

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 6 months of age and older.¹

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[‡]



**6 months to
<5 years old**
Dilute before use

VIALS WITH MAROON CAP/LABEL BORDER

For 6 months to <5 years, **DILUTE BEFORE USE** formulation:
pages 10–11[‡]

* 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 6 months to <12 years. 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 aged 5 years to <12 years (orange vial) cannot be used to prepare doses for individuals 6 months to <5 years or 12 years of age and older. Vials for individuals 6 months to <5 years (maroon vial) cannot be used to prepare doses for individuals 5 years of age and older.

 **COMIRNATY**[®]
(COVID-19 Vaccine, mRNA)

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

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

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

	The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial	The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial	The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial	The Pfizer-BioNTech COVID-19 Vaccine Multiple Dose Vial
Vial colour	Vials with Purple Cap/Label Border 	Vials with Gray Cap/Label Border 	Vials with Orange Cap/Label Border 	Vials with Maroon Cap/Label Border 
Age range	12 years and older	12 years and older	5 to <12 years	6 months to <5 years
Dilution required	Yes	No	Yes	Yes
Amount of diluent required per vial (0.9% Sodium Chloride Injection, USP)	1.8 mL per vial	DO NOT DILUTE before use	1.3 mL per vial	2.2 mL per vial
Number of doses per vial[†]	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)
Dose amount	30 micrograms per dose	30 micrograms per dose	10 micrograms per dose	3 micrograms per dose
Dose volume	0.3 mL per dose	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)	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	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	Do not store at -25 to -15°C
Refrigerated storage time (2 to 8°C)	1 month	10 weeks	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)	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 [§]	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	12 months after manufacturing date printed on vial label

ULT: Ultra-low temperature.

Adapted from the COMIRNATY Product Monograph.¹

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.

[†] 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 to 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** and **maroon vials**). The information in the Product Monograph and here supersedes the number of hours printed on vial labels and cartons.

HOW TO PREPARE AND ADMINISTER IN AGES 12 YEARS AND OLDER – DILUTE BEFORE USE (VIALS WITH PURPLE CAP/LABEL BORDER)

12+ years old
Dilute before use



Before Dilution¹

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

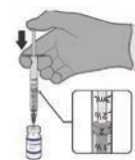


1. When vial is at room temperature, gently invert vaccine vial 10 times. Do not shake.

- 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

Dilution¹

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 Dilution¹



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 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 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

COMIRNATY[®] is now the official name of the Pfizer-BioNTech COVID-19 vaccine (COVID-19 Vaccine, mRNA)

HOW TO PREPARE AND ADMINISTER IN AGES 12 YEARS AND OLDER – DILUTE BEFORE USE (VIALS WITH PURPLE CAP/LABEL BORDER)

12+ years old
Dilute before use

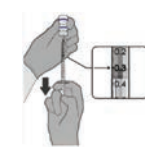


To prepare individual 0.3-mL doses for administration¹



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 discoloration 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 **16 years or older**, a **booster dose** may be administered intramuscularly at least 6 months after completion of the primary series.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. In these individuals, a third dose may be considered as part 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.

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 or gray vial) cannot be used to prepare doses for individuals aged 6 months to <12 years.

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

COMIRNATY[®] is now the official name of the Pfizer-BioNTech COVID-19 vaccine (COVID-19 Vaccine, mRNA)

HOW TO PREPARE AND ADMINISTER IN AGES 12 YEARS AND OLDER – DO NOT DILUTE BEFORE USE (VIALS WITH GRAY CAP/LABEL BORDER)

12+ years old
Do not dilute



Before Use¹

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 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

* 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.

HOW TO PREPARE AND ADMINISTER IN AGES 12 YEARS AND OLDER – DO NOT DILUTE BEFORE USE (VIALS WITH GRAY CAP/LABEL BORDER)

12+ years old
Do not dilute

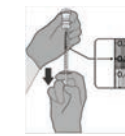


To prepare individual 0.3-mL doses for administration¹



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 discoloration 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 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 **16 years or older**, a **booster dose** may be administered intramuscularly at least 6 months after completion of the primary series.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. In these individuals, a third dose may be considered as part 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.

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 6 months to <12 years.

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

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

5 to <12 years old
Dilute before use



Before Dilution¹

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

Dilution¹

- 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 Dilution¹



- 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

* 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.

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

5 to <12 years old
Dilute before use

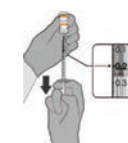


To prepare individual 0.2-mL doses for administration¹



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

In individuals **5 years through to <12 years**, a **booster dose** may be administered intramuscularly at least 6 months after completion of the primary series.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. In these individuals, a third dose may be considered as part 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.

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 6 months to <5 years or 12 years of age and older.

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

HOW TO PREPARE AND ADMINISTER IN AGES 6 MONTHS TO <5 YEARS – DILUTE BEFORE USE (VIALS WITH MAROON CAP/LABEL BORDER)

6 months to <5 years old
Dilute before use



Before Dilution¹

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

Dilution¹

- 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. Do not add more than 2.2 mL of diluent to the vaccine vial.**

- 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 vial now contains ten 0.2-mL doses of vaccine.

After Dilution¹



- 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

* 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.

HOW TO PREPARE AND ADMINISTER IN AGES 6 MONTHS TO <5 YEARS – DILUTE BEFORE USE (VIALS WITH MAROON CAP/LABEL BORDER)

6 months to <5 years old
Dilute before use

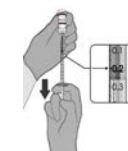


To prepare individual 0.2-mL doses for administration¹



- 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 discoloration 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). The initial 2 doses are administered 3 weeks apart, followed by a third dose administered at least 8 weeks after the second dose.**

Children who will turn from 4 years to 5 years of age between their doses in the vaccination series should receive their age-appropriate dose at the time of the vaccination. The interval between doses is determined by the child's age at the start of the vaccination series.

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

Vials of COMIRNATY intended for individuals aged 6 months to <5 years (maroon vial) cannot be used to prepare doses for individuals 5 years of age and older.

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

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 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)**.

References: 1. COMIRNATY Product Monograph. Pfizer Canada ULC. 2. Pfizer Inc. Data on File. 2022.

COMIRNATY[®]
(COVID-19 Vaccine, mRNA)



BIONTECH

