What is COVID-19?

COVID-19 is a novel coronavirus disease 2019 that is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Anyone can be infected with SARS-CoV-2 (COVID-19). However, some populations are at increased risk of exposure to the virus (e.g., due to living or work settings), and some populations are at increased risk of severe disease and death due to biological (e.g., advanced age, pre-existing medical conditions) and social (e.g., low socioeconomic status, belonging to a racialized population) factors.

Additional information about the Moderna COVID-19 Vaccine can be found in the product monograph.
General Clinic Precautions

All staff working in the clinic must take appropriate infection prevention and control measures, including donning appropriate personal protective equipment (PPE) when interacting with clients as they move through the immunization clinic and when responding to any adverse events following immunization.

The Vaccine

<table>
<thead>
<tr>
<th>Moderna COVID-19 Vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of vaccine</strong></td>
</tr>
<tr>
<td><strong>Date of authorization in Canada</strong></td>
</tr>
<tr>
<td><strong>Authorized ages for use</strong></td>
</tr>
<tr>
<td><strong>Dose</strong></td>
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<td><strong>Schedule</strong></td>
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<td><strong>Booster doses</strong></td>
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<tr>
<td><strong>Route of administration</strong></td>
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<tr>
<td><strong>Nature of the antigen</strong></td>
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<tr>
<td><strong>Adjuvant (if present)</strong></td>
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</tbody>
</table>
Storage requirements

<table>
<thead>
<tr>
<th>Frozen vials prior to use</th>
<th>Should be stored at temperatures of -25°C to -15°C and protected from light. Do not store on dry ice or below -40°C.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unpunctured vials</td>
<td>If not punctured, the Moderna COVID-19 vaccine should be thawed and stored at +2°C to +8°C for up to 30 days, or at +8°C to +25°C for up to 12 hours. During storage, vials should be protected from light. Do not refreeze thawed vials.</td>
</tr>
<tr>
<td>Punctured vials</td>
<td>The Moderna COVID-19 vaccine should be stored between +2°C to below +25°C and used within 6 hours from the time of first puncture. During storage, vials should be protected from light.</td>
</tr>
<tr>
<td>Formats available</td>
<td>Multi-dose vial (10 doses), preservative-free</td>
</tr>
<tr>
<td>Usage limit</td>
<td>6 hours at +2°C to +25°C</td>
</tr>
<tr>
<td>Drug Interactions</td>
<td>No interaction studies have been performed.</td>
</tr>
</tbody>
</table>

Who Should Not Receive the Vaccine

The Moderna COVID-19 vaccine is contraindicated in:

- Individuals who have ever had a **severe allergic reaction** (i.e. anaphylaxis) to a previous dose of an mRNA vaccine or to any of its components (including polyethylene glycol (PEG) and/or polysorbate) or its container, should not get either mRNA COVID-19 vaccine. PEG can rarely cause allergic reactions and is found in products such as medications, bowel preparation products for colonoscopy, laxatives, cough syrups, cosmetics, skin creams, medical products used on the skin and during operations, toothpaste, contact lenses and contact lens solution. PEG also can be found in foods or drinks, but is not known to cause allergic reactions from foods or drinks.
- Vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, or those with symptoms of COVID-19.
• As a precautionary measure and in light of the need to be able to monitor for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illness, it would be prudent to wait for all symptoms of acute illness to completely resolve.
• Individuals who have received another vaccine (not a COVID-19 vaccine) in the past 14 days.
• **Individuals under the age of 18**: The safety and efficacy in children under 18 years of age have not yet been established. The manufacturer plans to conduct clinical trials in children.

**Considerations for other patient groups**

- Guidance for special populations, including for example breastfeeding or pregnant individuals, individuals with allergies, individuals with autoimmune conditions, or individuals who are immunocompromised due to disease or treatment, is available in the [Vaccination Recommendations for Special Populations](https://example.com) guidance document.

Precautions during vaccination should be taken for:

• Patients who have a bleeding problem, bruise easily or use a blood-thinning medicine should receive the vaccine. Individuals receiving long-term anticoagulation with either warfarin or heparin are not considered to be at higher risk of bleeding complications following immunization and may be safely immunized through the intramuscular route as recommended, without discontinuation of their anticoagulation therapy.
  - There is some evidence to suggest that intramuscular administration may be safer when given with a small gauge needle (23 gauge or smaller) and when firm pressure is applied to the injection site for 5 to 10 minutes.

• Individuals with a history of severe allergic reactions (i.e. anaphylaxis) not related to vaccines or injectable medications—such as allergies to food, pet, venom, environmental, or latex, etc. **should be offered** the COVID-19 vaccines.
  - An extended period of observation post-vaccination of 30 minutes is recommended for these groups.

• For more detailed recommendations on people with allergies, please consult the [Vaccination Recommendations for Special Populations](https://example.com) guidance document.
**Side effects**

The Moderna COVID-19 vaccine, like other medicines and vaccines can cause side effects, although not everyone gets them. The most common side effects of receiving the Moderna COVID-19 vaccine are mild and include injection site pain, swelling or redness.

