Ministry of Health

COVID-19 Vaccine Administration

Version 5.0 April 27, 2022

Highlights of changes

- Updated with information for Moderna for 6-11 year olds (chapter 2)
- Updated with Medicago information (chapter 7)
- Updated references to the COVID-19 Vaccine: Canadian Immunization Guide throughout
- Updated suggested intervals between previous SARS-CoV-2 infection and COVID-19 vaccination to include second booster doses (page 10)
- Updated section for individuals who have received COVID-19 vaccines outside of Ontario (page 13)
- New section on guidance on managing COVID-19 vaccine administration errors and deviations (page 16)

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

This document can be used as a reference for vaccine clinics and vaccine administrators to support immunization for COVID-19. Complementary resources include the individual vaccine product monographs, the COVID-19: Vaccine Storage and Handling Guidance and the COVID-19 Vaccine: Canadian Immunization Guide. This document replaces the following guidance documents: COVID-19 Vaccine Administration Errors and Deviations Guidance, COVID-19 Guidance for Individuals Vaccinated outside of Ontario/Canada, COVID-19 Vaccination Recommendations for Special Populations

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 Government of Canada webpage.

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Quick Reference: Health Canada Authorized COVID-19 Vaccines Available for Use in Ontario

Product Brand Name	**Pfizer-BioNTech COVID-19 Vaccine**	**Moderna COVID-19 Vaccine**	**AstraZeneca COVID-19 Vaccine**	**Janssen (Johnson & Johnson) COVID-19 Vaccine**	**Novavax COVID-19 Vaccine**	**Medicago COVID-19 Vaccine**
Product Generic Name	BNT162b2	mRNA-1273	ChAdOx1-S [recombinant] /AZD1222	Ad26.COV2.S, recombinant	NVX-CoV2373	J07BX03
Date of authorization in Canada	December 9, 2020 (May 2, 2021 for ages 12-15) (November 19, 2021 for ages 5-11)	December 23, 2020 (August 27, 2021 for ages 12-17) (March 17, 2022 for ages 6-11)	February 26, 2021	March 5, 2021	February 17, 2022	February 24, 2022
Manufacturer	Pfizer-BioNTech	Moderna	AstraZeneca	Janssen (Johnson & Johnson)	Novovax Inc.	Medicago Inc.
Type of Vaccine	Messenger ribonucleic acid (mRNA)	Messenger ribonucleic acid (mRNA)	Non-replicating viral vector (ChAd)	Non-replicating viral vector (Ad26)	Recombinant protein subunit, Adjuvanted	Plant-based virus-like particles, recombinant

Product Brand Name	**Pfizer-BioNTech COVID-19 Vaccine**	**Moderna COVID-19 Vaccine**	**AstraZeneca COVID-19 Vaccine**	**Janssen (Johnson & Johnson) COVID-19 Vaccine**	**Novavax COVID-19 Vaccine**	**Medicago COVID-19 Vaccine**
Link to Health Canada Product Monograph	pfizer-biontech-covid-19-vaccine-pm1-en.pdf (canada.ca)	moderna-covid-19-vaccine-pm1.pdf (canada.ca)	astrazeneca-covid-19-vaccine-pm-en.pdf	Janssen-covid-19-vaccine-pm1.pdf (Canada.ca)	nuvaxovid-pm-en.pdf (canada.ca)	https://covid-vaccine.canada.ca/info/pdf/covifenz-pm-en.pdf
Dose	**Adults/adolescents dose** (≥12 years of age and over): 0.3 mL (30 mcg of mRNA) following reconstitution **Pediatric dose** (5 to 11 years): 0.2mL (10 mcg of mRNA) following reconstitution	**Adults/adolescents** (≥12 years of age and over): 0.5 mL (100 mcg of mRNA) **Pediatric dose** (6 to 11 years): 0.25mL (50 mcg of mRNA)	0.5 mL (5 x 10^{10} viral particles)	0.5 mL (5 x 10^{10} viral particles)	0.5mL (5mcg of recombinant protein)	0.5 mL (3.75 mcg SARS-CoV-2 recombinant spike protein)
Health Canada Authorized Interval	2 doses, 21 days apart	2 doses, 28 days apart	2 doses, 4 to 12 weeks apart	1 dose	2 doses, 21 days apart	2 doses, 21 days apart

