COMIRNATY®

HOW TO PREPARE AND ADMINISTER COMIRNATY ORIGINAL & OMICRON BA.4/BA.5

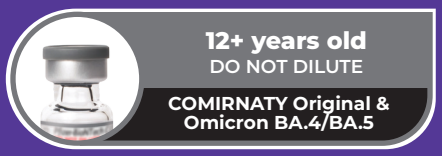
COMIRNATY BIVALENT VACCINE

COMIRNATY® Original & Omicron BA.4/BA.5 (COVID-19 mRNA Vaccine, Bivalent [Original and Omicron BA.4/BA.5]) is indicated for active immunization against coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 6 months of age and older.

The safety and effectiveness of a primary vaccination course of COMIRNATY Original & Omicron BA.4/BA.5 for individuals 6 months of age and older and booster dose of COMIRNATY Original & Omicron BA.4/BA.5 for individuals 5 years of age and older are inferred from studies which evaluated the primary series and booster vaccination with COMIRNATY and supported by studies of a booster dose of COMIRNATY Original & Omicron BA.4/BA.5 in individuals 6 months of age and older.[1]

Marketing authorization has been issued with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and effectiveness of the vaccine.

Instructions for Each Formulation Inside



MULTIPLE-DOSE VIALS WITH GRAY CAP/LABEL BORDER
For 12 years and older, DO NOT DILUTE formulation:
pages 4–5*

MULTIPLE-DOSE VIALS WITH ORANGE CAP/LABEL BORDER
For 5 years to <12 years, DILUTE BEFORE USE formulation:
pages 6–7†

MULTIPLE-DOSE VIALS WITH MAROON CAP/LABEL BORDER
For 6 months to <5 years, DILUTE BEFORE USE formulation:
pages 8–9‡

* Vials of COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine intended for individuals 12 years of age and older (gray vials) **cannot** be used to prepare doses for individuals aged 6 months to <12 years.

† Vials of COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine intended for individuals 5 years to <12 years (orange vials) **cannot** be used to prepare doses for individuals 6 months to <5 years or 12 years of age and older.

‡ Vials of COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine intended for individuals 6 months to <5 years (maroon vials) **cannot** be used to prepare doses for individuals 5 years of age and older.

Despite its official name, Canada may continue to receive vials of the vaccine labelled as Pfizer-BioNTech COVID-19 Vaccine.

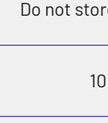
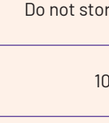
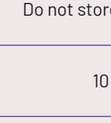
Pfizer BIONTECH

To report product quality complaints or for more detailed instructions, please contact Pfizer Customer Service at **1-833-VAX-COVI (1-833-829-2684)**.

To report a side effect following immunization, please contact your local health unit or Pfizer Safety Department by calling 1-866-723-7111 or by fax at 1-855-242-5652, or visit **www.pfizersafetyreporting.com**.

For more information on COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine and complete dosing instructions, please see the Product Monograph and go to **CVDvaccine.ca**.

A QUICK REFERENCE ON DOSING, DILUTION, AND STORAGE OF FORMULATIONS

Vial colour	COMIRNATY **Original & Omicron BA.4/BA.5** bivalent vaccine Multiple-Dose Vial  Vials with Gray Cap/ Label Border	COMIRNATY **Original & Omicron BA.4/BA.5** bivalent vaccine Multiple-Dose Vial  Vials with Orange Cap/ Label Border	COMIRNATY **Original & Omicron BA.4/BA.5** bivalent vaccine Multiple-Dose Vial  Vials with Maroon Cap/ Label Border
Age range	12 years and older	5 to <12 years	6 months to <5 years
Can be used for primary series	YES	YES	YES
Can be used for booster dose	YES	YES	**NO**
Dilution required	No	Yes	Yes
Amount of diluent required per vial (0.9% Sodium Chloride Injection, USP)	DO NOT DILUTE before use	1.3 mL per vial	**2.2 mL** per vial
Number of doses per vial*	6 doses per vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)
Dose amount	30 micrograms per dose (15 mcg of Original and 15 mcg of Omicron BA.4/BA.5)	10 micrograms per dose (5 mcg of Original and 5 mcg of Omicron BA.4/BA.5)	3 micrograms per dose (1.5 mcg of Original and 1.5 mcg of Omicron BA.4/BA.5)
Dose volume	0.3 mL per dose	0.2 mL per dose	0.2 mL per dose
STORAGE CONDITIONS			
ULT freezer storage time (-90 to -60°C)	18 months after manufacturing date printed on vial label	18 months after manufacturing date printed on vial label	18 months after manufacturing date printed on vial label
Freezer storage time (-25 to -15°C)	Do not store at -25 to -15°C	Do not store at -25 to -15°C	Do not store at -25 to -15°C
Refrigerated storage time (2 to 8°C)(within the expiry date)	10 weeks	10 weeks	10 weeks
Room temperature storage time (8 to 25°C)	12 hours prior to first puncture (including any thaw time)	12 hours prior to dilution (including any thaw time)	12 hours prior to dilution (including any thaw time)
After first puncture (2 to 25°C)	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours
Expiry date	18 months after manufacturing date printed on vial label	18 months after manufacturing date printed on vial label	18 months after manufacturing date printed on vial label

