

Preparation of Pfizer BioNTech Bivalent Original & Omicron BA.4/BA.5 COVID-19 Vaccine for Ages 5 to 11 Years

VIAL AND DOSE VERIFICATION



✓ Orange plastic cap and label with orange border

- Verify that:
 - The vial has an orange plastic cap and a label with an orange border **AND**
 - the product name on the vial states that the vaccine is **Bivalent Original & Omicron BA.4/BA.5**.
- **Do not use** COMIRNATY Original & Omicron BA.4/BA.5 with gray plastic cap and gray label border to prepare doses for individuals aged 5 years to <12 years.
- The date printed on the vial and carton reflects the date of manufacture. The vaccine should not be used after 12 months from the date of manufacture printed on the vial and carton.

THAWING PRIOR TO DILUTION



Can be stored in the refrigerator (2°C to 8°C) for up to 10 weeks prior to use within the expiry date

- Thaw vial(s) of COMIRNATY Original & Omicron BA.4/BA.5 before use either by:
 - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of 10 vials may take up to 4 hours to thaw, and thawed vials can be stored in the refrigerator for up to 10 weeks.
 - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
 - Thawed vials may be stored at room temperature [up to 25°C (77°F)] for

COMIRNATY Original & Omicron BA.4/BA.5 For Age 5 Years to <12 Years: DILUTE PRIOR TO USE (Vials with Orange Cap and Orange Label Border)

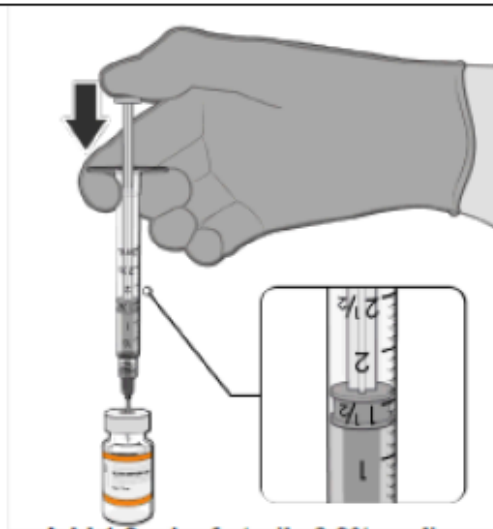
up to 12 hours prior to dilution.



Gently × 10

- Before dilution, allow the thawed vial to come to room temperature.
- When at room temperature, mix by inverting vaccine vial gently 10 times.
- Do not shake.
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles.
- Do not use if liquid is discoloured or if other particles are observed.

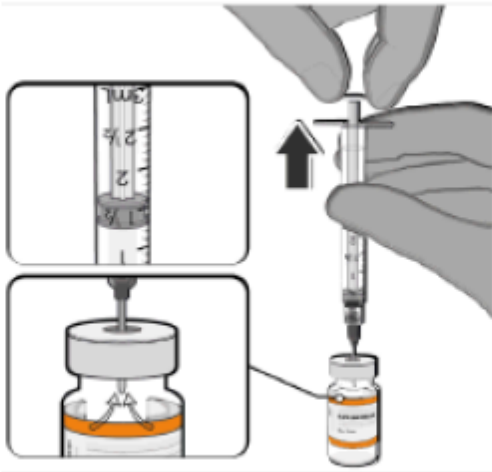
DILUTION



Add 1.3 mL of sterile 0.9% sodium chloride injection, USP.

- Obtain sterile 0.9% Sodium Chloride Injection, USP. Use only this as the diluent.
- Using aseptic technique, withdraw 1.3 mL of diluent into a transfer syringe (using 21-gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use antiseptic swab.
- Add 1.3 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.

**COMIRNATY Original & Omicron BA.4/BA.5 For Age 5 Years to <12 Years: DILUTE PRIOR TO USE
(Vials with Orange Cap and Orange Label Border)**



Pull back plunger to 1.3 mL to remove air from vial.

- Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL air into the empty diluent syringe.



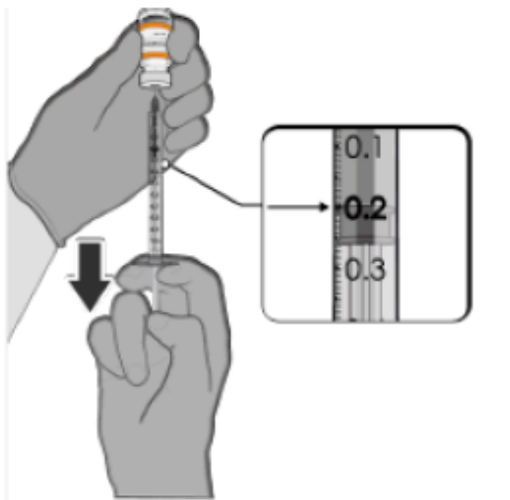
Gently × 10

- Gently invert the vial containing COMIRNATY Original & Omicron BA.4/BA.5 10 times to mix.
- Do not shake.
- Inspect the vaccine in the vial.
- The vaccine will be a white to off-white suspension. Do not use if vaccine is discoloured or contains particulate matter.



**Record the date and time of dilution.
Use within 12 hours after dilution.**

- Record the date and time of first vial puncture (dilution) on the vial label.
- Store between 2°C to 25°C (35°F to 77°F).
- Do not freeze or shake the diluted vaccine. If refrigerated, allow the diluted vaccine to come to room temperature prior to use.
- Discard any unused vaccine 12 hours after dilution.



Withdraw 0.2 mL dose of vaccine.

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of COMIRNATY Original & Omicron BA.4/BA.5 (for age 5 years to <12 years) preferentially using a low dead-volume syringe and/or needle.
- 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.
- Administer immediately, and no later than 12 hours after dilution.
- Low dead-volume syringes and/or needles can be used to extract 10 doses from a single vial. In order to ensure consistent withdrawal of 10 doses of 0.2 mL, it is important to adhere to minimizing volume loss during dose extraction.