COVID-19 (mRNA)
COVID-19 mRNA Vaccine BNT162b2  Supplier: Pfizer

INDICATIONS:
- Individuals 12 years of age and older.
The vaccine is not approved for use in those less than 12 years of age.

DOSES AND SCHEDULE:
Individuals 12 years of age and older:**A** - 2 doses given as 0.3 mL IM, 21 days apart. **B, C, D, E**

ADMINISTRATION:
- Prior to dilution and after thawing, gently invert the vial 10 times to mix; **do not shake**.
- Allow the vaccine to come to room temperature (up to +25°C) prior to dilution. **F** 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 discolouration. If any is observed do not administer the vaccine.
- The withdrawal of 6 doses from a single vial is dependant, in part, on the type of syringes and needles used to withdraw doses from the vials; low dead-volume syringes and/or needles should be used if available, as standard syringes and needles may not facilitate the extraction of a 6th dose from a single vial. Additional strategies for extraction of 6 doses:
  - Allow contents to settle for 20 seconds after final inversion.
  - Go slow: withdrawing the diluted vaccine too quickly may result in fizzing.
  - Adjustments to remove air bubbles and dose calibration should be done with the needle still in the vial to avoid loss of vaccine.
  - When drawing the 6th dose, place the needle tip just inside the rubber stopper; slightly tilt vial and ensure the needle bevel is facing down and close to the vial neck.
  - Use the same needle to withdraw and administer.
- If there is enough vaccine left in the vial for a complete 0.3 mL dose after 6 doses have been removed from the vial, another dose can be drawn and administered.
- Following withdrawal of all available 0.3 mL doses, the residual vaccine from up to three vials may be withdrawn into the same syringe to constitute a full dose provided the vials are from the same manufacturer and the same lot number. See addendum for more information.

**A** The minimum age for vaccine receipt is based on year of birth (i.e., the vaccine may be offered to individuals who will be turning 12 years of age within the current calendar year), per Provincial Health Officer recommendations.
**B** 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, or if the same product is unavailable, the second dose may be given with an available mRNA product.
**C** This is the schedule authorized by Health Canada. In BC, the preferred interval between doses is 6-8 weeks, except in outbreak communities at the direction of the Medical Health Officer and for individuals who meet approved criteria for an expedited dose 2. As of August 9th, 2021, invitations to book dose 2 will be sent out at 4 weeks after the first dose as outlined on the government of B.C. website. If administration of the second dose is delayed beyond 8 weeks, the series does not need to be restarted.
**D** 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.
**E** NACI recommends that mRNA vaccine (Pfizer-BioNTech or Moderna) can be offered as a second dose to individuals who received a first dose of the AstraZeneca/COVISHIELD vaccine, unless contraindicated.
**F** It is not required that the vaccine reach room temperature prior to dilution, however the vaccine must be fully thawed.
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ADMINISTRATION (continued):  
Storage and Handling / Dilution Requirements:  

- Frozen vials prior to use:  
  - The vaccine must be stored at ultra-low temperatures of -90°C to -60°C up to the end of its expiry date  
  - The vaccine can be stored at -25°C to -15°C for up to 2 weeks.  
  - 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 31 days.  
  - The vaccine may be at room temperature (up to +25°C) for no more than 2 hours prior to dilution.  
  - 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:  
  - Once thawed and the vial has come to room temperature (up to +25°C) 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.

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A 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).

B On August 27, 2021, Health Canada authorized an update to the Pfizer-BioNTech COVID-19 Vaccine Product Monograph to allow a 3-month extension to the expiry date for all Pfizer-BioNTech Covid-19 Vaccine vials with expiry dates of August 2021 through February 2022 printed on the vial and carton labels, provided ultra low temperature storage has been maintained (i.e., 90°C to -60°C).

C It is not required that the vaccine reach room temperature prior to dilution, however the vaccine must be fully thawed.
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ADMINISTRATION (continued):
Summary of Vial Thawing and Storage:

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
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<tbody>
<tr>
<td>Thaw in refrigerator (+2°C to +8°C):</td>
<td>At room temperature (up to +25°C):</td>
<td>Post dilution:</td>
</tr>
</tbody>
</table>
| - 2-3 hours for full vial trays (less time is needed for a fewer number of vials).  
- Store in refrigerator for up to 31 days. | - Store at room temperature for no more than 2 hours prior to 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. |
| Regular Use                                 | Immediate Use                               | Immediate Use                               |
| Store at ultra-low temperatures upon receiving the vaccines in:  
Ultra-low temperature freezer (-90°C to -60°C) | Thaw to room temperature (up to +25°C) for 30 minutes  
- Store at room temperature for no more than 2 hours prior to dilution. | Post dilution:                              |
| Or                                          | 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. |
| Or                                          |                                             |                                             |
| Or                                          |                                             |                                             |
| Or                                          |                                             |                                             |

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 an mRNA COVID-19 vaccine or to any component of the vaccine. These individuals should be offered an adenovirus vector COVID-19 vaccine and observed for a least 30 minutes after immunization.

