HOW TO PREPARE AND ADMINISTER

the Pfizer-BioNTech COVID-19 vaccine,
also known as COMIRNATY*

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

12+ years old
Dilute before use

VIALS WITH PURPLE CAP/LABEL BORDER
For 12 years and older, DILUTE BEFORE USE formulation:
pages 4–5†

12+ years old
Do not dilute

VIALS WITH GRAY CAP/LABEL BORDER
For 12 years and older, DO NOT DILUTE formulation:
pages 6–7†

5 to <12 years old
Dilute before use

VIALS WITH ORANGE CAP/LABEL BORDER
For 5 years to <12 years, DILUTE BEFORE USE formulation:
pages 8–9†

* 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 the Pfizer-BioNTech COVID-19 vaccine intended for individuals 12 years of age and older (purple vial or gray vial) 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 vial) cannot be used to prepare doses for individuals 12 years of age and older. When prepared according to their respective instructions, the Pfizer-BioNTech COVID-19 vaccine for individuals 12 years of age and older (DILUTE BEFORE USE: purple vial) and the Pfizer-BioNTech COVID-19 vaccine for individuals 12 years of age and older (DO NOT DILUTE: gray vial) can be used interchangeably to provide the COVID-19 vaccination series.

COMIRNATY® (COVID-19 Vaccine, mRNA) 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.
A QUICK REFERENCE TO DOSING, DILUTION, AND STORAGE OF FORMULATIONS

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Vials with Purple Cap/Label Border</td>
<td>Vials with Gray Cap/Label Border</td>
<td>Vials with Orange Cap/Label Border</td>
<td></td>
</tr>
<tr>
<td>Age range</td>
<td>12 years of age and older</td>
<td>12 years of age and older</td>
<td>5 to &lt;12 years of age</td>
</tr>
<tr>
<td>Dilution required</td>
<td>Yes</td>
<td>No</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>DO NOT DILUTE before use</td>
<td>1.3 mL per vial</td>
</tr>
<tr>
<td>Number of doses per vial</td>
<td>6 doses per vial (after dilution)</td>
<td>6 doses per vial</td>
<td>10 doses per vial (after dilution)</td>
</tr>
<tr>
<td>Dose amount</td>
<td>30 micrograms per dose</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>0.3 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
  - 12 months after manufacturing date printed on vial label
  - 12 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
  - Do not store at -25 to -15°C

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

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

- **After first puncture** (2 to 25°C)
  - Discard after 6 hours
  - Discard after 12 hours
  - Discard after 12 hours

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

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**Adapted from the COMIRNATY Product Monograph.**

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

‡ As long as all approved storage conditions have been maintained, expiry dates have been extended for the following purple vials:
  - Vials and cartons with an expiry date of August 2021 to March 2022 may remain in use for 6 months beyond the printed date.
  - Vials and cartons with an expiry date of June 2022 through August 2022 may remain in use for 3 months beyond the printed date.

§ Vial labels and cartons may state that a vial should be discarded 6 hours after first use (gray vials) or dilution (orange vials).

The information in the Product Monograph and here supersedes the number of hours printed on vial labels and cartons.

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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.
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

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

   - 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 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 to 25°C (35 to 77°F)
     - Should be discarded if not used within 6 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

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.

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 currently no data available from Pfizer and BioNTech clinical trials on the interchangeability of the Pfizer-BioNTech COVID-19 vaccine with other COVID-19 vaccines to complete the primary vaccination series or for a booster dose. Individuals who have received one dose of the Pfizer-BioNTech COVID-19 vaccine should receive all doses of the 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.

When prepared according to their respective instructions, the Pfizer-BioNTech COVID-19 vaccine for individuals 12 years of age and older (DILUTE BEFORE USE: purple vial) and the Pfizer-BioNTech COVID-19 vaccine for individuals 12 years of age and older (DO NOT DILUTE: gray vial) can be used interchangeably to provide the COVID-19 vaccination series.

Vials of the Pfizer-BioNTech COVID-19 vaccine intended for individuals 12 years of age and older (purple vial) 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 Use
Thawed vials can be stored in the refrigerator for up to 10 weeks prior to use. 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 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

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 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.

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

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 currently no data available from Pfizer and BioNTech clinical trials on the interchangeability of the Pfizer-BioNTech COVID-19 vaccine with other COVID-19 vaccines to complete the primary vaccination series or for a booster dose. Individuals who have received one dose of the Pfizer-BioNTech COVID-19 vaccine should receive all doses of the 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.

When prepared according to their respective instructions, the Pfizer-BioNTech COVID-19 vaccine for individuals 12 years of age and older (DILUTE BEFORE USE: purple vial) and the Pfizer-BioNTech COVID-19 vaccine for individuals 12 years of age and older (DO NOT DILUTE: gray vial) can be used interchangeably to provide the COVID-19 vaccination series.

Vials of the Pfizer-BioNTech COVID-19 vaccine intended for individuals 12 years of age and older (gray vial or purple vial) 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.

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

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

Please refer to the COMIRNATY Product Monograph for complete dosing and administration instructions.
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**HOW TO PREPARE AND ADMINISTER IN AGES 5 TO <12: DILUTE BEFORE USE (VIALS WITH ORANGE CAP/LABEL BORDER)**

### 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 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 to 25°C (35 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

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

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**HOW TO PREPARE AND ADMINISTER IN AGES 5 TO <12: DILUTE BEFORE USE (VIALS WITH ORANGE CAP/LABEL BORDER)**

### 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 currently no data available from Pfizer and BioNTech clinical trials on the interchangeability of the Pfizer-BioNTech COVID-19 vaccine with other COVID-19 vaccines to complete the primary vaccination series or for a booster dose. Individuals who have received one dose of the Pfizer-BioNTech COVID-19 vaccine should receive a second dose of the Pfizer-BioNTech COVID-19 vaccine to complete the vaccination series.

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

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

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**COMIRNATY**
(COVID-19 Vaccine, mRNA) is now the official name of the Pfizer-BioNTech COVID-19 vaccine
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FOR MORE INFORMATION

on the 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](http://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).