Subject to change based on emerging data, regulatory guidance, manufacturing and technical developments, among other risks. Content is current as of May 19, 2021.

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 12 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

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.

Refer to the CVId vaccine.ca website for complete storage, handling, and administration instructions.
THE S.T.E.P.S.

1. On arrival, inspect the thermal shipping container to confirm you received the number of vials you ordered.
2. Immediately store, preferably in an ultra-low temperature freezer at -60°C to -80°C (-76°F to -112°F). Vials may also be stored at -25°C to -30°C (-13°F to -22°F) for up to 2 weeks. Keep vials frozen and light protected, in the original carton, until ready to use. Vials should be used within 2 days at -25°C to -30°C (-13°F to -22°F) for up to 2 weeks may be returned one time to the recommended storage condition of -60°C to -80°C (-130°F to -184°F). Total cumulative time vials are stored at -25°C to -30°C (-13°F to -22°F) should be limited to 15 days 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 packs 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 CVaccine.ca for more information about storage and handling of dry ice.
- For information about transportation of the vials, please go to CVaccine.ca.

T ALLY DOSE AND THAW

1. After thawing and prior to dilution, ensure the vial is equilibrated to room temperature. Invert vaccine vial gently 10 times. Do not shake.

2. Using aseptic technique, withdraw 1.8 mL of 0.9% Sodium Chloride Injection, USP, into a transfer syringe. Use only this as the diluent. 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.

3. Gently invert the diluted vial 10 times to mix. Do not shake.

Inspect the vaccine in the vial prior to dilution. The liquid is a white to off-white suspension. Do not use if vaccine is discoloured or contains particulate matter.

P REPAIR AND ADMINISTER

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

1. 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 luer lock syringe (preferably a 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 injury.

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.

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

If 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 during the solution change.

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

• Make sure the prepared syringe is not cold to the touch.
• Use a visual inspect to verify the correct dose.
• The final dosing volume of 0.3 mL.
• The absence of particulates and discolouration
• If the visual inspection fails (i.e., a dose volume is not equal to 0.3 mL, and/or presence of particulates and/or discolouration), do not proceed with injection. Please refer to the CVaccine.ca website for information on how to restart the vaccination preparation step.
• Administer immediately, and no later than 15 minutes after dilution. Do not use any vials which have been opened and are not being used immediately.

After dilution, vials of Pfizer-BioNTech COVID-19 Vaccine contain 6 doses of 0.3 mL of vaccine. Low-dose volume syringes and/or needles (e.g., low-dose 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 minimum volume loss during dose extraction. If standard syringes and needles are used, there may not be sufficient volume to extract 6 doses of 0.3 mL.

Irrespective of the type of syringe and needle:

• Each dose must contain 0.3 mL of vaccine.
• 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.
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Do not pool excess vaccine from multiple vials.

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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).