Package leaflet: Information for the user

COMIRNATY, COVID-19 mRNA Vaccine (nucleoside modified), 30 micrograms/dose Dispersion for Injection (SIN16396P)
COMIRNATY, COVID-19 mRNA Vaccine (nucleoside modified), 10 micrograms/dose Dispersion for Injection (SIN16397P)
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
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.

Available Strengths of COMIRNATY

	Monovalent Presentations
	COMIRNATY (Omicron XBB.1.5)
Age Range of Recipient	**Strength per dose in micrograms**
Infants and children 6 months to <5 years of age	3 micrograms of raxtozinameran
Children from 5 to <12 years of age	10 micrograms of raxtozinameran
Adults and adolescents 12 years and older	30 micrograms of raxtozinameran

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 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 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.

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

Strength and Age of Individual	Vial Cap and Vial Label Colour	Dilution requirement	Site of Administration	Dose Schedule for Primary Series
3 micrograms/dose for individuals 6 months to <5 years of age[a]	Maroon	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	• **Primary course:** 3 injections o Dose 1 and 2: 3 weeks apart o Dose 3: at least 8 weeks after second dose
10 micrograms/dose for individuals 5 to <12 years of age	Blue	Do not dilute	Muscle of your upper arm	• **Primary course:** 2 injections (preferably 3 weeks) apart
30 micrograms/dose for individuals 12 years of age and older	Grey	Do not dilute	Muscle of your upper arm	

a. Individuals who will turn from 4 years to 5 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.

A booster may be administered 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)
- 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/sleep
- decreased appetite ('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

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)

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.

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.

Shelf Life of Frozen Vials

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 Color**	**Shelf Life of Unopened Frozen Vials When Stored at -90 °C to -60 °C**
COMIRNATY (Omicron XBB.1.5)	Maroon (3 micrograms)	18 months
	Blue (10 micrograms)	12 months
	Grey (30 micrograms)	18 months

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 section 6.6 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

- Vials may be stored at temperatures between 8 °C to 30 °C for a total of 24 hours, inclusive of storage before and after puncture. 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.

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

During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Thawed vials can be handled in room light conditions.

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

Strength and Age Range of Recipient	Vial Cap and Vial Label Colour	Presentation (Vial Fill Volume in mL and Number of Doses per Unit)	Variant and Active substance	Appearance
3 micrograms/dose for individuals 6 months to <5 years of age	Maroon	Multidose vial (0.4 mL) contains ten 0.2 mL doses per vial after dilution	Omicron XBB.1.5 – Raxtozinameran	White to off-white solution.
10 micrograms/dose for individuals 5 to <12 years of age	Blue	Multidose vial (2.25 mL) contains six 0.3 mL doses per vial	Omicron XBB.1.5 – Raxtozinameran	Clear to slightly opalescent solution.
30 micrograms/dose for individuals 12 years of age and older	Grey	Multidose vial (2.25 mL) contains six 0.3 mL doses per vial	Omicron XBB.1.5 – Raxtozinameran	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
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.

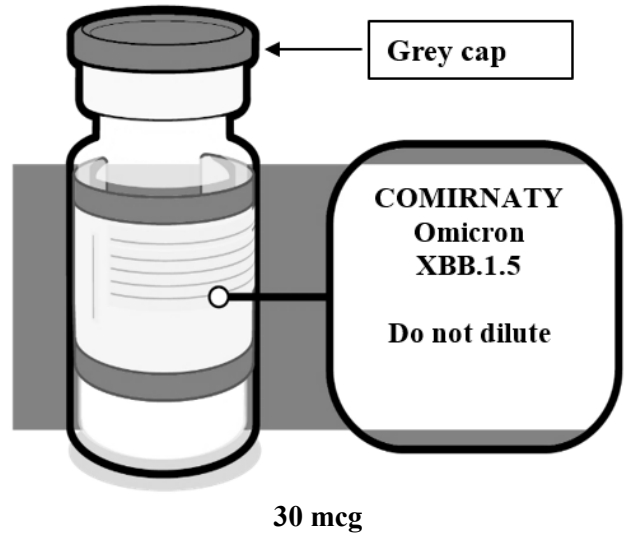
The following information is intended for healthcare professionals only:

