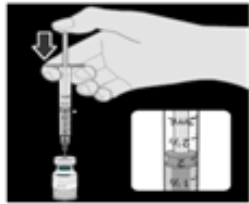


## Preparation of Comirnaty® Vaccine

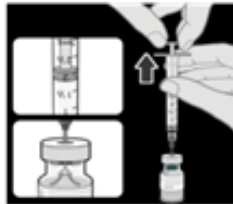
**Frozen vaccine should be thawed before use as described**



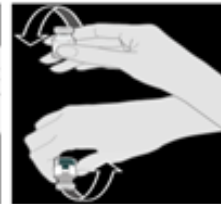
Gently invert the undiluted vial 10 times before dilution. Do not shake



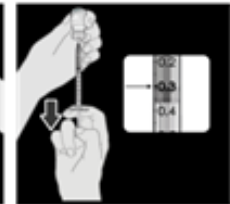
The thawed vaccine must be diluted in its original vial with 1.8 mL sodium chloride 9 mg/mL (0.9%) solution for injection, using a 21 gauge or narrower needle and aseptic techniques.



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



Gently invert the diluted dispersion 10 times. Do not shake.



After dilution, the vial contains 2.25 mL from which 6 doses of 0.3 mL can be extracted.

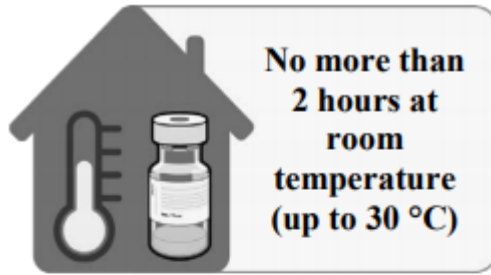
- Using aseptic technique•
- Withdraw 0.3 mL of Comirnaty®.



Indicate the date and time of reconstitution

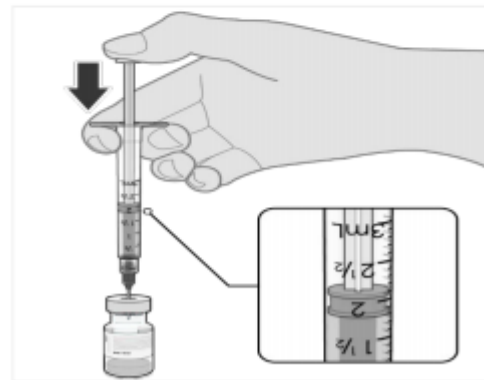
**Open vaccine vials should be discarded after 6 hours**

### THAWING PRIOR TO DILUTION



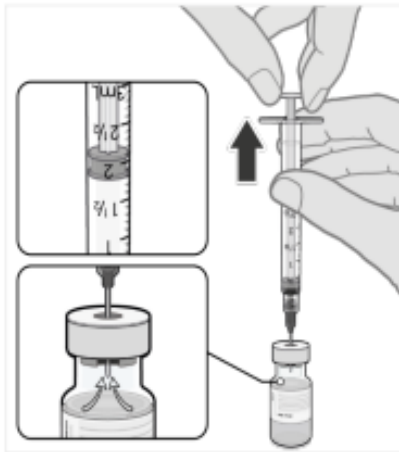
- The multidose vial is stored frozen and must be thawed prior to dilution. Frozen vials should be transferred to an environment of 2 °C to 8 °C to thaw; a 195 vial pack may take 3 hours to thaw. Alternatively, frozen vials may also be thawed for 30 minutes at temperatures up to 30 °C for immediate use.
- The unopened vaccine can be stored for up to 5 days at 2 °C to 8 °C. Within the 5 days 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 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



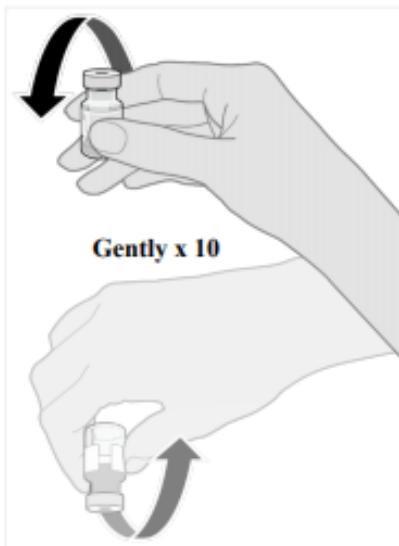
**1.8 mL of 0.9% sodium chloride injection**

- 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.



**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**

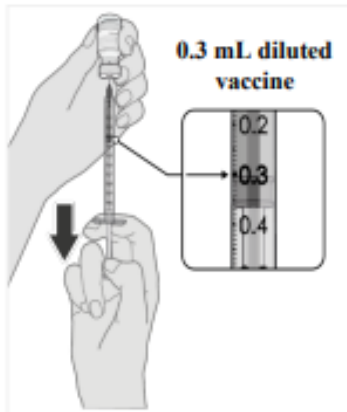
- Gently invert the diluted dispersion 10 times. Do not shake.
- The diluted vaccine should present as an off-white dispersion with no particulates visible. Discard the diluted vaccine if particulates or discolouration are present.



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

- The diluted vials should be marked with the appropriate date and time.
- After dilution store at 2 °C to 30 °C 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 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.
- Discard any unused vaccine within 6 hours after dilution.