

Subject to change based on emerging data, regulatory guidance, manufacturing and technical developments, among other risks. Content is current as of March 15, 2021.

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.

THE S.T.E.P.S. TO PFIZER-BIONTECH COVID-19 VACCINATION

Your guide to proper storage, handling, and
administration for Pfizer-BioNTech COVID-19 Vaccine*

Pfizer-BioNTech COVID-19 Vaccine 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 16 years of age and older.

The use of Pfizer-BioNTech COVID-19 Vaccine is permitted under an interim authorization delivered in accordance with section 5 of the COVID-19 [Interim order \(IO\)](#).[‡] Patients should be advised of the nature of the authorization. The interim authorization is associated with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and efficacy of the product. For further information on authorization under this pathway, please refer to Health Canada's *IO Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*.

[‡] <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html#a2.8>

Refer to the CVDvaccine.ca website for complete storage, handling, and administration instructions.

* Some vials and cartons of Pfizer-BioNTech COVID-19 Vaccine Multiple-Dose Vial may be labeled as BNT162b2 (SARS-CoV-2-mRNA Vaccine) 5-Dose Vial and the manufacturer and distributor information may vary from what is contained in this leaflet.

† Low dead-volume syringes and/or needles (e.g., low dead-volume luer lock syringes) 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 a 6th dose from a single vial. Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information on this document and in the Product Monograph regarding the number of doses per vial after dilution supersedes the number of doses stated on the vial labels and carton.

STORE

- Upon delivery, inspect the thermal shipping container to confirm you received the number of vial trays you ordered.
- Immediately store, preferably in an ultra-low-temperature freezer at -80°C to -60°C (-112°F to -76°F). Vials may also be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Keep vials frozen and protected from light, in the original cartons, until ready to use. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -80°C to -60°C (-112°F to -76°F). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks.

If an ultra-low-temperature freezer is not available, the thermal shipping container may be used to temporarily store Pfizer-BioNTech COVID-19 Vaccine. If using the thermal shipping container as temporary storage, the container must be opened, inspected, and replenished with dry ice within 24 hours of receipt so that any low areas of the side compartments and the dry ice pods on top are completely filled with dry ice pellets. The thermal shipping container may be used as temporary storage for up to 30 days from delivery with regular re-icing.

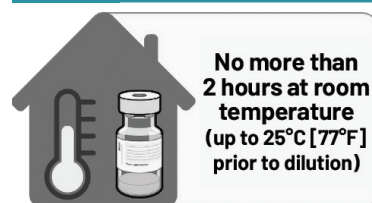
- Refer to re-icing guidelines in the Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Reference Guide and Video at CVDvaccine.ca for more information about storage and handling of dry ice

For information about transportation of the vials, please go to CVDvaccine.ca.

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TALLY DOSES AND THAW



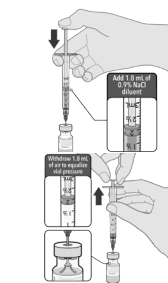
No more than 2 hours at room temperature (up to 25°C [77°F]) prior to dilution

- It is important to plan ahead to determine how many multiple-dose vials will be needed. Remove one multiple-dose vial for every 6 patients* from the freezer or thermal shipping container (each vial contains 6 doses of 0.3 mL of vaccine after dilution).
 - Record the number of multiple-dose vials removed from the freezer, along with the date and time, or keep track using a system that works for your staff.
 - Thaw vial(s) of Pfizer-BioNTech COVID-19 Vaccine before use either by:
 - Allowing vial(s) to thaw in the refrigerator (2°C to 8°C [35°F to 46°F]). A carton of vials may take up to 3 hours to thaw, while individual vials may take less time. Thawed vials can be stored in the refrigerator for up to five days (120 hours).
 - Allowing vial(s) to sit at room temperature (up to 25°C [77°F]) for 30 minutes if vaccine is required for immediate use.
- Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours of exposure to room temperature. Do not refreeze thawed vials. The thawed undiluted vaccine is a white to off-white suspension. During preparation and use, regularly inspect multiple-dose vials to confirm there are no particulates and there is no discoloration.