Other side effects that have been reported include headache, fatigue, muscle ache and stiffness, chills, fever, nausea and/or vomiting, and enlarged lymph nodes. Most of these side effects experienced were mild to moderate and on average did not last longer than three days. Please see the [product monograph](#) for a complete list of reported side effects/adverse reactions.

| Very common side effects | May affect more than 1 in 10 people | • Pain at injection site  
• Lymphadenopathy/ Axillary swelling and tenderness  
• Fatigue  
• Headache  
• Muscle ache and stiffness | • Chills  
• Nausea/vomiting |
| Uncommon side effects | May affect up to 1 in 100 people | Fever |

**Adverse Events Following Immunization**

**What information should be provided to individuals related to potential adverse events following immunization (AEFIs) with the Moderna COVID-19 vaccine?**

As per s.38 of the *Health Protection and Promotion Act*, those administering vaccines should ensure that the vaccine recipients or their parents/guardians are advised to immediately call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop a reaction that could be related to the vaccine, particularly any of the following:

- Hives
- Swelling of the mouth and throat
- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C or 104°F)
- Convulsions (seizures)
- Other serious reactions

Health care providers (e.g., physicians, nurses and pharmacists) are required by law (i.e., Health Protection and Promotion Act, s. 38) to report AEFIs. Reports should be made using the Ontario AEFI Reporting Form and sent to the local public health unit.

The Ontario Ministry of Health in collaboration with Public Health Ontario monitors reports of adverse events after immunization. This monitoring is done in collaboration with the Public Health Agency of Canada and Health Canada.

The Brighton Collaboration has developed a list of Adverse Events of Special Interests.

Point-of-care Guidance

- As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic event following the administration of this vaccine.
- The vaccine is administered through an intramuscular injection into the upper arm (deltoid muscle).
- In order to be fully effective in preventing SARS-CoV2 infection, the vaccine must be administered twice: a single dose of the vaccine is administered followed by a second single dose 28 days later.
  - A minimum of 21 days between the first and second dose with a recommended interval of 28 days.
  - If administration of the second dose of the vaccine is delayed, it should be administered as soon as possible.
- In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series as delays between doses do not result in a reduction in final antibody concentrations for most multi-dose products. However, maximum protection may not be attained until the complete vaccine series has been administered.
- The vaccine series must be completed with the same COVID-19 vaccine product.
• Do not mix the Moderna COVID-19 vaccine with other vaccines/products in the same syringe.
• Moderna COVID-19 vaccine should not be given simultaneously with other live or inactivated vaccines.

**Vaccine Preparation:**

Additional information on vaccine preparation can be found in the product monograph.

• Thaw each vial before use:
  o Thaw in refrigerated conditions between 2°C to 8°C for 2 hours and 30 minutes. Let each vial stand at room temperature for 15 minutes before administering.
  o Alternatively, thaw at room temperature between 15°C to 25°C for 1 hour.
  o Do not re-freeze vials after thawing.
• Swirl the vial gently after thawing and between each withdrawal. Do not shake.

**Vaccine Administration:**

• Moderna COVID-19 Vaccine is a white to off-white suspension. It may contain white or translucent product-related particulates. Inspect Moderna COVID-19 Vaccine vials visually for foreign particulate matter and/or discoloration prior to administration. If either of these conditions exists, the vaccine should not be administered.
• Moderna COVID-19 Vaccine should be administered by the intramuscular (IM) route only. Do not inject the vaccine intravascularly, subcutaneously or intradermally. The preferred site is the deltoid muscle of the upper arm. A needle length of ≥1 inch should be used as needles <1 inch may be of insufficient length to penetrate muscle tissue in some adults.
• Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
• Withdraw each 0.5 mL dose of vaccine from the vial using a new sterile needle and syringe for each injection. The dose in the syringe should be used promptly.
• Moderna COVID-19 Vaccine is preservative free. Once a dose is withdrawn from the vial, it should be administered immediately. Once the vial has been entered (needle-punctured), it should be discarded after 6 hours. Do not refreeze. Any unused vaccine or waste material should be disposed of in accordance with local requirements.

All clients should be reminded to continue to practice recommended public health measures for prevention and control of COVID-19 infection and transmission regardless of receipt of COVID-19 vaccine.

Storage, Stability and Disposal

Storage Prior to Use

• The Moderna COVID-19 Vaccine multiple-dose vials are stored frozen between -25° to -15°C (-13° to 5°F). Store in the original carton to protect from light.
• Do not store on dry ice or below -40°C (-40°F).
• Vials can be stored refrigerated between 2° to 8°C (36° to 46°F) for up to 30 days prior to first use.
• Unpunctured vials may be stored between 8° to 25°C (46° to 77°F) for up to 12 hours.
• Do not refreeze once thawed.

Thawing Vials Prior To Use

• The Moderna COVID-19 Vaccine multiple-dose vial contains a frozen suspension that does not contain a preservative and must be thawed prior to administration.
• Remove the required number of vial(s) from storage and thaw each vial before use.
• Thaw in refrigerated conditions between 2° to 8°C (36° to 46°F) for 2 hours and 30 minutes. After thawing, let vial stand at room temperature for 15 minutes before administering.
  o Alternatively, thaw at room temperature between 15° to 25°C (59° to 77°F) for 1 hour.
• After thawing, do not refreeze.
Punctured vials

- Once the vial has been entered (needle-punctured), it can be stored at room temperature or refrigerated, but must be discarded after 6 hours. Do not refreeze.
- For more information, consult the product leaflet or information contained within the product monograph available through Health Canada’s Drug Product Database. Refer to Storage and Handling of Immunizing Agents in the CIG, Part 1 – Key Immunization Information for additional general information.

Special Handling Instructions

- Moderna COVID-19 Vaccine must not be mixed with other medicinal products or diluted. Any unused vaccine or waste material should be disposed of in accordance with local requirements.

Disposal

- Any unused vaccine or waste material should be disposed of in accordance with local requirements.