

Ministry of Health

Administration of Moderna COVID-19 Vaccine

Version 2.1 – April 27, 2021

Highlights of changes

- Clarification of dose intervals (Page 3)
- Link out to the National Advisory Committee on Immunization for vaccine effectiveness data (Page 4)
- Clarification on receiving another vaccine following the COVID-19 vaccine (Page 5)
- Added description of sources of Tromethamine (Page 6)
- Clarification on AEFI reporting (Pages 8 & 9)
- Clarification on the requirement of safety-engineered needles (Page 10)

This guidance provides basic information only. This document is not intended to provide or take the place of medical advice, diagnosis or treatment or legal advice.

In the event of any conflict between this guidance document and any applicable emergency orders, or directives issued by the Minister of Health, Minister of Long-Term Care, or the Chief Medical Officer of Health (CMOH), the order or directive prevails.

- Please check the Ministry of Health (MOH) [COVID-19 website](#) regularly for updates to this document.

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 (AEFI).

The Vaccine

Moderna COVID-19 Vaccine	
Type of vaccine	COVID-19 mRNA
Date of authorization in Canada	December 23, 2020
Authorized ages for use	18 years of age and older. The safety and efficacy in children under 18 years of age have not yet been established.
Dose	100 mcg of mRNA per 0.5 mL

Schedule	2 doses	
	Minimum interval ¹	21 days
	Authorized Interval ²	28 days
	Recommended interval	<p>4 months*^</p> <p>To increase the number of individuals benefiting from the first dose of vaccine, the province is following recommendations from the National Advisory Committee on Immunization (NACI) to extend the second dose of COVID-19 vaccine to 4 months after receipt of the first dose.</p> <p>*Note: Residents of long-term care homes, retirement homes, Elder Care Lodges, assisted living facilities, on-reserve First Nation members, remote and isolated First Nation communities (being supported by Operation Remote Immunity) should receive their vaccine at the interval of 21-28 days.</p> <p>^There is specific guidance for medical exceptions to extended dose intervals for COVID-19 vaccines which can be found in the Vaccine Clinical Advisory Group Recommendations on Exceptions to the Extended Dose Intervals for COVID-19 vaccines.</p>

¹ National Advisory Committee on [Immunizations](#) (NACI). Recommendations on the use of COVID-19 vaccines

² Health Canada: Product Monograph Moderna [COVID-19 vaccine](#)

Booster doses	At present there is no evidence for an additional booster after the 2-dose series
Route of administration	Intramuscular (IM) injection into the deltoid muscle
Nature of the antigen	Prefusion spike protein
Adjuvant (if present)	None
Storage requirements	
Frozen vials prior to use	Should be stored at temperatures of -25°C to -15°C and protected from light, in the original packaging. Do not store on dry ice or below -40°C.
Unpunctured vials	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, in the original packaging. Do not refreeze thawed vials.
Punctured vials	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.
Formats available	Multi-dose vial (10 doses), preservative-free
Usage limit	6 hours at +2°C to +25°C
Drug Interactions	No interaction studies have been performed.

Evidence on vaccine effectiveness for COVID-19 vaccines currently authorized for use in Canada continues to evolve. For up to date information on vaccine efficacy and effectiveness, please consult the National Advisory Committee on Immunization (NACI) statements and publications on the [Health Canada webpage](#).

Who Should Delay Receiving the Vaccine

- Vaccination should be deferred in symptomatic individuals with confirmed or suspected SARS-CoV-2 infection, those with an acute illness, or those with [symptoms of COVID-19](#) in order to avoid attributing any complications resulting from infection with SARS-CoV-2 or other illnesses to vaccine-related adverse events and to minimize the risk of COVID-19 transmission at an immunization clinic/venue. It would be prudent to wait for all symptoms of an acute illness to completely resolve before receiving the vaccine.
- Symptomatic and asymptomatic individuals who have been advised to self-isolate due to suspected or confirmed COVID-19 infection or due to close contact with a COVID-19 positive case should not attend a vaccine clinic and should wait to get their vaccine until their isolation period is over.
 - Note: Please refer to [Guidance for COVID-19 Immunization in Long-Term Care Homes and Retirement Homes](#) for specific guidance on vaccinating high risk contacts, those with symptoms or confirmed SARS-CoV-2 infection, in long-term care and retirement homes.
- Individuals who have recently received another vaccine (not a COVID-19 vaccine) should wait at least 14 days before getting a COVID-19 vaccine.
- Individuals who intend to receive a vaccine within 4 weeks of receiving the COVID-19 vaccine.
 - Anyone who receives a dose of a COVID-19 vaccine should wait 28 days before receiving another vaccine (except in the case when another vaccine is required for post-exposure prophylaxis).

Considerations for other patient groups

- COVID-19 vaccines can safely be given to persons with evidence of a prior SARS-CoV-2 infection. Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.
 - Having prolonged COVID-19 symptoms (sometimes called Long COVID or Post-Acute COVID-19 Syndrome) is not a contraindication to receiving the COVID-19 vaccine.

