The Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA)*

COMIRNATY (COVID-19 Vaccine, mRNA) is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 5 years of age and older.†

Instructions for Each Formulation Inside

For 12 years and older, DILUTE BEFORE USE formulation: pages 3–4†

For age 5 years to <12 years, DILUTE BEFORE USE formulation: pages 5–6†

* The Pfizer-BioNTech COVID-19 vaccine is now called COMIRNATY®. COMIRNATY® and the Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.

† Vials of Pfizer-BioNTech COVID-19 Vaccine intended for individuals 12 years of age and older (purple cap) cannot be used to prepare doses for individuals aged 5 years to <12 years, and the vials for individuals aged 5 years to <12 years (orange cap) cannot be used to prepare doses for individuals 12 years of age and older.

COMIRNATY® is now the official name of the Pfizer-BioNTech COVID-19 vaccine

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

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### A QUICK REFERENCE TO DOSING, DILUTION, AND STORAGE OF FORMULATIONS

<table>
<thead>
<tr>
<th>Vial colour</th>
<th>Pfizer-BioNTech COVID-19 Vaccine Multiple-Dose Vial</th>
<th>Pfizer-BioNTech COVID-19 Vaccine Multiple-Dose Vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purple Vial Cap</td>
<td>Orange Vial Cap</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age range</th>
<th>12 years of age and older</th>
<th>5 to &lt;12 years of age</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dilution required</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Amount of diluent required per vial (0.9% Sodium Chloride Injection, USP)</td>
<td>1.8 mL per vial</td>
<td>1.3 mL per vial</td>
</tr>
<tr>
<td>Number of doses per vial (after dilution)</td>
<td>6 doses per vial</td>
<td>10 doses per vial</td>
</tr>
<tr>
<td>Dose amount</td>
<td>30 micrograms per dose</td>
<td>10 micrograms per dose</td>
</tr>
<tr>
<td>Dose volume</td>
<td>0.3 mL per dose</td>
<td>0.2 mL per dose</td>
</tr>
</tbody>
</table>

### Storage conditions

- **ULT freezer storage time** (-90 to -60°C)
  - Until expiry date printed on vial label
  - 6 months after manufacturing date printed on vial label

- **Freezer storage time** (-25 to -15°C)
  - 2 weeks
  - Do not store at -25 to -15°C

- **Refrigerated storage time** (2 to 8°C)
  - 1 month
  - 10 weeks

- **Room temperature storage time prior to dilution** (8 to 25°C)
  - 2 hours prior to dilution (including any thaw time)
  - 12 hours prior to dilution

- **After dilution** (2 to 25°C)
  - Discard after 6 hours
  - Discard after 12 hours†

- **Expiry date**
  - Date printed on vial label†
  - 6 months after manufacturing date printed on vial label

* Vial labels and cartons may state that a vial should be discarded 6 hours after dilution. The information in the Product Monograph here supersedes the number of hours printed on vial labels and cartons.

† As a reminder, vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of August 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as all approved storage conditions have been maintained.

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**COMIRNATY** is now the official name of the Pfizer-BioNTech COVID-19 vaccine
HOW TO PREPARE AND ADMINISTER IN AGES 12 AND OLDER – DILUTE BEFORE USE (PURPLE CAP)

Before Dilution

Undiluted vials cannot be at room temperature (up to 25°C) for more than 2 hours (including thaw time). 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

2. Using aseptic technique, withdraw 1.8 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. Do not add more than 1.8 mL of diluent to the vaccine vial.
   • Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL of air into the empty diluent syringe
   • Discard any saline remaining in the diluent vial

The vial now contains six 0.3-mL doses of vaccine.

After Dilution

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

5. Record the date and time of dilution on the vaccine vial label.
   • Diluted vaccine:
     o Can be handled in room light conditions. Avoid exposure to direct sunlight and ultraviolet light
     o Must be kept at temperatures between 2°C to 25°C (35°F to 77°F)
     o Should be discarded if not used within 6 hours from the time of dilution

To prepare individual 0.3-mL doses for administration

1. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw 0.3 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 0.3 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 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 vial. If standard syringes and needles are used, there may not be sufficient volume to extract 6 doses from a single vial.1

3. Immediately administer the vaccine intramuscularly and no later than 6 hours after dilution.

4. Ensure the vaccine recipient/parent understands the vaccine is administered intramuscularly as a primary series of two doses (0.3 mL each), three weeks apart.
   In individuals 18 years or older, a booster dose may be administered intramuscularly at least 6 months after completion of the primary series
   There are no data available on the interchangeability of Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive all doses of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.
   COMIRNATY and the Interim Order authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation, and can be used interchangeably to provide the COVID-19 vaccination series in individuals 12 years of age and older.
   Vials of Pfizer-BioNTech COVID-19 Vaccine intended for individuals 12 years of age and older (purple cap) cannot be used to prepare doses for individuals aged 5 years to <12 years.

Please refer to the COMIRNATY Product Monograph for complete dosing and administration instructions.
Before Dilution

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

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. Do not add more than 1.3 mL of diluent to the vaccine vial.
   • 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 vial now contains ten 0.2-mL doses of vaccine.

After Dilution

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 discolored or contains particulate matter

5. Record the date and time of dilution on the vaccine vial label.
   • Diluted vaccine:
     o Can be handled in room light conditions. Avoid exposure to direct sunlight and ultraviolet light
     o Must be kept at temperatures between 2°C to 25°C (35°F to 77°F)
     o Should be discarded if not used within 12 hours from the time of dilution*

To prepare individual 0.2-mL doses for administration

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

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

4. Ensure the vaccine recipient/parent understands the vaccine is administered intramuscularly as a primary series of two doses (0.2 mL each), three weeks apart.

There are no data available on the interchangeability of Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

Vials of Pfizer-BioNTech COVID-19 Vaccine intended for individuals aged 5 years to <12 years (orange cap) cannot be used to prepare doses for individuals 12 years of age and older.

* Vial labels and cartons may state that a vial should be discarded 6 hours after dilution. The information in this Product Monograph and here supersedes the number of hours printed on vial labels and cartons. Please refer to the COMIRNATY Product Monograph for complete dosing and administration instructions.
FOR MORE INFORMATION

on Pfizer-BioNTech COVID-19 Vaccine, please go to CVDvaccine.ca or contact Pfizer Customer Service at 1-833-VAX-COVI (1-833-829-2684).

Please consult the Product Monograph at www.pfizer.ca/pm/en/COVID-19Vaccine.pdf 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).