Product Brand Name	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 Vaccine	Janssen (Johnson & Johnson) COVID-19 Vaccine	Novavax COVID-19 Vaccine	Medicago COVID-19 Vaccine
Minimum Interval[1]	19 days apart	21 days apart	28 days apart	N/A	21 days apart	21 days apart
Recommended Interval[2]	8 weeks apart	8 weeks apart	At least 8 weeks apart	N/A	8 weeks apart	8 weeks
Authorized Age Indication	5 years of age and older[3]	6 years of age and older[3]	18 years of age and older	18 years of age and older	18 years of age and older	18-64 years of age

[1] NACI's Minimum Interval Recommendation (Table 1: Immunization schedule for a primary series, by COVID-19 vaccine).

[2] There is emerging evidence that longer intervals between the first and second doses of COVID-19 vaccines result in more robust and durable immune response, higher vaccine effectiveness and may be associated with a lower risk of myocarditis and/or pericarditis in adolescents and young adults. See the Canadian Immunization Guide for more information.

[3] Ontario, in alignment with NACI, has made a preferential recommendation for use of the Pfizer-BioNTech vaccine for individuals ages 5-29 years.

Product Brand Name	Pfizer-BioNTech COVID-19 Vaccine	Moderna COVID-19 Vaccine	AstraZeneca COVID-19 Vaccine	Janssen (Johnson & Johnson) COVID-19 Vaccine	Novavax COVID-19 Vaccine	Medicago COVID-19 Vaccine
Potential allergen included in vaccine and/or its container[4]	Polyethylene glycol (PEG)[5] **Pediatric 10mcg formula:** Polyethylene glycol (PEG) Tromethamine (tromethamol or Tris)	Polyethylene glycol (PEG)[5] Tromethamine (tromethamol or Tris)	Polysorbate 80[5]	Polysorbate 80[5]	Polysorbate 80[5]	Polysorbate 80[5] May contain trace amount of polyethylene glycol [PEG], kanamycin and carbenicillin

[4] This table identifies ingredients of the authorized, available COVID-19 vaccines that have been associated with allergic reactions in other products (NACI). This is not a complete list of substances. Any component of the COVID-19 vaccine or its container could be a potential allergen.

[5] Potential cross-reactive hypersensitivity between PEG and polysorbates has been reported in the literature.

COVID-19 Vaccine Precautions & Population Specific Considerations

See the COVID-19 Vaccine: Canadian Immunization Guide's section on Contraindications and Precautions for recommendations for individuals with allergies or severe immediate allergic reactions to a COVID-19 vaccine, acute illness, bleeding disorders, immune thrombocytopenia, venous thromboembolism, thrombosis with thrombocytopenia syndrome, myocarditis and/or pericarditis following vaccination, Guillain-Barré syndrome and Bell's palsy.

Individuals with known allergies to components of the vaccines may speak with an appropriate physician or NP for evaluation. This assessment will enable the development of a vaccination care plan which may include receiving the vaccine under the supervision of your physician. Documentation of the discussion with the physician/NP may be provided to the clinic and can include a vaccination care plan (including what types of parameters the clinic should meet to provide safe vaccination administration, such as availability of advanced medical care to manage anaphylaxis), details/severity of the previous allergic episode(s), confirm that appropriate counselling on the safe administration of vaccine was provided, and include the date, the clinician's name, signature and contact information as well as the individual's name and date of birth.

History of fainting/ dizziness, or fear of injections/ needles

Individuals with a history of fainting/dizziness, or fear of injections/needles can receive the COVID-19 vaccine. Considerations may include:

- Immunize while seated to reduce injuries due to fainting,
- If considered high-risk, immunize while lying down.
- These individuals may bring a support person.
- See CARD resources to support immunization

Breastfeeding or Pregnant

All pregnant and breastfeeding individuals are eligible and should receive all recommended doses of a COVID-19 vaccine (including booster doses) as soon as possible. See the Provincial Council for Maternal and Child Health's decision making tool, the Society of Obstetricians and Gynaecologists of Canada Statement on COVID-19 Vaccination in Pregnancy and the Canadian Immunization Guide for more information.

Autoimmune Conditions or Immunocompromised due to disease or treatment

It is recommended that all moderately to severely immunocompromised individuals receive a 3-dose primary series of a COVID-19 vaccine. These individuals are encouraged to speak with their treating health care provider regarding the timing of vaccination in relation to therapy for their underlying health condition and/or treatment modification in view of possible decreased vaccine effectiveness with the use of immunosuppressive therapy. See the COVID-19 Vaccine: Canadian Immunization Guide's section on immunocompromised persons and the COVID-19 Vaccine and Booster Dose Recommendations for more information.

