Package leaflet: Information for the user

Pfizer-BioNTech/Comirnaty 30 micrograms/dose concentrate for dispersion for injection
COVID-19 mRNA Vaccine (nucleoside modified)
tozinameran

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 Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine is and what it is used for

Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine is a vaccine used for preventing COVID-19 caused by SARS-CoV-2 virus.

Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine 30 micrograms/dose concentrate for dispersion for injection is given to adults and adolescents from 12 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 Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine does not contain the virus to produce immunity, it cannot give you COVID-19.

2. What you need to know before you receive Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine

Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine 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 Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine in the past.
- you are feeling nervous about the vaccination process or 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

There is an increased risk of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) after vaccination with Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine (see section 4). 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. Following vaccination, you 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, Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine may not fully protect all those who receive it and it is not known how long you will be protected.

You may receive a third dose of Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine. The efficacy of Comirnaty, even after a third dose, may be lower in people who are immunocompromised. In these cases, you should continue to maintain physical precautions to help prevent COVID-19. In addition, your close contacts should be vaccinated as appropriate. Discuss appropriate individual recommendations with your doctor.

Children
Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine 30 micrograms/dose concentrate for dispersion for injection is not recommended for children aged under 12 years.

There is a paediatric presentation available for children 5 to 11 years of age. For details, please refer to the Package Leaflet for Comirnaty 10 micrograms/dose concentrate for dispersion for injection.

Other medicines and Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine
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 think you may be pregnant, tell your doctor, nurse or pharmacist before you receive this vaccine.

Comirnaty can be used during pregnancy. A large amount of information from pregnant women vaccinated with Comirnaty 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 can be given during 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.

Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine 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’.

3. How Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine is given

Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine is given after dilution 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 vaccination course.

If you are immunocompromised, you may receive a third dose of Comirnaty at least 28 days after the second dose.

A booster dose of Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine may be given at least 6 months after the second dose in individuals 12 years of age and older.

If you have any further questions on the use of Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all vaccines, Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine 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
- 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
- insomnia
- injection site itching
- allergic reactions such as rash or itching
- feeling weak or lack of energy/sleepy
- 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

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)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to FDA Philippines via online reporting through the FDA Philippines website at https://www.fda.gov.ph/pharmacovigilance/ and include batch/lot number if available. By reporting side effects, you can help provide more information on the safety of this medicine.

In addition, you can report side effects to Pfizer, Inc. at the contact information provided below.

Reporting Link dedicated for Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine	***Alternate reporting via email and fax***	***Contact numbers***
https://www.pfizersafetyreporting.com/#/en	***Email:*** PHL.AEReporting@pfizer.com ***Fax:*** 1 800 1110 1520 (Toll Free)	+63 9178108146 +63 2 8451 9288 +63 2 8415 9200 ext 19288

5. How to store Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine

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. Unopened vials may be stored and transported at -25 °C to -15 °C for a single period of up to 2 weeks and can be returned to -90 °C to -60 °C; not exceeding the expiry date (EXP).

Cartons with an expiry date of December 2021 to March 2022 printed on the label may remain in use for 6 months beyond the printed date (to reflect combined 9- and 12-months shelf-life extension), as long as approved storage conditions between -90 °C to -60 °C have been maintained.

Cartons with an expiry date of June 2022 through December 2022 printed on the label may remain in use for 3 months beyond the printed date, as long as approved storage conditions between -90 °C to -60 °C have been maintained.

Updated expiry dates are shown below for Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine 30 micrograms/dose concentrate for dispersion for injection, Purple cap.

Approved Shelf Life at Manufacturing	Printed Expiry Date		Updated Expiry Date
6 Months	December 2021	→	June 2022[a]
6 Months	January 2022	→	July 2022[a]
6 Months	February 2022	→	August 2022[a]
6 Months	March 2022	→	September 2022[a, b]
9 Months	June 2022	→	September 2022[b]
9 Months	July 2022	→	October 2022
9 Months	August 2022	→	November 2022
9 Months	September 2022	→	December 2022
9 Months	October 2022	→	January 2023
9 Months	November 2022	→	February 2023
9 Months	December 2022	→	March 2023

[a] - Expiry date update combining 9- and 12-months shelf-life extension
[b] - Due to implementation of the change in shelf-life from 6 to 9 months in October 2021, two different expiry dates could be extended to September 2022.

All vials with an expiry date of April 2023 and beyond will already reflect the 12 months shelf-life.