Traceability

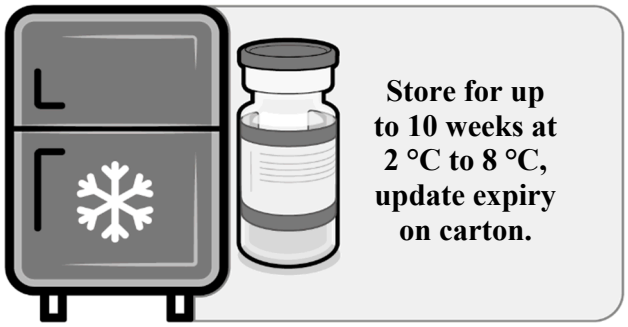
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

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

COMIRNATY (Omicron XBB.1.5) (Do Not Dilute) (For 12 Years of Age and Older) (Vials with Grey Cap)

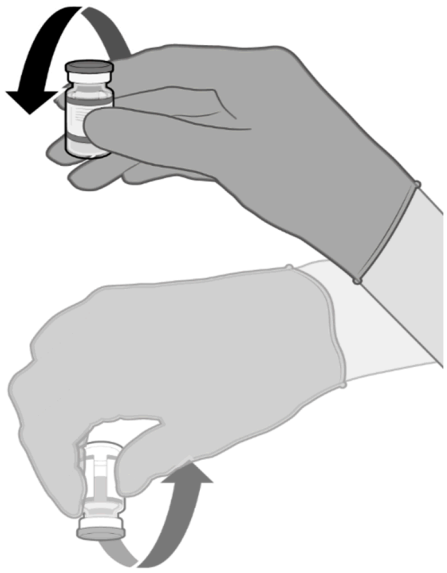
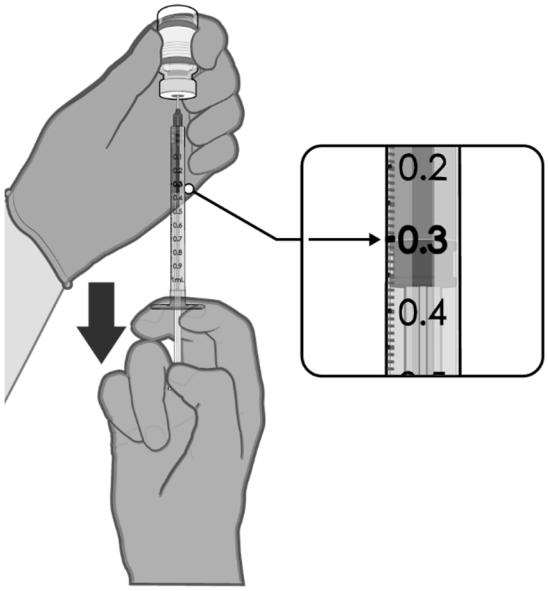
<table>
<tr><th colspan="2">COMIRNATY (Omicron XBB.1.5) (Do Not Dilute) (For 12 Years of Age and Older) (Vials with Grey Cap)</th></tr>
<tr><td colspan="2">VIAL VERIFICATION</td></tr>
<tr><td> 
</td><td>

Prior to administration, verify the name and strength of the vaccine on the vial label and the color of the vial cap and vial label border.
If the vial has a grey plastic cap and a grey border around the label, and the product name is different, or if the vial has a purple, orange, blue, or maroon plastic cap, refer to the handling instructions for that presentation.

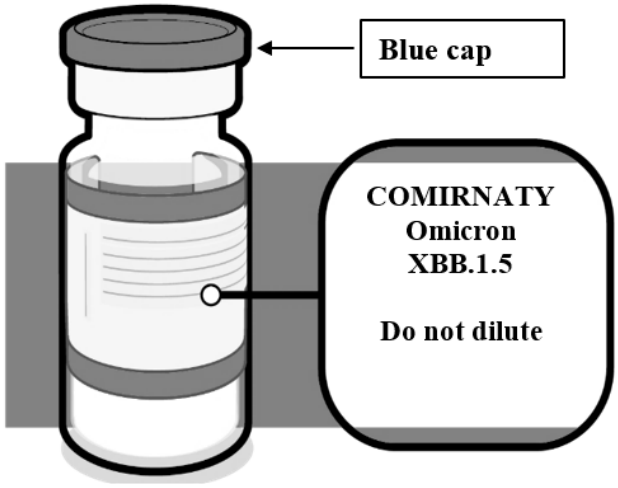
</td></tr>
<tr><td colspan="2">HANDLING PRIOR TO USE</td></tr>
<tr><td> 
</td><td>

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 of multidose vials may take 6 hours to thaw. Ensure vials are completely thawed prior to use.
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 for immediate use.