It is recommended that re-vaccination with a new COVID-19 vaccine primary series be initiated post-transplantation for hematopoietic stem cell transplant (HSCT), hematopoietic cell transplants (HCT) (autologous or allogeneic), and recipients of CAR-T-cell therapy given the loss of immunity following therapy or transplant.[6] Optimal timing for re-immunization should be determined on a case-by-case basis in consultation with the clinical team. For additional information on organ transplantation, consult the Canadian Society of Transplantation statement on COVID-19 vaccination.

[6] As per the Canadian Immunization Guide, HSCT recipients should be viewed as vaccine naïve (i.e. never immunized) and require re-immunization after transplant.

- For additional information on rheumatic diseases, consult the Canadian Rheumatology Association statement on COVID-19 vaccination.
- For additional information on inflammatory bowel disease, consult the Canadian Association of Gastroenterology statement on COVID-19 vaccination.
- For additional information on immunodeficiency conditions, consult the COVID-19 resources on the Canadian Society of Allergy and Clinical Immunology webpage.
- For frequently asked questions about COVID-19 vaccine and adult cancer patients, consult Cancer Care Ontario.

Symptoms, either current or displayed recently, of chest pain or shortness of breath

- Vaccine should not be offered to persons displaying current or recent history of chest pain or shortness of breath.
- Persons displaying current or recent history of chest pain or shortness of breath should consult with a health care provider prior to vaccination and/or if symptoms are severe, should be directed to the emergency department or instructed to call 911.

Suggested intervals between previous SARS-CoV-2 infection and COVID-19 vaccination

Ontario, in alignment with NACI, continues to recommend that COVID-19 vaccines should be offered to individuals with previous SARS-CoV-2 infection without contraindications to the vaccine. Below are suggested intervals between previous SARS-CoV-2 infection and COVID-19 vaccination.

Infection timing relative to COVID-19 vaccination	**Population**	**Suggested interval between infection* and vaccination**
Infection prior to completion or initiation of primary vaccination series	Individuals 5 years of age and older who are not considered moderately to severely immunocompromised and with no previous history of multisystem inflammatory syndrome in children (MIS-C)	Receive the vaccine 8 weeks after symptom onset or positive test (if asymptomatic)
	Individuals 5 years of age and older who are moderately to severely immunocompromised and with no previous history of MIS-C	Receive the vaccine dose 4 to 8 weeks after symptom onset or positive test (if asymptomatic)
	Individuals 5 years of age and older with a previous history of MIS-C (regardless of immunocompromised status)	Receive the vaccine dose when clinical recovery has been achieved or ≥90 days since the onset of MIS-C, whichever is longer
Infection after primary series but before first	Individuals currently eligible for booster dose(s)	3 months after symptom onset or positive test (if asymptomatic).

booster dose and/or second booster dose		If they are 12 to 17 years old, as per the recommended interval for the booster dose, at least 6 months (168 days) should have passed after completing the primary series before receiving their booster dose.

*A previous infection with SARS-CoV-2 is defined as:

- Confirmed by a molecular (e.g., PCR) or rapid antigen test; or
- Symptomatic **AND** a household contact of a confirmed COVID-19 case.

These suggested intervals are based on immunological principles and expert opinion, and may change as evidence on COVID-19, variants of concern (VOCs), and COVID-19 vaccines emerge. When considering whether or not to administer vaccine doses following the suggested intervals outlined in this table, biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and severe disease should also be taken into account. These intervals are a guide and clinical discretion is advised.

Before vaccination, the individual should no longer be considered infectious, symptoms of acute illness should be completely resolved, and their isolation period must be completed. These suggested waiting times are intended to minimize the risk of transmission of COVID-19 at an immunization venue and to enable monitoring for COVID-19 vaccine adverse events without potential confounding from symptoms of COVID-19 or other co-existing illnesses.

A longer interval between infection and vaccination may result in a better immune response as this allows time for the immune response to mature in breadth and strength, and for circulating antibodies to decrease, thus avoiding immune interference when the vaccine is administered.