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

When stored frozen at -90 °C to -60 °C, 195-vial packs of the vaccine can be thawed at 2 °C to 8 °C for 3 hours or individual vials can be thawed at room temperature (up to 30 °C) for 30 minutes.

Transfers of frozen vials stored at ultra-low temperature (< -60 °C)

- Closed-lid vial trays containing 195 vials removed from ultra-low temperature frozen storage (< -60 °C) may be at temperatures up to 25 °C for up to 5 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from ultra-low temperature frozen storage (< -60 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- After vial trays are returned to frozen storage following temperature exposure up to 25 °C, they must remain in frozen storage for at least 2 hours before they can be removed again.

Transfers of frozen vials stored at -25 °C to -15 °C

- Closed-lid vial trays containing 195 vials removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 3 minutes.
- Open-lid vial trays, or vial trays containing less than 195 vials, removed from frozen storage (-25 °C to -15 °C) may be at temperatures up to 25 °C for up to 1 minute.

Once a vial is removed from the vial tray, it should be thawed for use.

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 1 month at 2 °C to 8 °C; not exceeding the expiry date (EXP). Within the 1-month shelf-life at 2 °C to 8 °C, up to 12 hours may be used for transportation. Prior to use, the unopened vaccine can be stored for up to 2 hours at temperatures up to 30 °C.

Thawed vials can be handled in room light conditions.

After dilution, store and transport 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.

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 Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine contains

- The active substance is COVID-19 mRNA Vaccine called tozinameran. After dilution, the vial contains 6 doses of 0.3 mL with 30 micrograms tozinameran 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
  - potassium chloride
  - potassium dihydrogen phosphate
  - sodium chloride
  - disodium phosphate dihydrate
  - sucrose
  - water for injections
  - sodium hydroxide (for pH adjustment)
  - hydrochloric acid (for pH adjustment)

What Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine 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 of 6 doses in a 2 mL clear vial (type I glass), with a rubber stopper and a purple flip-off plastic cap with aluminium seal.

Pack size: 195 vials

Pfizer Inc., New York, NY 10017

BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

For any information about this medicine, please contact the Emergency Use Authorization (EUA) Holder:
Pfizer, Inc.
19F - 20F, 8 Rockwell Bldg., Hidalgo Drive
Rockwell Center, Poblacion, Makati City 1210
Metro Manila, Philippines
Fax number: 1 800 1110 1520 (Toll Free)
Contact numbers: +63 9175171575, +63 2 8451 9288, +63 2 8415 9200 ext 19288

Please submit your medical information inquiries to https://pmiform.com/CONS/PH or for healthcare professionals please visit www.pfizermedicalinformation.ph.

Scan the code with a mobile device to get the latest version of the package leaflet.

For Comirnaty COVID-19 vaccine:

URL: www.comirnatyglobal.com

For Pfizer-BioNTech COVID-19 vaccine:

URL: www.cvdvaccine.com

The following information is intended for healthcare professionals only:

Administer Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine intramuscularly after dilution as a primary course of 2 doses (0.3 mL each) 3 weeks apart.

A booster dose of Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine may be given at least 6 months after the second dose in individuals 12 years of age and older.

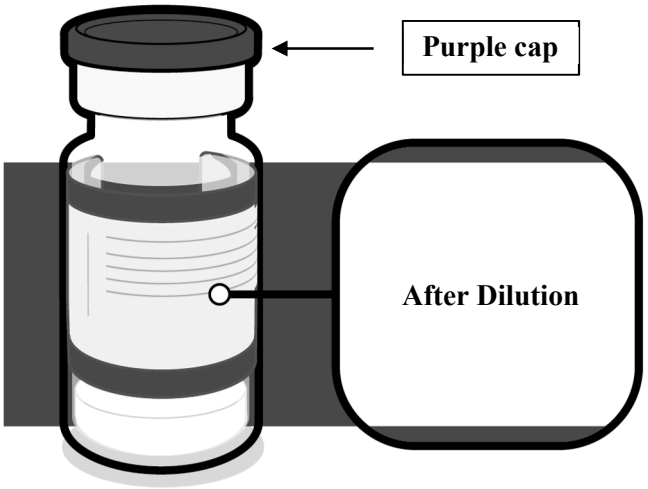
A third dose may be given at least 28 days after the second dose to individuals who are severely immunocompromised.

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.