ULT: ultra-low temperature.

Adapted from the COMIRNATY Original & Omicron BA.4/BA.5 Product Monograph[1]

*** Low dead-volume syringes and/or needles can be used to extract 6 or 10 doses from a single multiple-dose vial. If standard syringes and needles are used, there may not be sufficient volume to extract 6 or 10 doses from a single multiple-dose vial.**

Before Use[1]

Thawed vials can be stored in the refrigerator for up to 10 weeks prior to use. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. Do not refreeze thawed vials.

1. When vial is at room temperature, gently invert vaccine vial 10 times. Do not shake.

- Inspect the liquid in the vial prior to use
- 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

The multiple-dose vial contains six 0.3-mL doses of vaccine.

2. Record the date and time of first vial puncture on the vaccine vial label.

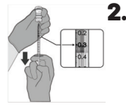
- Thawed vaccine:
  - Can be handled in room light conditions. Avoid exposure to direct sunlight and ultraviolet light
  - Must be kept at temperatures between 2°C to 25°C (35°F to 77°F)
  - Should be discarded if not used within 12 hours after first puncture

HOW TO PREPARE AND ADMINISTER IN AGES **12 YEARS AND OLDER** – DO NOT DILUTE BEFORE USE (multiple-dose vials with gray cap/label border)

To prepare individual 0.3-mL doses for administration[1]

1. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 mL of the vaccine.

- Adjustments to remove air bubbles should be done with the needle still in the vial to avoid loss of vaccine



2. Verify the final dosing volume of 0.3 mL and confirm there are no particulates and that no discolouration is observed.

Irrespective of the type of syringe and needle used:

- Each dose must contain 0.3 mL of vaccine
- If the amount of vaccine remaining in the multiple-dose vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume
- Do not pool excess vaccine from multiple vials

Low dead-volume syringes and/or needles can be used to extract 6 doses from a single multiple-dose vial. If standard syringes and needles are used, there may not be sufficient volume to extract 6 doses from a single multiple-dose vial.[1]

3. Immediately administer the vaccine intramuscularly and no later than 12 hours after first puncture.

4. Administration

<u>Primary Vaccination Series</u>

COMIRNATY Original & Omicron BA.4/BA.5 is administered intramuscularly as a primary course of two doses (0.3 mL each) 3 weeks apart.

If an individual starts a primary vaccination course of COMIRNATY, they may complete the primary vaccination course with COMIRNATY Original & Omicron BA.4/BA.5.

The interchangeability of COMIRNATY Original & Omicron BA.4/BA.5 with COVID-19 vaccines from other manufacturers to complete the primary course has not been established. Individuals who have received a dose of COMIRNATY Original & Omicron BA.4/BA.5 should receive COMIRNATY Original & Omicron BA.4/BA.5 to complete the primary course.

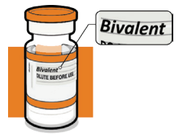
<u>Booster Dose</u>

A booster dose (0.3 mL) of COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine may be administered intramuscularly at least 3 to 6 months after completing the primary course of COMIRNATY and/or a previous booster dose of COMIRNATY in individuals 12 years of age or older.

Vials of COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine intended for individuals aged 12 years of age and older (gray vials) **<u>cannot</u>** be used to prepare doses for individuals 6 months to <12 years.

