COVID-19 mRNA Vaccine
COMIRNATY®       Supplier: Pfizer
(Adult/Adolescent presentation: 30 mcg/0.3 mL)
Purple Vial Cap

INDICATIONS:
• Individuals 12 years of age and older. See COVID-19 Vaccine Eligibility.
The vaccine is not approved for use in those less than 12 years of age.

DOSES AND SCHEDULE:
• Primary series for individuals 12 years of age and older $A, B$: 2 doses given as 0.3 mL (30 mcg) IM, 8 weeks apart. $C, D, E, F$
  
  For individuals who are moderately to severely immunosuppressed (see COVID-19 Vaccine Eligibility), a 3-dose primary series is recommended. $G$ The 3rd dose should be provided at least 28 days after the 2nd dose. For those 12 years of age and older, Moderna COVID-19 vaccine is preferentially recommended for all doses in the primary series. If Moderna is unavailable, Pfizer-BioNTech can be given.

• First booster dose for individuals 12 years of age and older $H$: 1 dose given as 0.3 mL (30 mcg) IM, at least 6 months after completion of the primary series. $D, I$

• Second booster dose for individuals 18 years of age and older: 1 dose given as 0.3 mL (30 mcg) IM, at least 6 months after the first booster dose. $D, J$ See BOOSTER DOSES for more information.

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$A$ The minimum age for vaccine receipt is based on age at presentation (i.e., the Pfizer COVID-19 vaccine adult/adolescent formulation may be offered to individuals on or after their 12th birthday). However if the pediatric formulation (10 mcg) is unavailable, the adult/adolescent formulation (30 mcg) may be given to individuals who will be turning 12 years of age within the current calendar year, per Provincial Health Officer recommendations.

$B$ The Pfizer-BioNTech COVID-19 vaccine is preferred for those 12-29 years of age due to the lower risk of myocarditis/pericarditis with this vaccine (with the exception of those 12-29 years of age who are moderately to severely immunosuppressed due to a potentially greater immune response induced by the Moderna vaccine in these populations). However, if the Pfizer-BioNTech vaccine is unavailable, or upon client request, the Moderna COVID-19 vaccine can be used provided informed consent includes the elevated risk of myocarditis/pericarditis associated with this product.

$C$ While the Health Canada authorized schedule for this product is 21 days between dose 1 and 2, the recommended interval is 8 weeks and is associated with optimal vaccine effectiveness. If administration of the second dose is delayed beyond 8 weeks, the series does not need to be restarted.

$D$ Clients requesting a shorter interval should be informed that this is not optimal for protection, but their request for an earlier dose should be granted without need for MHO approval, provided the minimum interval between doses has been observed.

$E$ 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.

$F$ 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.

$G$ For individuals who received a single dose of Janssen vaccine, one additional dose of Moderna COVID-19 vaccine is recommended at least 28 days later.

$H$ The Pfizer-BioNTech COVID-19 vaccine is preferred for those 12-29 years of age due to the lower risk of myocarditis/pericarditis with this vaccine (with the exception of the booster dose for those 18-29 years of age who are moderately to severely immunosuppressed, see BOOSTER DOSES).

$I$ The minimum interval between completion of the primary series and the booster dose is 8 weeks. This interval may be applied for a minority of individuals for practical reasons, including pregnant persons.

$J$ The minimum interval between the booster doses is 4 months.
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ADMINISTRATION:
- This product requires dilution.
- 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. A 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.
- Low dead-volume syringes and/or needles should be used if available to extract the maximum number of doses.

Storage and Handling / Dilution Requirements: B
- 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 C and kept in the original packaging, until ready to use.
  - 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. D
  - This multi-dose product contains no preservative.