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

- For the following populations, a complete COVID-19 vaccine series should 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 limited data on the use of COVID-19 vaccine in these populations:
  - immunosuppressed due to disease or treatment
  - those with an autoimmune condition
  - pregnancy and breastfeeding
- For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, consultation with an allergist is advised. If there is a specific concern about a possible allergy to a component of the COVID-19 vaccine being administered, an extended period of observation post-vaccination of 30 minutes may be warranted; alternately, the vaccine can be administered in an emergency room setting, also with a prolonged observation period.
- 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 COVID-19 vaccine following receipt of anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19. Therefore, COVID-19 vaccination should be deferred for at least 90 days to avoid potential interference of the antibody therapy with vaccine-induced immune response. Deferral is not required following treatment with tocilizumab or sarilumab.
- Individuals diagnosed with Multisystem Inflammatory Syndrome in Children (MIS-C) or Adults (MIS-A) should delay COVID-19 vaccination until they have recovered from illness and for 90 days after the date of diagnosis of MIS-C or MIS-A.
- Due to the theoretical risk that mRNA vaccines may temporarily affect cell-mediated immunity, resulting in false-negative TST or IGRA test results, these tests should be administered and read before COVID-19 immunization or delayed for at least 4 weeks after immunization. COVID-19 immunization may take place at any time after all steps of tuberculin skin testing have been completed.
- The 2nd dose of mRNA COVID-19 vaccine should be deferred in those who experienced a physician-diagnosed myocarditis or pericarditis event following the first dose with no other cause identified, until further information about the risk of recurrence is available. Deferral is not required for those with a prior history of myocarditis or pericarditis that is unrelated to COVID-19 mRNA vaccines and are no longer being followed by a medical professional for heart issues.

SPECIAL CONSIDERATIONS:

- COVID-19 vaccines can be administered concomitantly or at any time before or after the administration of another inactivated or live 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.

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A For more information see the CRA Recommendation on COVID-19 Vaccination in Persons with Autoimmune Rheumatic Disease.
B For more information see the SOGC Statement on COVID-19 Vaccination in Pregnancy.
C A recent study in the United States supports the safety of mRNA COVID-19 vaccines among pregnant people.
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SPECIAL CONSIDERATIONS (continued):
- 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.

Rare cases of facial paralysis/Bell’s palsy have been reported.

Pericarditis and myocarditis in association with the mRNA vaccines have been observed in Israel and the US, where these vaccines have been used in younger people longer than in Canada, especially after the second dose. In the US data, they have noted that the observed rates exceed what would be expected (given that these are inflammatory disorders of the lining of the heart and heart muscle, respectively, and occur for a variety of reasons including in association with viral infections). These events have occurred more frequently after the second dose at a rate of about 1 per 100,000 second doses, and have been observed mostly in males under 30 years of age. Most cases recover fully with conservative treatment. In BC, we have ensured that health care providers are aware of this observation and the possibility of it being causally linked to the vaccine, and how to diagnose and report this event when it occurs after mRNA vaccine, which is yet to be detected as occurring above the expected frequency in our safety reports in BC and Canada. This is an emerging safety signal and will need to be studied further.

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

ADDENDUM: Pooling residual vaccine from up to three vials to constitute an extra dose

Following withdrawal of all available 0.3 mL doses, a full 0.3 mL dose may be constituted from the residual vaccine volume from up to three separate vials, provided the vials are from the same manufacturer and same lot number. In order to minimize the risk of microbial contaminants and maintain product quality, the following processes should be followed:

- Only vials containing residual vaccine volume are to be used to prepare a full dose when using multiple vials to constitute a single dose. Residual volume should not be combined with contents from a different vial that still contains at least one full dose of the vaccine (to minimize the chance of contaminating the contents of a vial that still contains multiple doses of the vaccine).
- Given this vaccine does not contain preservative and therefore has a short timeline for its use following dilution (i.e., 6 hours), pooling of residual vaccine from two or three vials must occur as soon as possible - it is not recommended to save multiple vials with residual volume for use at one time (e.g., the end of the clinic).
- Perform hand hygiene before handling the vaccine. Strictly adhere to aseptic technique while handling the vaccine and minimize the number of vial punctures.
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ADDENDUM (continued):

- Firmly and briskly wipe the surface of the rubber stopper with an alcohol swab for initial and subsequent uses, being sure to apply friction, and allow it to dry for at least 10 seconds.
- To assist with the withdrawal of residual vaccine from the vial, invert the vial and ensure the end of the needle is below fluid level and situated in the groove of the vial stopper.
- Once the residual vaccine is withdrawn, keep the needle in the vial when expelling air bubble(s) to minimize vaccine wastage.
- Check the syringe to ensure it contains the total 0.3 mL dose prior to administration.
- If not administered immediately, the syringe should be clearly labeled with the date and time of the vial with the shortest timeframe for use.