Please refer to the COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine Product Monograph for complete dosing and administration instructions.

Before Dilution[1]

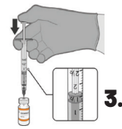


Undiluted vials can be stored in the refrigerator for up to 10 weeks before use. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. Do not refreeze thawed vials.

1. **When vial is at room temperature, gently invert vaccine vial 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 discoloured or other particles are present

Dilution[1]

2. **Using aseptic technique, withdraw 1.3 mL of sterile 0.9% Sodium Chloride Injection, USP into a transfer syringe with a 21-gauge or narrower needle.**



Only use sterile 0.9% Sodium Chloride Injection, USP as the diluent.
Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

3. **Cleanse the vaccine vial stopper with a single-use antiseptic swab. Add diluent to the vaccine vial. <u>Do not add more than 1.3 mL of diluent to the vaccine vial</u>.**
   - Equalize vial pressure before removing the needle from the vial by withdrawing 1.3 mL of air into the empty diluent syringe
   - Discard any saline remaining in the diluent vial

The multiple-dose vial now contains ten 0.2-mL doses of vaccine.

After Dilution[1]

4. **Gently invert the diluted vial 10 times to mix. Do not shake.**
   - Inspect the liquid in the vial
   - The vaccine will be a white to off-white suspension. Do not use if vaccine is discoloured or contains particulate matter

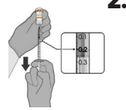
5. **Record the date and time of first vial puncture (dilution) on the vaccine vial label.**
   - Diluted vaccine:
     - Can be handled in room light conditions. Avoid exposure to direct sunlight and ultraviolet light
     - Must be kept at temperatures between 2°C to 25°C (35°F to 77°F)
     - Should be discarded if not used within 12 hours from the time of dilution
     - Do not freeze or shake the diluted vaccine. If refrigerated, allow the diluted vaccine to come to room temperature prior to use

HOW TO PREPARE AND ADMINISTER IN AGES **5 TO <12 YEARS** – DILUTE BEFORE USE (multiple-dose vials with orange cap/label border)

5 to <12

To prepare individual 0.2-mL doses for administration[1]

1. **Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the diluted vaccine.**
   - Adjustments to remove air bubbles should be done with the needle still in the vial to avoid loss of vaccine



2. **Verify the final dosing volume of 0.2 mL and confirm there are no particulates and that no discolouration is observed.**

   Irrespective of the type of syringe and needle used:
   - 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
   - Do not pool excess vaccine from multiple vials

Low dead-volume syringes and/or needles should be used in order to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial.[1]

3. **Immediately administer the vaccine intramuscularly and no later than 12 hours after dilution.**

4. **Administration**

<u>Primary Vaccination Series</u>

COMIRNATY Original & Omicron BA.4/BA.5 is administered intramuscularly as a primary series of two doses (0.2 mL each) 3 weeks apart.

If an individual starts a primary vaccination course of COMIRNATY, they may complete the primary vaccination course with COMIRNATY Original & Omicron BA.4/BA.5.

The interchangeability of COMIRNATY Original & Omicron BA.4/BA.5 with COVID-19 vaccines from other manufacturers to complete the primary course has not been established. Individuals who have received a dose of COMIRNATY Original & Omicron BA.4/BA.5 should receive COMIRNATY Original & Omicron BA.4/BA.5 to complete the primary course.

<u>Booster Dose</u>

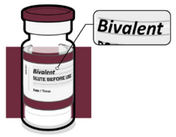
A booster dose (0.2 mL) of COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine may be administered intramuscularly at least 6 months after completing the primary course of COMIRNATY and/or a previous booster dose of COMIRNATY in individuals 5 years to <12 years of age.

Vials of COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine intended for individuals aged 5 years to <12 years (orange vials) **<u>cannot</u>** be used to prepare doses for individuals 12 years of age and older or for individuals 6 months to <5 years.

Please refer to the COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine Product Monograph for complete dosing and administration instructions.

Before Dilution[1]

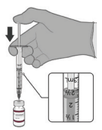
Undiluted vials can be stored in the refrigerator for up to 10 weeks before use. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. Do not refreeze thawed vials.