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. For additional information:

- Public Health Ontario resource on the Management of Anaphylaxis Following Immunization in the Community
- The Canadian Immunization Guide

Those administering vaccines should ensure that 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 symptoms:

- Hives
- Swelling of the face, throat or mouth
- Altered level of consciousness/serious drowsiness
- Trouble breathing, hoarseness or wheezing
- High fever (over 40°C or 104°F)
- Convulsions or seizures
- Other serious reactions (e.g., "pins and needles" or numbness)

A reduced post-vaccination observation period, between 5 -15 minutes could be considered for the administration of booster dose(s) of COVID-19 vaccine during the pandemic, if specific conditions are met such as the client's past experience with COVID-19 vaccine doses and other relevant conditions as outlined in the NACI 2020-2021 influenza vaccine advice. This would be an exception to usual immunization guidance and this approach could be used in these settings (i.e., mass immunization clinic, primary care clinics, pharmacies) at this time on a temporary basis, weighing the risks of a reduction in observation period (e.g., small increased risk of delayed identification of an adverse event that may require immediate medical attention) and reducing risk of SARS-CoV-2 transmission where physical distancing cannot be maintained and allowing more individuals to be immunized in a given time period.

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 (AEFIs) to a physician or nurse in accordance with Section 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 AEFI.
- Specified health care providers (e.g., physicians, nurses and pharmacists) are required under s.38(3) of the HPPA to report AEFIs 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 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.

Out of Province Vaccines

For guidance on managing and documenting individuals who have received COVID-19 vaccines outside of Ontario, please consult the Government of Canada's COVID-19: Recommendations for those vaccinated with vaccines not authorized by Health Canada for those staying in Canada to live, work or study.

Individuals who have received COVID-19 vaccines outside of Ontario or Canada should contact their local public health unit to have their COVID-19 immunization record documented in COVaxON.

Proof of immunization (e.g., an immunization record, proof of vaccination certificate (PVC)[7]) is required to verify the COVID-19 vaccine product received out of province.[8] PHUs are responsible for documenting immunization information for individuals who have received COVID-19 vaccine doses outside of Ontario into COVaxON. The

[7] See Canadian Immunization Guide to Immunization records.
[8] The Canadian Immunization Guide outlines that vaccination should only be considered valid if there is written documentation of vaccine administration.

information stated on the client's immunization record or proof of immunization will need to be entered. See the COVaxON job aid and functionality change communications for more information.

Point-of-Care Guidance for COVID-19 Vaccines

Co-Administration

- NACI recommends that for individuals 12+, mRNA, viral vector, recombinant protein subunit (Novavax; 18+) or recombinant virus-like particles (VLP) (Medicago; 18 to 64) COVID-19 vaccines may be given simultaneously with (i.e., same day), or at any time before or after non-COVID-19 vaccines (including live and non-live vaccines). Informed consent should include a discussion of the benefits and risks given the current absence of data on Medicago and Novavax given simultaneously with other vaccines.
- Unlike adolescent and adult populations, COVID-19 vaccines for children 5-11 years old should not routinely be given simultaneously with (i.e. same day) with other vaccines (live or inactivated) at this time (NACI). In the absence of evidence, it would be prudent to wait for a period of at least 14 days BEFORE or AFTER the administration of another vaccine before administrating a COVID-19 vaccine to prevent erroneous attribution of an AEFI to one particular vaccine or the other. However, this suggested minimum waiting period between vaccines is precautionary and therefore concomitant administration or a shortened interval between COVID-19 vaccines and other vaccines may be warranted on an individual basis in some circumstances. These circumstances may include:
    - When there is a risk of the individual being unable to complete an immunization series due to limited access to health services or being unlikely to return at a later date;
    - When an individual may not return to receive a seasonal influenza vaccine;
    - When another vaccine is required for post-exposure prophylaxis;
    - When individuals require accelerated vaccination schedules prior to immunosuppressive therapy or transplant; and
    - At the clinical discretion of the health care provider

Vaccine Product Recommendations

For a primary series:

1. NACI continues to preferentially recommend that a complete primary series of an mRNA COVID-19 vaccine (Pfizer-BioNTech, Moderna) should be offered to individuals in the authorized age group without contraindications to the vaccine.
2. Novavax or Medicago may be offered to individuals in the authorized age group without contraindications to the vaccine who are not able or willing to receive an mRNA COVID-19 vaccine.
3. A complete primary series of a viral vector COVID-19 vaccine (AstraZeneca, Janssen) may be offered to individuals in the authorized age group without contraindications to the vaccine only when all other authorized COVID-19 vaccines are contraindicated.