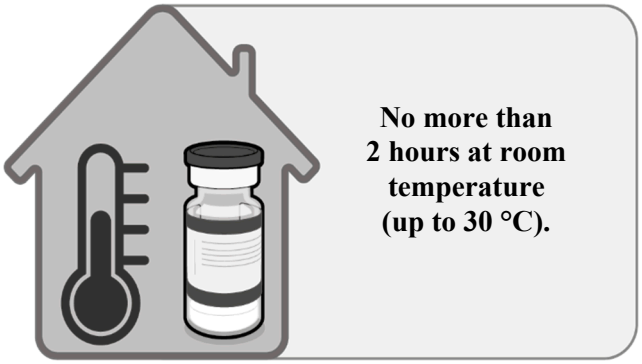
Handling instructions
Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared dispersion.

VIAL VERIFICATION OF PFIZER-BIONTECH/COMIRNATY COVID-19 mRNA VACCINE 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (12 YEARS AND OLDER)



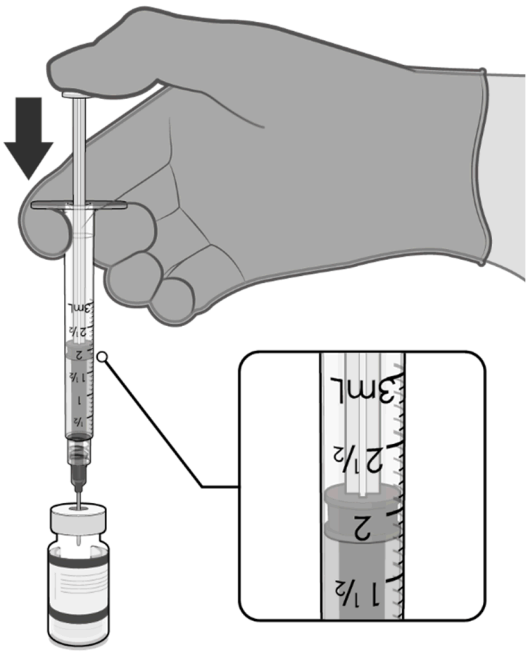
- Verify that the vial has a purple plastic cap.
- If the vial has a grey plastic cap, please make reference to the Product Information for Comirnaty 30 micrograms/dose dispersion for injection.
- If the vial has an orange plastic cap, please make reference to the Product Information for Comirnaty 10 micrograms/dose concentrate for dispersion for injection.

THAWING PRIOR TO DILUTION OF PFIZER-BIONTECH/COMIRNATY COVID-19 mRNA VACCINE 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (12 YEARS AND OLDER)



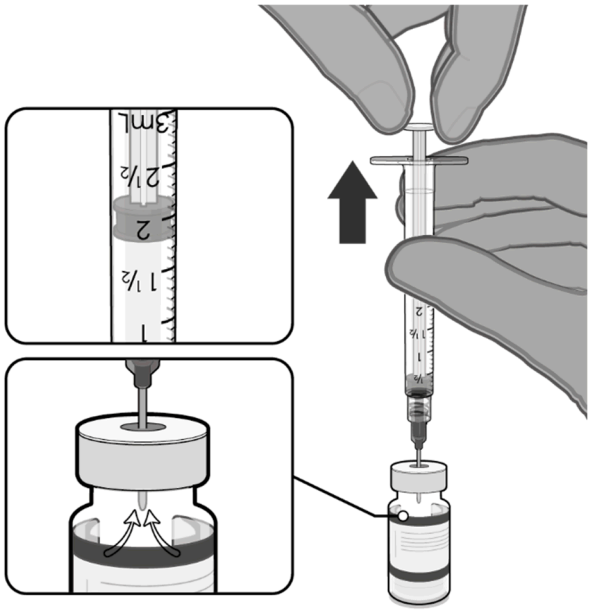
- The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use.
- The unopened vial can be stored for up to 1 month at 2 °C to 8 °C; not exceeding the expiry date (EXP) (see section 5 for more information). Within the 1-month shelf-life at 2 °C to 8 °C, up to 12 hours may be used for transportation.
- Allow the thawed vial to come to room temperature. Prior to use, the unopened vial can be stored for up to 2 hours at temperatures up to 30 °C. Thawed vials can be handled in room light conditions.
- Gently invert the vial 10 times prior to dilution. Do not shake.
- Prior to dilution, the thawed dispersion may contain white to off-white opaque amorphous particles.