1. **When vial is at room temperature, gently invert vaccine vial 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 discoloured or other particles are present

Dilution[1]

2. **Using aseptic technique, withdraw 2.2 mL of sterile 0.9% Sodium Chloride Injection, USP into a transfer syringe with a 21-gauge or narrower needle.**



Only use sterile 0.9% Sodium Chloride Injection, USP as the diluent.
Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent.

3. **Cleanse the vaccine vial stopper with a single-use antiseptic swab. Add diluent to the vaccine vial. <u>Do not add more than 2.2 mL of diluent to the vaccine vial</u>.**
   - Equalize vial pressure before removing the needle from the vial by withdrawing 2.2 mL of air into the empty diluent syringe
   - Discard any saline remaining in the diluent vial

The multiple-dose vial now contains ten 0.2-mL doses of vaccine.

After Dilution[1]

4. **Gently invert the diluted vial 10 times to mix. Do not shake.**
   - Inspect the liquid in the vial
   - The vaccine will be a white to off-white suspension. Do not use if vaccine is discoloured or contains particulate matter

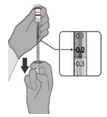
5. **Record the date and time of first vial puncture (dilution) on the vaccine vial label.**
   - Diluted vaccine:
     - Can be handled in room light conditions. Avoid exposure to direct sunlight and ultraviolet light
     - Store between 2°C to 25°C (35°F to 77°F)
     - Should be discarded if not used within 12 hours from the time of dilution
     - Do not freeze or shake the diluted vaccine. If refrigerated, allow the diluted vaccine to come to room temperature prior to use

HOW TO PREPARE AND ADMINISTER IN AGES **6 MONTHS TO <5 YEARS** – DILUTE BEFORE USE (multiple-dose vials with maroon cap/label border)

6 months to <5 years

To prepare individual 0.2-mL doses for administration[1]

1. **Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.2 mL of the diluted vaccine.**
   - Adjustments to remove air bubbles should be done with the needle still in the vial to avoid loss of vaccine



2. **Verify the final dosing volume of 0.2 mL, and confirm there are no particulates and that no discolouration is observed.**

   Irrespective of the type of syringe and needle used:
   - 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
   - Do not pool excess vaccine from multiple vials

Low dead-volume syringes and/or needles should be used in order to extract 10 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract 10 doses from a single vial.[1]

3. **Immediately administer the vaccine intramuscularly and no later than 12 hours after dilution.**

4. **Ensure the vaccine recipient's parent/caregiver understands the vaccine is administered intramuscularly as a primary series of three doses (0.2 mL each). It is recommended to administer the second dose 3 weeks after the first dose, followed by a third dose administered at least 8 weeks after the second dose.**

If an infant or child starts a primary vaccination course with COMIRNATY, they may complete the primary vaccination course with COMIRNATY Original & Omicron BA.4/BA.5.

The interchangeability of COMIRNATY Original & Omicron BA.4/BA.5 with COVID-19 vaccines from other manufacturers to complete the primary course has not been established. Individuals who have received a dose of COMIRNATY Original & Omicron BA.4/BA.5 should receive COMIRNATY Original & Omicron BA.4/BA.5 to complete the primary course.

Vials of COMIRNATY Original & Omicron BA.4/BA.5 intended for individuals aged 6 months to <5 years (maroon cap/maroon label border) **<u>cannot</u>** be used to prepare doses for individuals 5 years of age and older.

Please refer to the COMIRNATY Original & Omicron BA.4/BA.5 bivalent vaccine Product Monograph for complete dosing and administration instructions.

For more information

on **COMIRNATY Original & Omicron BA.4/BA.5** bivalent vaccine, please go to **CVDvaccine.ca** or contact Pfizer Customer Service at **1-833-VAX-COVI (1-833-829-2684)**.

For more information:

Please consult the Product Monograph at https://www.pfizer.ca/en/our-products/comirnaty-original-omicron-ba4-ba5-covid-19-mrna-vaccine-bivalent-original-and-omicron-ba4-ba5 for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also available upon request by calling **1-833-VAX-COVI (1-833-829-2684)**.

Reference: 1. COMIRNATY Original & Omicron BA.4/BA.5 Product Monograph. Pfizer Canada ULC.

COMIRNATY® Pfizer BIONTECH

MEMBER OF INNOVATIVE MEDICINES CANADA

REVIEWED BY PAAB

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