For Booster Dose(s):

4. NACI continues to preferentially recommend that booster doses of an mRNA COVID-19 vaccine (Pfizer-BioNTech, Moderna) should be offered to individuals without contraindications to the vaccine.
5. A booster dose of Novavax may be offered to individuals without contraindications who are not able or willing to receive an mRNA vaccine.
6. A booster dose of a viral vector vaccine should only be offered when all other Health Canada authorized COVID-19 vaccines are contraindicated.
7. Medicago is not currently authorized for use as a booster dose in Canada.

Please see the COVID-19 Vaccine Booster Dose Recommendations for more details.

Recommended Intervals for Mixed Primary Series

Where a different vaccine product is used to complete the two-dose primary vaccine series, the second dose should be given at a recommended dose interval of 8 weeks. If AstraZeneca was given as the first dose, the second dose can be given at a recommended interval of at least 8 weeks. If using the Health Canada authorized interval between first and second doses, the interval of the vaccine product used for the first dose should be followed. There is emerging evidence that longer intervals between the first and second doses of COVID-19 vaccines result in a more robust

and durable immune response and higher vaccine effectiveness (NACI). The decision to use the longer recommended dose interval should consider biological and social risk factors for exposure (e.g., local epidemiology, circulation of VOCs, living settings) and severe disease. These intervals are a guide and clinical discretion is advised.

COVID-19 Vaccine Errors and Deviations

For guidance on managing COVID-19 vaccine administration errors and deviations, please see the Government of Canada's COVID-19 Vaccine Guide for youth and adults: Managing COVID-19 vaccine administration errors and deviations and the Government of Canada's Quick reference guide on use of COVID-19 vaccine for children 5 to 11 years of age: Managing vaccine administration errors or deviations.

For inadvertent immunization errors and deviations that are not addressed in the Government of Canada's guidance and/or that involve multiple errors or have additional complexity, health care providers are encouraged to contact their local public health unit (PHU) for further advice.

If an inadvertent vaccine administration error or deviation results in an adverse event following immunization (AEFI), complete Ontario's AEFI reporting form, including details of the error or deviation. The completed AEFI form should be submitted to your local PHU.

The local PHU should be notified and vaccine administration errors or deviations should be handled and reported in accordance with both the site (if non-PHU) and PHU procedures.

- Vaccine administration errors and deviations that should be escalated to the Ministry of Health include those that may result in public safety concerns, cause misinformation, serious adverse events or death to any person; where large volumes of vaccine doses have been impacted or wasted; or where there is inadvertent administration of exposed and/or expired vaccine to a large number of patients. When in doubt, err on the side of caution and notify the Ministry of Health. For all issues that are escalated to the Ministry of Health, please report these per the following protocol: Email the Ministry of Health Communications team (media.moh@ontario.ca) and the

Implementation team (covid.immunization@ontario.ca), with the following header:

- Incident Report for [PHU/Site] on [Date]:
    - Description of Incident
    - Date of Incident:
    - Location of Incident:
    - Type of Incident:
    - Administration error or deviation:
    - Description of Incident:
    - Summary of action and steps taken to-date:
    - Next steps:

Chapter 1: Pfizer-BioNTech COVID-19 Vaccine

Considerations for Administration

In alignment with NACI's recommendation, the Ministry of Health has made a **preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 5-29 years of age.** This recommendation stems from an observed increase in the number of reports of myocarditis/pericarditis following vaccination with Moderna relative to Pfizer-BioNTech in adolescents and young adults, particularly among males, in Ontario, Canada, and internationally.

Children 5 to 11 years of age should receive the 10 mcg dose of the Pfizer-BioNTech vaccine (orange cap), whereas adolescents 12 years of age and older should receive the 30 mcg dose of the Pfizer-BioNTech vaccine (purple cap or grey cap).

Children who receive the 10 mcg Pfizer-BioNTech COVID-19 vaccine for their first dose and who have turned 12 years of age by the time the second dose is due may receive the 30 mcg Pfizer-BioNTech COVID-19 vaccine that is authorized for individuals ages 12 and older to complete their primary series. If the second dose of 10 mcg is given, the dose should still be considered valid and the series complete.