- If the patient is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine. Common side effects of the vaccine (e.g., fatigue, myalgia, arthralgia) may be similar to ongoing prolonged COVID-19 symptoms

Information on immunizing special populations, including individuals who are breastfeeding or pregnant, 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](#) guidance document. Point of care guidance for these individuals can be found in the [COVID-19 Vaccine – Pre-Screening Assessment Tool for Health Care Providers](#).

Precautions during vaccination should be taken for:

- Refer to [Vaccination Recommendations for Special Populations](#) for information on vaccination for all patients with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).
 - The components of the Moderna vaccine that may cause type I hypersensitivity reactions include polyethylene glycol (PEG) and tromethamine (trometamol or Tris). Due to potential cross-reactivity with PEG, allergies to polysorbate must also be considered.
 - 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.
 - Tromethamine can rarely cause allergic reactions and is found in products such as contrast media, oral and parenteral medications.

- Polysorbate 80 can rarely cause allergic reactions and is found in products such as medical preparations (such as vitamin oils, tablets, and anticancer agents) or cosmetics
- Individuals who fainted or became dizzy after receiving a vaccine or medical procedure, or those with high levels of fear about injections can receive the vaccine. To reduce injuries due to fainting, they should be immunized while seated, or if considered at high-risk, while lying down. These individuals are also advised they may bring a support person.
- Individuals who have a bleeding disorder, bruise easily or are taking blood-thinners can safely receive the vaccine. Individuals taking long-term anticoagulation (e.g. warfarin or heparin therapy) 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. In individuals with bleeding disorders, the condition should be optimally managed prior to immunization to minimize the risk of bleeding.
 - There is some evidence to suggest that IM administration with a small gauge needle (23 gauge or smaller) may be preferred to minimize the risk of bleeding, with firm pressure applied to the injection site for 5 to 10 minutes.
- For more detailed recommendations on people with allergies, as well as breastfeeding or pregnant individuals, individuals with autoimmune conditions, or individuals who are immunocompromised due to disease or treatment, please consult the [Vaccination Recommendations for Special Populations](#) guidance document.

Side effects

The Moderna COVID-19 vaccine, like other medicines and vaccines can cause side effects. In clinical trials 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.

Very common side effects	May affect more than 1 in 10 people	<ul style="list-style-type: none"> • Pain at injection site • Lymphadenopathy/ Axillary swelling and tenderness (enlarged lymph nodes) • Fatigue • Headache • Joint pain • Muscle pain
Common side effects	May affect 1 to less than 10 in 100 people	<ul style="list-style-type: none"> • Localized redness and swelling at injection site (very common after second dose) • Chills (very common after second dose) • Nausea and/or vomiting (very common after second dose)
Uncommon side effects	May affect up to 1 in 100 people	<ul style="list-style-type: none"> • Fever (very common after second dose)

Source: [National Advisory Committee on Immunizations, Appendix D: Frequency of solicited adverse events following immunization for COVID-19 vaccines in clinical trials.](#)

Adverse Events Following Immunization

All health care providers administering vaccines must be familiar with the anaphylaxis protocols for their clinic sites and ensure availability of anaphylaxis management kits (refer to the [Canadian Immunization Guide](#) for additional information).

Those administering vaccines should ensure that the vaccine recipients or their parents/guardians are advised to notify clinic staff, or if they have left the clinic, call their doctor/nurse practitioner or go to the nearest hospital emergency department if they develop 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

Guidance on reporting adverse events following immunization (AEFI) for health care providers

- Health care providers administering vaccines are required to inform vaccine recipients or their parent/guardian of the importance of immediately reporting adverse events following immunization to a physician or nurse in accordance with s. 38 of the *Health Protection and Promotion Act* (HPPA). Vaccine recipients or their parent/guardian may also contact their [local public health unit](#) to ask questions or to report an adverse event following immunization.
- Health care providers who administer immunizations (e.g., physicians, nurses and pharmacists) are required under the HPPA, to report AEFIs, in accordance with s. 38 of the HPPA to their local [public health unit](#). Reports should be made using the [Ontario AEFI Reporting Form](#).
- See Public Health Ontario's [vaccine safety webpage](#) and [Fact Sheet - Adverse Event Following Immunization Reporting For Health Care Providers In Ontario \(publichealthontario.ca\)](#) for additional guidance.
- The Ontario Ministry of Health in collaboration with Public Health Ontario monitors reports of AEFIs. This monitoring is done in collaboration with the Public Health Agency of Canada and Health Canada.

Point-of-care Guidance

- This is a two dose series, it is anticipated that maximum protection will be attained in up to 2 weeks following the completion of the vaccine series.
- 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 (except in the case when another vaccine is required for post-exposure prophylaxis).
- The vaccine series should be completed with the same COVID-19 vaccine product as the interchangeability of vaccines is not known at this time.
 - If the vaccine product used for a previously received dose is not known, or not available attempts should be made to complete the vaccine series with the same type of COVID-19 vaccine (e.g. using mRNA vaccine for both doses (NACI)).

Vaccine Preparation:

Additional information on vaccine preparation can be found in the [product monograph](#).

- Thaw each vial before use:
 - 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.
 - Alternatively, thaw at room temperature between 15°C to 25°C for 1 hour.
 - 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.
- It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.
- 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.

Information on vaccine storage, stability and disposal can be found in the [Vaccine Storage and Handling Guidance](#) document.