

COVID-19 (mRNA) COVID-19 mRNA Vaccine BNT162b2

Supplier: Pfizer

INDICATIONS:

- Vaccination will occur in phases. Sequencing of populations for whom the vaccine is currently indicated in British Columbia is available on the BCCDC [COVID-19 Vaccine Eligibility](#) page.

The vaccine is not approved for use in those less than 16 years of age.

DOSES AND SCHEDULE:

Individuals 16 years of age and older: 2 doses given as 0.3 mL IM, 35 days apart.^{A, B, C}

ADMINISTRATION:

- Prior to dilution and after thawing, gently invert the vial 10 times to mix; **do not shake**.
- Dilute the vaccine with 1.8 mL of the sodium chloride (0.9%) provided for this purpose, using a needle 21-gauge or narrower. Discard remaining diluent.
- Gently invert the vial containing the diluted product 10 times to mix; **do not shake**.
- After dilution, the vaccine will be an off-white suspension. Inspect vials to confirm there are no particulates and no discoloration. If any is observed do not administer the vaccine.
- Note: If there is enough vaccine left in the vial for a complete 0.3 mL dose after 5 doses have been removed from the vial, another dose can be drawn and administered. However, two separate vials should not be used to make up a full dose.

Storage and Handling / Dilution Requirements:^D

- Frozen vials prior to use:
 - The vaccine must be stored at ultra-low temperatures of -80°C to -60°C up to the end of its expiry date and kept in the original packaging, until ready to use.
 - The vaccine can be stored for up to 30 days in a validated thermal container with dry ice; requires re-icing with 20-23 kg of new dry ice every 5 days if opened twice daily.
- Vials prior to dilution:
 - The frozen vial contains 0.45 mL and needs to be thawed before mixing with the diluent. The vial can be thawed in the refrigerator for 2-3 hours or at room temperature (up to +25°C) for 30 minutes.
 - The vaccine may be stored at +2°C to +8°C for up to 120 hours (5 days).
 - The vaccine may be at room temperature (up to +25°C) for no more than 2 hours prior to dilution.

^A The vaccine series should be completed with the same COVID-19 vaccine product. If it is not possible to determine what product was used for the first dose, the second dose may be given with an available product.

^B An acceptable range for administration of the second dose is 21-42 days after the first dose. If administration of the second dose is delayed beyond 42 days, the second dose should be provided as soon as possible and the series does not need to be restarted.

^C The minimum interval between doses is 18 days. For optimal response, immunizers should observe recommended intervals as much as possible, however, doses given earlier than recommended may still be considered valid and need not be repeated if minimum intervals are observed.

^D For more information on storage and handling and temperature monitoring refer to [Appendix E: Management of Biologicals](#) and [Guidance for Receiving and Handling the Pfizer-BioNTech COVID-19 mRNA Vaccine \(including dry ice procedures\)](#).

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ADMINISTRATION (continued):

- While at room temperature avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.
- Do not refreeze thawed vials.

- Vials after dilution:
 - When thawed add 1.8 mL of sodium chloride diluent and discard any remaining diluent.
 - **This multi-dose product contains no preservative.**
 - The vaccine must be kept between +2°C to +25°C and **used within 6 hours** from the time of dilution. Avoid exposure to direct sunlight and ultraviolet light. After dilution, the vaccine vials can be handled in room light conditions.
 - The vaccine can be pre-loaded into a syringe for up to 6 hours. Ensure that the diluted vial of vaccine / pre-loaded syringe is clearly labelled with the date and time of dilution.

Summary of Vial Thawing and Storage:

Store at ultra-low temperatures upon receiving the vaccines in: Ultra-low temperature freezer (-80°C to -60°C) Or Thermal shipping container (-90°C to -60°C)	Regular Use	Step 1 Thaw in refrigerator (+2°C to +8°C): <ul style="list-style-type: none"> ● 2-3 hours for full vial trays (less time is needed for a fewer number of vials). ● Store in refrigerator for up to 5 days (120 hours). 	Step 2 Bring to room temperature (up to +25°C) <ul style="list-style-type: none"> ● Store at room temperature for no more than 2 hours prior to dilution. 	Step 3 Post dilution: <ul style="list-style-type: none"> ● 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.
	Immediate Use	Step 1 Thaw to room temperature (up to +25°C) for 30 minutes <ul style="list-style-type: none"> ● Store at room temperature for no more than 2 hours prior to dilution. 	Step 2 Post dilution: <ul style="list-style-type: none"> ● 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. 	

BOOSTER DOSES:

No booster doses are recommended at this time.

SEROLOGICAL TESTING:

Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:

1. History of anaphylactic reaction to a previous dose of the vaccine or to any component of the vaccine.

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PRODUCT COMPONENTS:

Potential allergens: 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide.

Other components: (4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate); 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide; 1,2-distearoyl-sn-glycero-3-phosphocholine; cholesterol; dibasic sodium phosphate dihydrate; monobasic potassium phosphate; potassium chloride; sodium chloride; sucrose.

PRECAUTIONS:

- For the following populations, a complete COVID-19 vaccine series may be offered to individuals in the authorized age group if a risk assessment deems that the benefits outweigh the potential risks for the individual, and if informed consent includes discussion about the absence of evidence on the use of COVID-19 vaccine in these populations:
 - immunosuppressed due to disease or treatment or those with an autoimmune disorder
 - pregnancy and breastfeeding (for more information see the [SOGC Statement on COVID-19 Vaccination in Pregnancy](#))
- Wait until symptoms of an acute illness are resolved before vaccinating with COVID-19 vaccine to differentiate symptoms of illness from vaccine side effects.
- There is insufficient evidence on the receipt of both a COVID-19 vaccine and any monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19. Therefore, timing of administration and potential interference between these two products are currently unknown and expert clinical opinion should be sought on a case-by-case basis.

SPECIAL CONSIDERATIONS:

- COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines. However, if a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated.
- Wait a period of at least 28 days after the administration of the complete two-dose vaccine series of an mRNA COVID-19 vaccine before the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis) due to the elicitation of an inflammatory cytokine response. Wait for a period of at least 14 days after the administration of another vaccine before administering a COVID-19 vaccine.
- A complete series of COVID-19 vaccine may be offered to individuals without contraindications who have recovered from PCR-confirmed SARS-CoV-2 infection.
- Recipients should practice public health measures for prevention of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine, at this time.

ADVERSE EVENTS:

Local: pain, swelling, redness.

Systemic: fatigue, headache, myalgia, chills, arthralgia, fever, nausea and vomiting.

REFERENCES:

1. [Pfizer vaccine product monograph](#)
2. [National Advisory Committee on Immunization: Recommendations on the use of COVID-19 Vaccine\(s\)](#)