DILUTION OF PFIZER-BIONTECH/COMIRNATY COVID-19 mRNA VACCINE 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (12 YEARS AND OLDER)



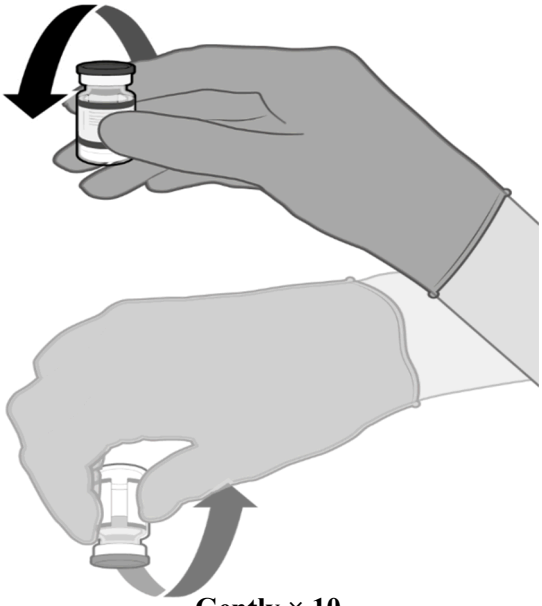
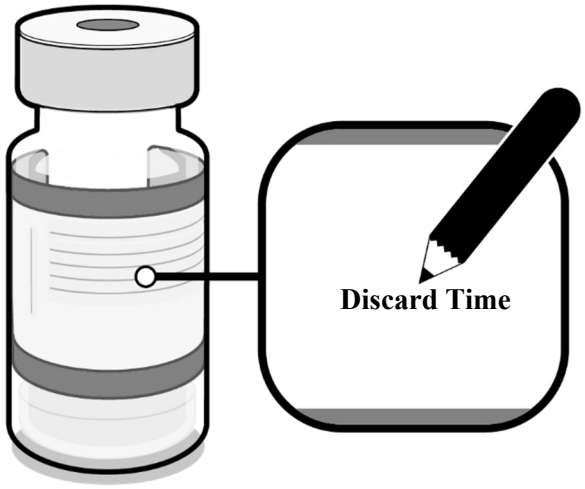
1.8 mL of sodium chloride 9 mg/mL (0.9%) solution for injection.

- The thawed vaccine must be diluted in its original vial with 1.8 mL of sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.

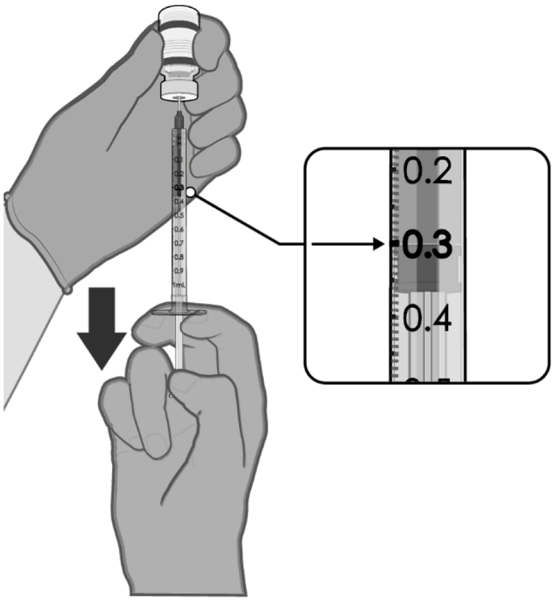


Pull back plunger to 1.8 mL to remove air from vial.

- Equalise vial pressure before removing the needle from the vial stopper by withdrawing 1.8 mL air into the empty diluent syringe.

 **Gently × 10**	• Gently invert the diluted dispersion 10 times. Do not shake. • The diluted vaccine should present as an off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.
 **Discard Time** **Record appropriate date and time.** **Use within 6 hours after dilution.**	• The diluted vials should be marked with the appropriate date and time. • After dilution, store at 2 ºC to 30 ºC and use within 6 hours, including any transportation time. • Do not freeze or shake the diluted dispersion. If refrigerated, allow the diluted dispersion to come to room temperature prior to use.

PREPARATION OF INDIVIDUAL 0.3 mL DOSES OF PFIZER-BIONTECH/COMIRNATY COVID-19 mRNA VACCINE 30 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION (12 YEARS AND OLDER)



0.3 mL diluted vaccine

- After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.
- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of Pfizer-BioNTech/Comirnaty COVID-19 mRNA Vaccine.

  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 within 6 hours after dilution.

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

Philippines EUA Product information for vaccine recipients (PBS/Sucrose 30mcg/dose formulation) revision number: **7.0**
Philippines EUA Product information for vaccine recipients (PBS/Sucrose 30mcg/dose formulation) revision date: **12 April 2022**
Reference Document: EU PIL
Reference date: 04 April 2022