available Presentations of COMIRNATY

Age Range of Recipient and Strength	**Presentation (Vial Cap and Vial Label Colour or Pre-filled Syringe)**	**Presentation (Vial Fill Volume in mL and Number of Doses per Unit)**	**Variant**	**Appearance**
6 months to <5 years 3 micrograms/dose	Yellow	Multidose vial (0.48 mL) contains three 0.3 mL doses per vial after dilution	Omicron JN.1	Clear to slightly opalescent solution.
5 to <12 years 10 micrograms/dose	Dark blue	Multidose vial (2.25 mL) contains six 0.3 mL doses per vial	Omicron JN.1	Clear to slightly opalescent solution.
	Light blue	Single dose vial (0.48 mL) contains one 0.3 mL dose	Omicron JN.1	Clear to slightly opalescent solution.

Age Range of Recipient and Strength	Presentation (Vial Cap and Vial Label Colour or Pre-filled Syringe)	Presentation (Vial Fill Volume in mL and Number of Doses per Unit)	Variant	Appearance
12 years and older 30 micrograms/dose	Dark grey	Multidose vial (2.25 mL) contains six 0.3 mL doses per vial	Omicron JN.1	White to off-white solution.
	Light grey	Single dose vial (0.48 mL) contains one 0.3 mL dose	Omicron JN.1	White to off-white solution.
	Pre-filled syringe	Single dose pre-filled syringe contains one 0.3 mL dose	Omicron JN.1	White to off-white solution.

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

Contents of the pack

Vials

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 aluminium seal.

Single dose vial pack size: 10 single dose vials per carton.

Multidose vial pack size: 10 multidose vials per carton.

Pre-filled syringes

Supplied in a single dose glass pre-filled syringe (type I glass syringe) with plunger stopper (synthetic bromobutyl rubber) and a tip cap (synthetic bromobutyl rubber) without needle.

Pack size: 10 pre-filled syringes

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.

The following information is intended for healthcare professionals only:

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.

Vials

Handling instructions prior to use

Frozen vials must be completely thawed prior to use. Frozen vials should be transferred to 2 °C to 8 °C to thaw. Thaw times for 10-vial packs are noted in table below:

Vial Cap and Vial Label Colour	**Time That May Be Required For a 10-vial Pack to Thaw (at 2 °C to 8 °C)**
Light Grey Light Blue Yellow	2 hours
Dark Grey Dark Blue	6 hours

- Upon moving frozen vaccine to 2 °C to 8 °C storage, update the expiry date on the carton. The updated expiry date should reflect 10 weeks from the date of transfer to refrigerated conditions (2 °C to 8 °C) and 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.
- If the vaccine is received at 2 °C to 8 °C (35 °F to 46 °F) it should continue to be stored at 2 °C to 8 °C (35 °F to 46 °F). Check that the carton has been previously updated to reflect the 10-week refrigerated expiry date.
- Unopened vials can be stored for up to 12 hours at temperatures up to 30 °C. Total storage time between 8 °C to 30 °C, inclusive of storage before and after puncture, should not exceed 24 hours.

Preparation for administration

Vial verification

Prior to administration, check the name and strength of the vaccine on the vial label and the colour of the vial cap and vial label border to ensure it is the intended presentation. Check whether the vial is a single dose vial or a multidose vial and check if the vial requires dilution.

COMIRNATY (Omicron JN.1) (Do Not Dilute) (For 12 Years of Age and Older) (Vials with Grey Cap)
COMIRNATY (Omicron JN.1) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue Cap)

INSTRUCTIONS APPLICABLE TO BOTH SINGLE DOSE AND MULTIDOSE VIALS

- Check appearance of vaccine prior to mixing and administration.
    - *Grey cap vials:* Prior to mixing, the vaccine is a white to off-white dispersion and may contain white to off-white opaque amorphous particles.
    - *Blue cap vials:* Prior to mixing, the vaccine is a clear to slightly opalescent dispersion and may contain white to off-white opaque amorphous particles.
- Gently invert the vial 10 times. **Do not shake.**
- Do not use the vaccine if particulates or discolouration are present after mixing.

Preparation of individual doses

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw a 0.3 mL single dose.
- *For Dark Grey or Dark Blue cap multidose vials (6 doses per vial):*
    - After first puncture, record appropriate date and time on the vial and store at 2 °C to 30 °C for up to 12 hours. Do not re-freeze.
    - Each dose must contain 0.3 mL of vaccine. Low dead-volume syringes and/or needles should be used in order to extract all 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 the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial and any excess volume.

COMIRNATY (Omicron JN.1) (Dilute Before Use) (For Age 6 Months to <5 Years) (Vials with Yellow Cap)

Prior to dilution

- After the thawed vial has reached room temperature, gently invert it 10 times prior to dilution. **Do not shake.**
- Check appearance of vaccine.
    - *Yellow cap vials:* Prior to dilution, the vaccine is a clear to slightly opalescent dispersion and may contain white to off-white opaque amorphous particles.

Dilution instructions

- Thawed vaccine must be diluted in its original vial with sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques. Volume of sodium chloride 9 mg/mL (0.9%) required are noted below:
    - *Yellow cap vials:* 1.1 mL of sodium chloride 9 mg/mL
- Equalise vial pressure before removing the needle from the vial stopper by withdrawing air into the empty diluent syringe. Volume of air required are noted below:
    - *Yellow cap vials:* 1.1 mL of air
- Gently invert the diluted dispersion 10 times. **Do not shake.**
- Check appearance of vaccine after dilution.
    - *Yellow cap vials:* 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.
- After dilution, mark vial with appropriate date/time, store at 2 °C to 30 °C and use within 12 hours. Do not re-freeze.

Preparation of individual doses

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw a single dose.
    - *Yellow cap vials (3 doses per vial):* Each dose must contain 0.3 mL of vaccine. Standard syringes can be used.
- If the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial and any excess volume.

Pre-filled syringes

Preparation and administration of individual doses of the refrigerated storage only, glass pre-filled syringes

- Prior to use, the pre-filled syringes can be stored for up to 12 hours at temperatures between 8 °C to 30 °C and can be handled in room light conditions.
- Do not shake.
- Remove tip cap by slowly turning the cap counterclockwise while holding the luer lock.
- Attach a needle appropriate for intramuscular injection and administer the entire volume.

Disposal

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