A It is not required that the vaccine reach room temperature prior to dilution, however the vaccine must be fully thawed.
B 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).
C The expiry dates for certain lots of the Pfizer-BioNTech COVID-19 vaccine have been extended by 6 months for vials/cartons with printed expiry dates of August 2021 to March 2022 and 3 months for vials/cartons with printed expiry dates of June 2022 to August 2022, provided ultra low temperature storage has been maintained (i.e., -90°C to -60°C).
D It is not required that the vaccine reach room temperature prior to dilution, however the vaccine must be fully thawed.
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(Agent/Adolescent presentation: 30 mcg/0.3 mL)

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ADMINISTRATION (continued):
- 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:

<table>
<thead>
<tr>
<th>Store at ultra-low temperatures upon receiving the vaccines in:</th>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regular Use</td>
<td>Thaw in refrigerator (+2°C to +8°C):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ultra-low temperature freezer (-90°C to -60°C)</td>
<td>• 2-3 hours for full vial trays (less time is needed for a fewer number of vials).</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Store in refrigerator for up to 31 days.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Or</td>
<td>At room temperature (up to +25°C):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Immediate Use</td>
<td>• Store at room temperature for no more than 2 hours prior to dilution.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermal shipping container (-90°C to -60°C)</td>
<td>Post dilution:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Store at +2°C to +25°C and use within 6 hours (from the time of dilution).</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Any unused vaccine must be discarded after 6 hours.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

BOOSTER DOSES:
A first booster dose of a COVID-19 mRNA vaccine is recommended for individuals 12 years of age and older at least 6 months after the primary series has been completed.

A second booster dose of a COVID-19 mRNA vaccine is recommended for the following individuals at least 6 months after the first booster dose: ^
- Residents of LTC and alternate level of care clients awaiting placement in LTC
- Residents of assisted living facilities 70 years of age and older (Indigenous persons 55 years of age and older)
- Individuals 70 years of age and older in the community
- Indigenous persons 55 years of age and older in the community

^ All other individuals 18 years of age and older may receive a second booster dose now should they wish to, however it is preferable to delay their second booster dose until the fall.
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BOOSTER DOSES (continued):

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Preferred vaccine for booster dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-29 years of age – immunocompetent individuals</td>
<td>Pfizer-BioNTech A</td>
</tr>
<tr>
<td>Individuals 12-17 years of age who are moderately to severely immunosuppressed</td>
<td>Pfizer-BioNTech B</td>
</tr>
<tr>
<td>Individuals 18 years of age and older who are moderately to severely immunosuppressed</td>
<td>Moderna B</td>
</tr>
<tr>
<td>30 years of age and older – immunocompetent individuals</td>
<td>Pfizer-BioNTech or Moderna</td>
</tr>
</tbody>
</table>

SEROLOGICAL TESTING:
Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:
1. History of anaphylactic reaction to any component of the vaccine is generally considered a contraindication, however for more details on the administration of COVID-19 vaccines to individuals with allergies to components of the COVID-19 vaccines, please see the PRECAUTIONS section.

PRODUCT COMPONENTS:
Other components: (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate); 1,2-distearoyl-sn-glycero-3-phosphocholine; cholesterol; dibasic sodium phosphate dihydrate; monobasic potassium phosphate; potassium chloride; sodium chloride; sucrose.

PRECAUTIONS:
- For individuals with a history of anaphylactic reaction to a previous dose of an mRNA COVID-19 vaccine, re-vaccination (i.e., administration of a subsequent dose in the series when indicated) may be offered with the same vaccine or the same mRNA platform if a risk assessment deems that the benefits outweigh the potential risks for the individual and if informed consent is provided. Prior to re-vaccination, consultation with an allergist or another appropriate physician (e.g., Medical Health Officer) is advised. If re-vaccinated, vaccine administration should be done in a controlled setting with expertise and equipment to manage anaphylaxis, with an extended period of observation of at least 30 minutes after re-vaccination.