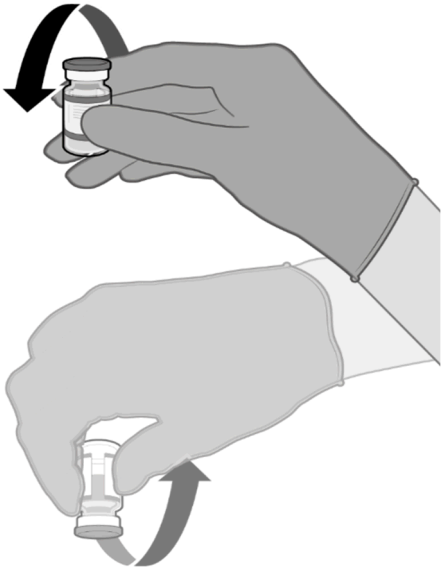
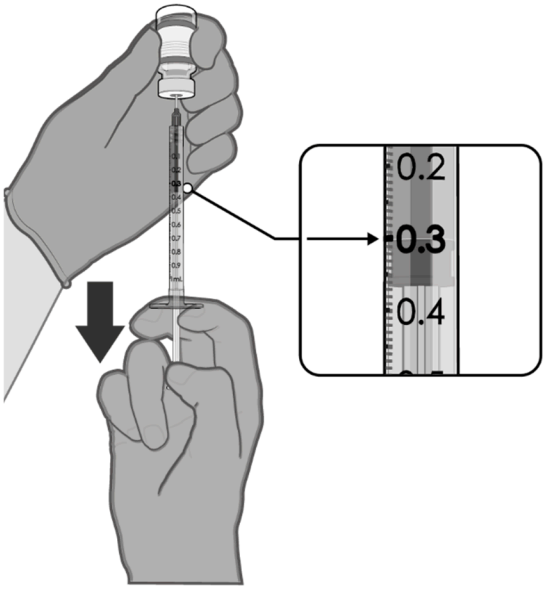
</td></tr>
</table>

COMIRNATY (Omicron XBB.1.5) (Do Not Dilute) (For 12 Years of Age and Older) (Vials with Grey Cap)	
 **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	
 **0.3 mL vaccine**	• Multidose vials contain 6 doses of 0.3 mL each. • Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. • Withdraw a 0.3 mL dose. 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.

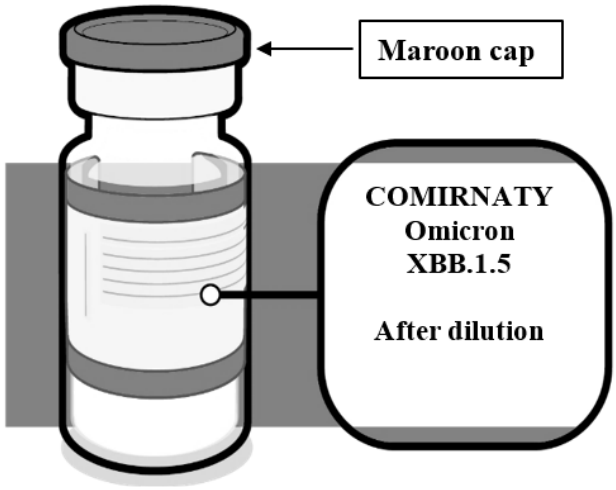
COMIRNATY (Omicron XBB.1.5) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue Cap)

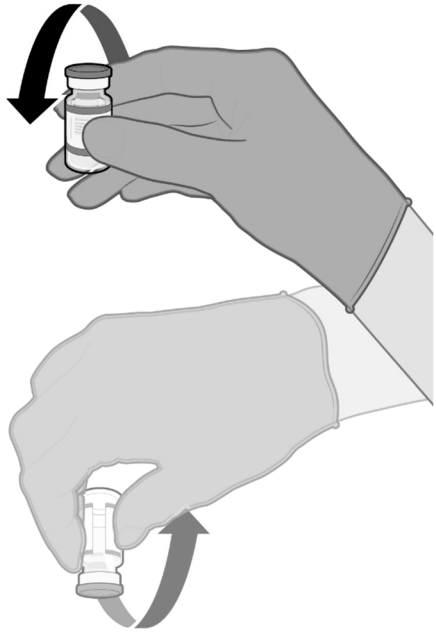
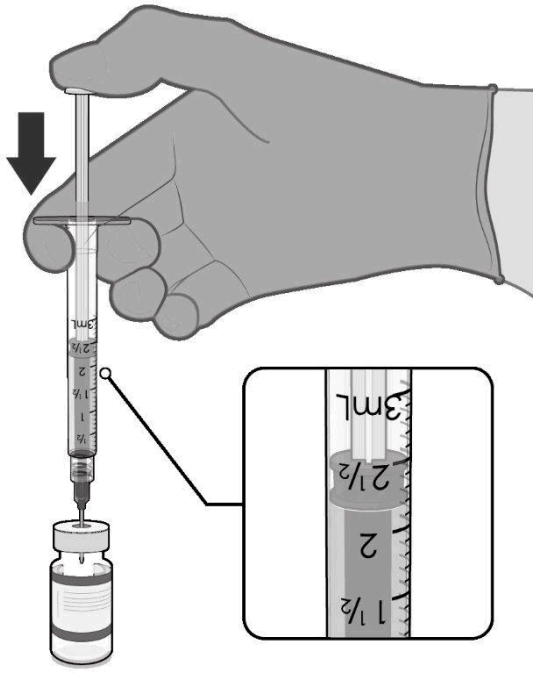
<table>
<tr><th colspan="2">COMIRNATY (Omicron XBB.1.5) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue Cap)</th></tr>
<tr><td colspan="2">VIAL VERIFICATION</td></tr>
<tr><td> 

