Your guide to proper storage, handling, and administration for COMIRNATY

COMIRNATY™
(BNT162b2 [mRNA]) COVID-19 Vaccine

COMIRNATY (BNT162b2[mRNA]) COVID-19 Vaccine has provisional approval for active immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2, in individuals 16 years of age and older. The use of this vaccine should be in accordance with official recommendations. During the initial pandemic stage, COMIRNATY (BNT162b2[mRNA]) COVID-19 Vaccine may be distributed with the packaging with either the name Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY COVID-19 mRNA Vaccine (nucleoside modified).

▼This vaccine is subject to additional monitoring **in Australia**. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

Shelf Life and Special Precautions for Storage

Shelf life

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

Unopened vial

Once removed from the freezer, the unopened vaccine can be stored for up to 5 days at 2 °C to 8 °C, and up to 2 hours at temperatures up to 30 °C, prior to use.
Once thawed, COMIRNATY should not be re-frozen.
Closed-lid vial trays containing 195 vials removed from frozen storage (< -60 °C) may be at room temperature (< 25 °C) for up to 5 minutes for transfer between ultra-low-temperature environments. After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again.

Diluted medicinal product
Chemical and physical in-use stability has been demonstrated for 6 hours at 2°C to 30°C after dilution in sodium chloride 9 mg/mL (0.9%) solution for injection.

Special precautions for storage

Store in a freezer at -90°C to -60°C.
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.

When you are ready to thaw or use the vaccine:

- Open-lid vial trays, or vial trays containing less than 195 vials removed from frozen storage (<-60°C) may be at room temperature (<25°C) for up to 3 minutes to remove vials or for transfer between ultra-low-temperature environments
- Once a vial is removed from the vial tray, it should be thawed for use
- After vial trays are returned to frozen storage following room temperature exposure, they must remain in frozen storage for at least 2 hours before they can be removed again

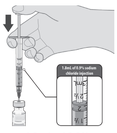
COMIRNATY should be prepared by a healthcare professional using aseptic technique to ensure the sterility of the prepared suspension.

Thawing Prior to Dilution

No more than 2 hours at room temperature (up to 30°C)

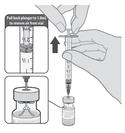
- The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2°C to 8°C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30°C for immediate use
- **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 suspension may contain white to off-white opaque amorphous particles

Dilution



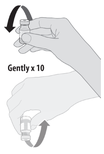
1.8 mL of 0.9% sodium chloride injection

- 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. Do not use any other diluent.



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 x 10

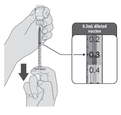
- **Gently invert the diluted suspension 10 times. Do not shake**
- The diluted vaccine should present as an off-white suspension with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present

Record appropriate date and time. Use within 6 hours after dilution*

- The diluted vials should be marked with the appropriate date and time of dilution.
- Do not freeze or shake the diluted suspension. If refrigerated, allow the diluted suspension to come to room temperature prior to use

*Chemical and physical in-use stability has been demonstrated for 6 hours at 2°C to 30°C after dilution in sodium chloride 9 mg/mL (0.9%) solution for injection.

Preparation of Individual 0.3 mL Doses of COMIRNATY



- 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 COMIRNATY
  - 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
- Verify a final injection volume of 0.3 mL prior to administration
- Discard syringe and needle after administration to a single patient
- Use a new, sterile needle and syringe to draw up each new dose
- Discard any unused vaccine 6 hours after dilution
- **COMIRNATY (BNT162b2 [mRNA]) COVID-19 Vaccine is administered intramuscularly after dilution as a course of 2 doses (0.3 mL each) at least 21 days apart. The preferred site is the deltoid muscle of the upper arm**

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

Disposal

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

Find additional resources about COMIRNATY at

www.comirnatyglobal.com

BIONTECH Pfizer

SPONSOR
Pfizer Australia Pty Ltd
Level 17, 151 Clarence Street
Sydney NSW 2000
www.pfizer.com.au

PBS Information: This product is not listed on the PBS and is not listed on the National Immunisation Program.

Review the full Product Information at
https://www.pfi.sr/cmrpi

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