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A Preferred due to the lower risk of myocarditis/pericarditis with this vaccine. However, if the Pfizer-BioNTech vaccine is unavailable, or upon client request, the Moderna COVID-19 vaccine can be used provided informed consent includes the elevated risk of myocarditis/pericarditis associated with this product.

B Age-based booster dosing recommendations apply to Moderna COVID-19 booster doses for moderately to severely immunosuppressed clients (See DOSES and SCHEDULE). However, a 0.5 mL (100 mcg) dose may be provided upon request for those 18-69 years of age.

C Alternatively, such individuals may be offered Novavax COVID-19 vaccine. A viral vector COVID-19 vaccine should only be considered when all other authorized COVID-19 vaccines are contraindicated or have been refused, due to the reduced effectiveness and the possible adverse effects specifically associated with viral vector vaccines (e.g., Thrombosis with Thrombocytopenia Syndrome [TTS]).
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PRECAUTIONS (continued):
• For individuals with suspected hypersensitivity or non-anaphylactic allergy to COVID-19 vaccine components, the vaccine should be administered in a controlled setting with expertise and equipment to manage anaphylaxis, with an extended period of observation post-vaccination of at least 30 minutes. Wait until symptoms of an acute illness are resolved before vaccinating with COVID-19 vaccine to differentiate symptoms of illness from vaccine side effects.
• 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.
• Additional doses of a COVID-19 vaccine should be deferred in individuals who experienced a physician-diagnosed myocarditis or pericarditis event following a previous dose of a COVID-19 mRNA vaccine. However, those with a history compatible with pericarditis who had no cardiac workup or had normal investigations may proceed to further vaccination once symptoms have resolved and 90 days have passed since receipt of the dose associated with the event. For those with confirmed myocarditis (with or without pericarditis), an individual risk/benefit discussion between the patient and their healthcare provider should occur so that the patient (with their parent/guardian as applicable) can make an informed decision about proceeding with a subsequent dose. If another dose is offered, the Pfizer-BioNTech COVID-19 vaccine should be offered because of the lower rate of myocarditis/pericarditis compared to the Moderna vaccine. Informed consent should include the unknown rates of recurrence of myocarditis and/or pericarditis following receipt of additional doses of the Pfizer-BioNTech COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop. 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. For more information refer to the NACI summary.

SPECIAL CONSIDERATIONS:
• COVID-19 vaccines can be administered concomitantly or at any time before or after the administration of another inactivated or live vaccine.
• Deferral of COVID-19 vaccination is no longer recommended for individuals who have received anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for treatment or prevention of COVID-19.
• COVID-19 vaccine may be offered to individuals without contraindications who have recovered from SARS-CoV-2 infection.
• COVID-19 booster doses may be deferred in those who have tested positive for COVID-19 (by PCR or rapid antigen test) until 3 months from symptom onset or, for asymptomatic cases, from the time of the positive test. For more information refer to the NACI statement.
• Recipients should practice public health measures for prevention of SARS-CoV-2 infection and transmission regardless of vaccination with COVID-19 vaccine.
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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 internationally and in Canada (see Public Health Agency of Canada reports). Of reported events to the Public Health Agency of Canada to April 15, 2022 meeting the Brighton Case Definition Levels 1-3, the frequency of occurrence has been 1.7 per 100,000 doses administered following any dose of the Moderna 100 mcg vaccine, and 1.1 per 100,000 doses administered following any dose of the Pfizer-BioNTech 30 mcg vaccine. This event is seen more often after the second dose, and in males 12-29 years of age. The reported rates within 7 days of immunization among males 18-29 years of age after the second vaccine dose are 16.36 per 100,000 for the Moderna vaccine and 3.14 per 100,000 for the Pfizer-BioNTech vaccine. Most cases recover fully. In BC, information to support health care provider recognition and reporting of this event in association with the mRNA vaccines has been issued. The exact cause of these events is not known but is thought to be related to the immune response to the spike protein which is also important in immunity against COVID-19 virus.

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