EQUILIBRATE AND DILUTE



- After thawing and prior to dilution, ensure the vial is equilibrated to room temperature. Invert vaccine vial gently 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 liquid is discoloured or if other particles are observed.



- Using aseptic technique, withdraw 1.8 mL of 0.9% Sodium Chloride Injection, USP into a transfer syringe. Use only this as the diluent. Using a 3-mL syringe is recommended, although a 5-mL syringe is also acceptable. A needle 21-gauge or narrower should be used. Cleanse the vaccine vial stopper with a single-use antiseptic swab. Allow vial stopper to dry. Then add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial.
 - You may feel some pressure in the vial as you add the diluent. Ensure vial pressure is equalized by withdrawing 1.8 mL of air into the empty diluent syringe before removing the needle from the vial. Make sure to discard any remaining saline in the diluent vial in a sharps container. Discard vials in a sharps container as medical waste to ensure they are permanently destroyed.



- Gently invert the diluted vial 10 times to mix. **Do not shake.** Inspect the vaccine in the vial. After dilution, the vaccine will be an off-white suspension. Do not use if vaccine is discoloured or contains particulate matter.



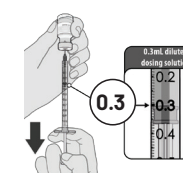
- Record the date and time of dilution in the appropriate place on the Pfizer-BioNTech COVID-19 Vaccine vial label. The thawed and diluted vaccine can be handled in normal room light conditions. Avoid exposure to direct sunlight and ultraviolet light.
 - Use within 6 hours from the time of dilution. If not used within 6 hours, it should be discarded. Store between 2°C to 25°C (35°F to 77°F).

Summary of vial thawing and storage

Store in the freezer upon receiving the vaccines: Preferred: Ultra-low-temperature freezer (-80°C to -60°C) or Temporary short-term: Regular freezer (-25°C to -15°C) for up to 2 weeks or Temporary: Thermal shipping container (-90°C to -60°C) † Storage of the vials between -96°C to -60°C is not considered an excursion from the recommended storage condition	REGULAR USE	STEP 1	STEP 2	STEP 3
			Thaw in refrigerator (2°C to 8°C)[†] • 2-3 hours for full vial trays • Less time is needed for a fewer number of vials † Storage in refrigerator: Up to 5 days	Bring to room temperature (up to 25°C)[‡] ‡ Storage at room temperature: No more than 2 hours prior to dilution
	IMMEDIATE USE	STEP 1	STEP 2	STEP 2
		Thaw to room temperature (up to 25°C):[§] 30 minutes § Storage at room temperature: No more than 2 hours prior to dilution		Post-dilution, • Store at 2°C to 25°C and use within 6 hours (from the time of dilution) • Any unused vaccine must be discarded after 6 hours

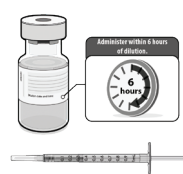
PREPARE AND ADMINISTER

To prepare individual 0.3 mL doses from the diluted multiple-dose vial:



- To prepare individual doses, cleanse the vial stopper with a single-use antiseptic swab using aseptic technique. Allow vial stopper to dry. Draw up 0.3 mL of the diluted vaccine into a new sterile low dead-volume syringe* (preferably a low dead-volume 1-mL luer lock syringe) appropriate for intramuscular injection. Should a 1-mL luer lock syringe not be available, a 3-mL luer lock syringe with 1/10-mL graduation is also acceptable. Remember to use safe sharps handling techniques to avoid needlestick. 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. Adjustments to remove air bubbles should be done with the needle still in the vial to avoid loss of vaccine.

