



COMIRNATY® Omicron XBB.1.5 for 12 years of age and older

COVID-19 mRNA vaccine, Monovalent (Omicron XBB.1.5), multidose vial (gray cap and label)

COMIRNATY Omicron XBB.1.5 is administered intramuscularly as a single dose of 0.3 mL, regardless of prior COVID-19 vaccination status. For individuals who have previously been vaccinated with a COVID-19 vaccine, COMIRNATY Omicron XBB.1.5 should be administered at least 6 months after the most recent dose of a COVID-19 vaccine or COVID-19 infection (whichever is later).

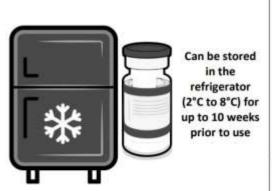
Vaccine is provided in Multiple Dose Vials: **DO NOT DILUTE**

The COMIRNATY Omicron XBB.1.5 multiple dose vial with *a gray cap and a gray label* border contains a volume of 2.25 mL and does not contain preservative. Vials of COMIRNATY Omicron XBB.1.5 is intended for individuals 12 years of age and older (gray cap/gray label border) and cannot be used to prepare doses for individuals aged 6 months to <12 years of age.

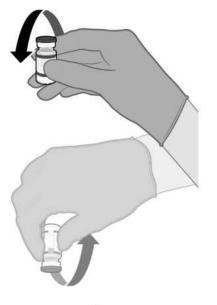
- Please ensure each vial is thawed prior to administration. Reminder DO NOT DILUTE prior to use
- Vials may be thawed in the refrigerator (2°C to 8°C) or at room temperature (up to 25°C)
- The thawed suspension may contain white to off-white opaque amorphous particles.
- One multiple dose vial contains 6 doses of 0.3 mL.
- 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.
- Low dead-volume syringes and/or needles can be used to extract 6 doses from a single vial. In order to ensure consistent withdrawal of 6 doses of 0.3 mL, it is important to adhere to minimizing volume loss during dose extraction.

COMIRNATY Omicron XBB.1.5 For 12 Years of Age and Older: DO NOT DILUTE (Single Dose & Multiple Dose Vials with Gray Cap and Gray Label Border)

THAWING PRIOR TO USE



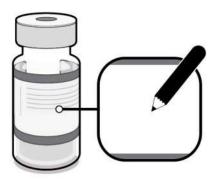
- Thaw single dose or multiple dose vial(s) of COMIRNATY Omicron XBB.1.5 before use either by:
 - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)].
 - Single dose vials: A 10 vial pack of single dose vials may take 2 hours to thaw.
 - Multiple dose vials: A 10 vial pack of multiple dose vials may take 6 hours to thaw.
 - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes.
- Thawed vials can be stored in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 10 weeks prior to use within the expiry date.
- Thawed vials may be stored at room temperature [up to 25°C (77°F)] for up to 12 hours prior to use.



Gently × 10

- Before use, mix by inverting vaccine vial gently 10 times.
- Do not shake.
- Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should appear as a white to off-white suspension with no visible particles.
- Do not use if liquid is discoloured or if particles are observed after mixing.

COMIRNATY Omicron XBB.1.5 For 12 Years of Age and Older: DO NOT DILUTE (Single Dose & Multiple Dose Vials with Gray Cap and Gray Label Border)



Record the discard time on the vial label. Use within 12 hours after first puncture.

Multiple Dose Vial Only:

- Store between 2°C to 25°C (35°F to 77°F).
- Discard any unused vaccine 12 hours after first puncture. Record the discard time on the vial label.

Vials must be discarded 12 hours after first puncture

Full Product Monograph available online: https://covid-vaccine.canada.ca/info/pdf/comirnaty-omicron-xbb-1-5-pm-en.pdf