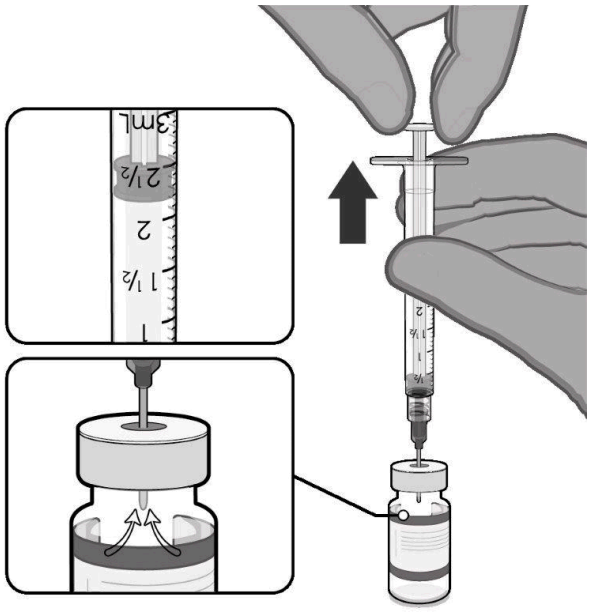
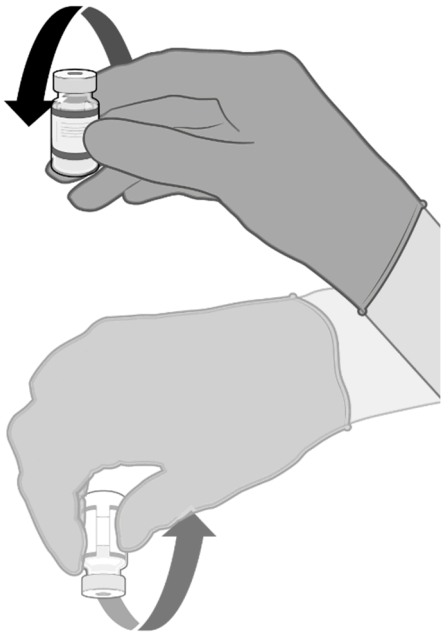
10 mcg</td><td>• Prior to administration, verify the name and strength of the vaccine on the vial label and the color of the vial cap and vial label border.
• If the vial has a blue plastic cap and a blue border around the label and the product name is different, or if the vial has a grey, purple, orange, or maroon plastic cap, refer to the handling instructions for that presentation.</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 of multidose vials may take 6 hours to thaw. Ensure vials are completely thawed prior to use.
• 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.</td></tr>
</table>

