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

• Fall booster dose for individuals 12 years of age and older: 1 dose given as 0.3 mL (30 mcg) IM, at least 6 months after completion of the primary series or a previous booster dose. H See BOOSTER DOSES for more information.

ADMINISTRATION:
• No dilution required. Do not dilute this presentation of the vaccine.
• Low dead-volume syringes and/or needles should be used if available to extract the maximum number of doses.
• Prior to use and after thawing, gently invert the vial 10 times to mix; do not shake. Prior to mixing, the thawed vaccine may contain white to off-white opaque amorphous particles.

A The minimum age for vaccine receipt is based on age at presentation. 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 A minimum interval of at least 3 months between completion of the primary series or a previous booster dose and the fall booster may be considered in the context of heightened epidemiologic risk or for operational considerations. The exception to this is the Janssen vaccine for which the minimum interval is 8 weeks between the single dose of Janssen vaccine and the booster dose.
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ADMINISTRATION (continued):

• After mixing the vaccine should appear as a white to off-white suspension with no visible particles. Do not use if liquid is discolored or if particles are observed after mixing.

Storage and Handling:

• Frozen vials prior to use:
  o The vaccine must be stored at ultra-low temperatures of -90°C to -60°C up to the end of its expiry date and kept in the original packaging, until ready to use.
  o **Do not store vaccine at -25°C to -15°C.**
  o 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.

• Product should be thawed/held prior to use, in one of the following ways:
  o From the freezer to the refrigerator:
    ▪ A carton of 10 vials may take up to 6 hours to thaw in the refrigerator (+2°C to +8°C).
    ▪ The vaccine may be stored at +2°C to +8°C for up to 10 weeks.
  o From the freezer to room temperature:
    ▪ Vials can be thawed at room temperature (up to +25°C) for 30 minutes.
    ▪ The vaccine can be stored at room temperature (up to +25°C) for up to 12 hours prior to first vial puncture.
  o Do not refreeze thawed vials.
  o The vaccine must be kept between +2°C to +25°C and **used within 12 hours** after first vial puncture. Avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.
  o The vaccine can be pre-loaded into a syringe for up to 12 hours. Ensure that the vial of vaccine/pre-loaded syringe is clearly labelled with the date and time of first vial puncture.

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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** The date printed on the vial and carton is the date of manufacture. When stored at -90°C to -60°C, the vaccine may be used for up to 18 months from the date of manufacture.

**C** Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture; however the information in the Product Monograph stating 12 hour stability supersedes the number of hours printed on vial labels and cartons.
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ADMINISTRATION (continued):
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>At room temperature (up to +25°C):</td>
<td>Post puncture:</td>
</tr>
<tr>
<td>Ultra-low temperature freezer (-90°C to -60°C)</td>
<td>6 hours for cartons of 10 vials (less time is needed for a fewer number of vials).</td>
<td>Store at room temperature (up to +25°C) for no more than 12 hours prior to first vial puncture.</td>
<td>Store at +2°C to +25°C and use within 12 hours (from the time of first vial puncture). Any unused vaccine must be discarded after 12 hours.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Immediate Use</th>
<th>Thaw to room temperature (up to +25°C) for 30 minutes</th>
<th>Post puncture:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Store at room temperature for no more than 12 hours prior to first vial puncture.</td>
<td>Store at +2°C to +25°C and use within 12 hours (from the time of first vial puncture). Any unused vaccine must be discarded after 12 hours.</td>
</tr>
</tbody>
</table>

Booster Doses:
A booster dose of Pfizer-BioNTech bivalent COVID-19 mRNA vaccine is recommended for individuals 5-11 years of age at least 6 months A after the primary series has been completed.

A fall booster dose of a bivalent COVID-19 mRNA vaccine is recommended for individuals 12 years of age and older at least 6 months A after completion of the primary series or a previous booster dose, regardless of the number of booster doses previously received.

Recommended vaccine for booster dose

<table>
<thead>
<tr>
<th>Individuals 5-11 years of age</th>
<th>Pfizer Bivalent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunocompetent individuals 12-17 years of age</td>
<td>Pfizer Bivalent</td>
</tr>
<tr>
<td>Individuals 12 years of age and older who are moderately to severely immunosuppressed</td>
<td>Moderna Bivalent B</td>
</tr>
<tr>
<td>Immunocompetent individuals 18 years of age and older</td>
<td>Moderna Bivalent OR Pfizer Bivalent</td>
</tr>
</tbody>
</table>

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

A A minimum interval of at least 3 months between completion of the primary series or a previous booster dose and the fall booster may be considered in the context of heightened epidemiologic risk or for operational considerations.

B If a Moderna Bivalent COVID-19 mRNA vaccine is not readily available, or upon client request, the Pfizer Bivalent COVID-19 mRNA vaccine can be given.
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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:
Potential allergens: 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide. Other components: ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate); 1,2-distearoyl-sn-glycero-3-phosphocholine; cholesterol; sodium chloride; sucrose; tromethamine; tromethamine hydrochloride.

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.

• 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

Alternatively, such individuals may be offered Novavax COVID-19 vaccine if they are age-eligible. Janssen 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):
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 3-6 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.

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