It is recommended to use the same needle to withdraw and administer the dose whenever possible. If a second needle is required for administration, pull back on the syringe plunger until a small amount of air enters the syringe prior to removing the first needle to avoid loss of dosing solution during the needle change.



- For each additional dose, use a new sterile syringe and needle and ensure the vial stopper is cleansed with antiseptic and then dried before each withdrawal. Administer immediately, and no later than 6 hours after dilution. Be sure to immediately dispose of used needles in a sharps container.

- Prior to administration, adhere to normal standard of care and aseptic techniques.

- Make sure the prepared syringe is not cold to the touch.
- Do a visual inspection to verify **both**:
 - The final dosing volume of 0.3 mL
 - The absence of particulates and discoloration

If the visual inspection fails (i.e., dose volume is not equal to 0.3 mL, and/or presence of particulates and/or discoloration), do not administer the injection. Please refer to the CVDvaccine.ca website for information on how to restart the vaccine preparation step.

- Administer immediately, and no later than 6 hours after dilution. Administer the vaccine intramuscularly in the deltoid muscle of the non-dominant arm. Do not inject the vaccine intravascularly, subcutaneously or intradermally.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain 6 doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles (e.g., low dead-volume luer lock syringes) 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. If standard syringes and needles are used, there may not be sufficient volume to extract a 6th dose from a single vial.

Irrespective of the type of syringe and needle:

- 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

- Document the date and time of administration, and schedule a follow-up dose 21 days from the first immunization.

As the healthcare provider, you should communicate to the recipient or their caregiver information consistent with the Patient Medication Information section of the Product Monograph prior to the individual receiving Pfizer-BioNTech COVID-19 Vaccine. It's important to communicate:

- Health Canada has authorized the use of this vaccine under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*.
- The recipient or their caregiver has the option to accept or refuse Pfizer-BioNTech COVID-19 Vaccine, and to seek information about available alternative treatments and the risks and benefits of those alternatives.
- The significant known and potential risks and benefits of Pfizer-BioNTech COVID-19 Vaccine, and the extent to which such risks and benefits are unknown.
- Pfizer-BioNTech COVID-19 Vaccine is **contraindicated** in individuals who are hypersensitive to the active substance or to any ingredient in the formulation. For a complete list of ingredients, please refer to the Product Monograph or the CVDvaccine.ca website.
- Anaphylaxis has been reported. As with all vaccines, training for immunizers, appropriate medical treatment and supervision after immunization should always be readily available in case of a rare anaphylactic event following the administration of this vaccine. Vaccine recipients should be kept under observation for at least 15 minutes after immunization; 30 minutes is a preferred interval when there is a specific concern about a possible vaccine reaction. A second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of Pfizer-BioNTech COVID-19 Vaccine.
- Recipients or their caregivers should contact their healthcare professional if they experience an adverse event after receiving Pfizer-BioNTech COVID-19 Vaccine. Please refer them to the Patient Medication Information section of the Product Monograph or the CVDvaccine.ca website.

For more information please refer to the CVDvaccine.ca website.

SAFELY DISPOSE AND SHIP BACK MATERIALS

- Discard diluted vials that:

- Have been fully discharged and used to administer vaccinations (do not pool excess vaccine from multiple vials).
- Are more than 6 hours from time of dilution.

Discard vials in a sharps container as medical waste to ensure they are permanently destroyed. Discard vial trays as medical waste so they cannot be reused.

- Return the thermal shipping container and all its reusable components within 30 days of delivery. A preprinted return shipping label will be included inside the thermal shipping container. When coordinating the return, apply the preprinted return shipping label over the existing shipping label. In addition, place a blank label over the UN1845 markings on the box to indicate the container no longer contains dry ice. You can contact the carrier identified on the return label to arrange the return. For additional assistance, contact **Pfizer Customer Service at 1-833-VAX-COVI (1-833-829-2684)**.

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**FIND ADDITIONAL RESOURCES
about Pfizer-BioNTech COVID-19 Vaccine at
CVDvaccine.ca**

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).