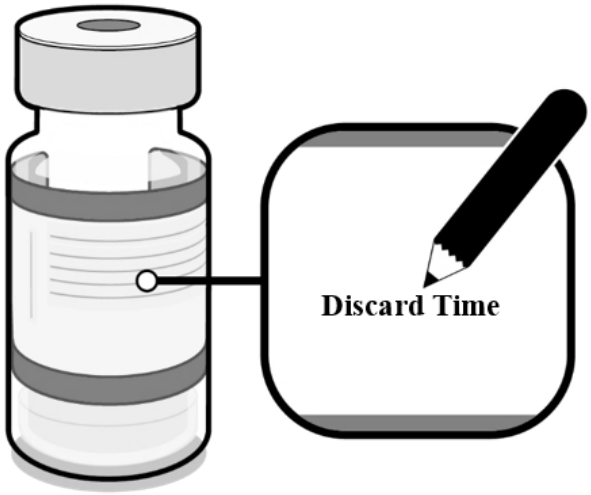
COMIRNATY (Omicron XBB.1.5) (Do Not Dilute) (For Age 5 Years to <12 Years) (Vials with Blue Cap)	
 **Gently × 10**	• Gently invert the diluted dispersion 10 times. Do not shake. • Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles. • After mixing, the vaccine should present as a clear to slightly opalescent dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.
PREPARATION OF INDIVIDUAL 0.3 mL DOSES	
 **0.3 mL vaccine**	• Multidose vials contain 6 doses of 0.3 mL each. • Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. • Withdraw a 0.3 mL dose. Low dead-volume syringes and/or needles should be used in order to extract 10 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 ten doses 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 within 12 hours after first puncture.

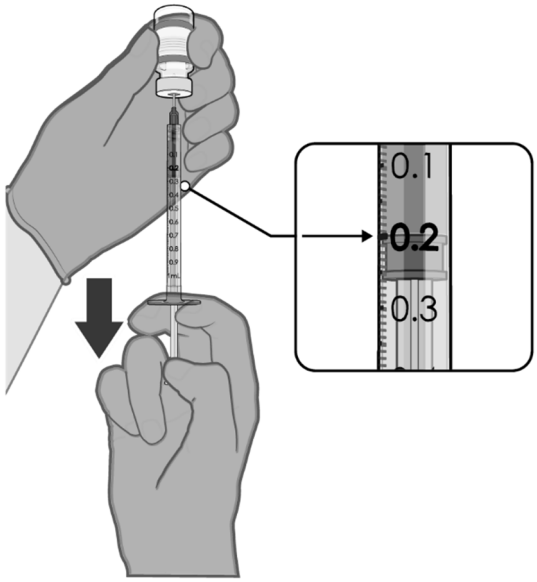
COMIRNATY (Omicron XBB.1.5) (Dilute Before Use) (For Age 6 Months to <5 Years) (Vials with Maroon Cap)

<table>
<tr><th colspan="2">COMIRNATY (Omicron XBB.1.5) (Dilute Before Use) (For Age 6 Months to <5 Years) (Vials with Maroon Cap)</th></tr>
<tr><td colspan="2">VIAL VERIFICATION</td></tr>
<tr><td> 
</td><td>• Prior to administration, verify the name and strength of the vaccine on the vial label and the color of the vial cap and vial label border.
• If the vial has a maroon plastic cap and a maroon border and the product name is different, or if the vial has a purple, grey, orange, or blue plastic cap, refer to the handling instructions for that presentation.</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 2 hours to thaw. Ensure vials are completely thawed prior to use.
• 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>

COMIRNATY (Omicron XBB.1.5) (Dilute Before Use) (For Age 6 Months to <5 Years) (Vials with Maroon Cap)	
MIXING PRIOR TO DILUTION	
 **Gently × 10**	• Allow the thawed vial to come to room temperature and gently invert it 10 times prior to dilution. Do not shake. • Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.
DILUTION	
 **2.2 mL of 0.9% sodium chloride**	• The thawed vaccine must be diluted in its original vial with 2.2 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.

COMIRNATY (Omicron XBB.1.5) (Dilute Before Use) (For Age 6 Months to <5 Years) (Vials with Maroon Cap)	
 **Pull back plunger to 2.2 mL to remove air from vial.**	• Equalise vial pressure before removing the needle from the vial stopper by withdrawing 2.2 mL air into the empty diluent syringe.
 **Gently × 10**	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.

<table>
<tr><th colspan="2">COMIRNATY (Omicron XBB.1.5) (Dilute Before Use) (For Age 6 Months to <5 Years) (Vials with Maroon Cap)</th></tr>
<tr><td> 

Record appropriate date and time.
Use within 12 hours after dilution.</td><td>• The diluted vials should be marked with the appropriate date and time.
• After dilution, store at 2 °C to 30 °C and use within 12 hours.
• 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 0.2 mL DOSES</td></tr>
<tr><td> 

0.2 mL diluted vaccine</td><td>• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
• Withdraw a 0.2 mL dose.

Low dead-volume syringes and/or needles should be used in order to extract 10 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 ten doses from a single vial.
• Each dose must contain 0.2 mL of vaccine.
• If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume.
• Discard any unused vaccine within 12 hours after dilution.</td></tr>
</table>

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

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Date of Last Revision: September 2023