Warnings & Precautions

Myocarditis & Pericarditis

There have been Canadian and international reports of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining around the heart) following vaccination with COVID-19 mRNA vaccines. Global experience to date has indicated that the majority of reported cases have responded well to conservative therapy (rest, treatment with non-steroidal anti-inflammatory drugs (NSAIDS)) and tend to recover quickly. Symptoms have typically been reported to start within one week after vaccination. Cases of myocarditis/pericarditis following COVID-19 mRNA vaccination occur more commonly in adolescents and young adults (12 to 29 years of age), more often after the second dose and more often in males than females. It is unknown if and/or to what extent myocarditis/pericarditis will occur in children 5 to 11 years old following immunization with the 10 mcg dose of the Pfizer-BioNTech vaccine. Safety surveillance data from the US suggests that the risk of myocarditis or pericarditis may be lower in children aged 5 to 11 years following Pfizer-BioNTech (10 mcg) vaccination compared to adolescents and young adults (who receive a 30 mcg Pfizer-BioNTech dose). Among children 5 to 11 years of age, very rare cases were most often reported following dose 2 and among males. Post-market safety surveillance is ongoing (NACI, 2022). Providers are encouraged to consult the enhanced epidemiologic surveillance summary from Public Health Ontario for trends and risk of myocarditis/pericarditis following mRNA vaccines in Ontario.

NACI continues to strongly recommend that a complete series with an mRNA COVID-19 vaccine be offered to all eligible individuals in Canada, including those 5 years of age and older, in the authorized age group without contraindications to the vaccine.

The benefits of vaccination with COVID-19 vaccines continue to outweigh the risks of COVID-19 illness and related, possibly severe outcomes for all age groups.

- Anyone receiving an authorized mRNA COVID-19 vaccine should be informed of the risk of myocarditis and pericarditis, and advised to seek medical attention if they develop symptoms including chest pain, shortness of breath, palpitations (pounding or heart racing), or feeling of rapid or abnormal heart rhythm (NACI).

In most circumstances, and as a precautionary measure until more information is available, individuals with a diagnosed episode of myocarditis (with or without pericarditis) within 6 weeks of receipt of a previous dose of an mRNA COVID-19 vaccine should defer further doses of the vaccine. This includes any person who had an abnormal cardiac investigation including electrocardiogram (ECG), elevated

troponins, echocardiogram or cardiac MRI after a dose of an mRNA vaccine. This is a precaution based on recommendations issued by the National Advisory Committee on Immunization (NACI) in the Canadian Immunization Guide. NACI, Public Health Ontario (PHO), and the Ontario Ministry of Health (MOH) are following this closely and will update this recommendation as more evidence becomes available.

- In situations where there is uncertainty regarding **myocarditis** diagnosis, discussion should occur with an appropriate physician or nurse practitioner on potential options for (re)immunization with the same or alternative COVID-19 vaccine, including a risk-benefit analysis for the individual. Those with a history compatible with pericarditis and who either had no cardiac workup or had normal cardiac investigations, can receive the next dose once they are symptom free and at least 90 days has passed since vaccination.
- Some people with confirmed myocarditis with or without pericarditis may choose to receive another dose of vaccine after discussing the risks and benefits with their health care provider. Individuals can be offered the next dose once they are symptom free and at least 90 days has passed since vaccination.
    - If another dose of vaccine is offered, they should be offered the Pfizer-BioNTech 30 mcg vaccine due to the lower reported rate of myocarditis and/or pericarditis following the Pfizer-BioNTech 30mcg vaccine compared to the Moderna 100 mcg vaccine. Informed consent should include discussion about the unknown risk of recurrence of myocarditis and/or pericarditis following receipt of additional doses of Pfizer-BioNTech COVID-19 vaccine in individuals with a history of confirmed myocarditis and/or pericarditis after a previous dose of mRNA COVID-19 vaccine, as well as the need to seek immediate medical assessment and care should symptoms develop.
    - For more information consult Public Health Ontario's Myocarditis and Pericarditis Following COVID-19 mRNA Vaccines resource.
    - Interim clinical guidance and an algorithm for the identification and management of myocarditis and pericarditis following mRNA COVID-19 vaccination in children is available from the Hospital for Sick Children.
    - A clinical framework is also available from the Canadian Journal of Cardiology Myocarditis and Pericarditis following COVID-19 mRNA Vaccination: Practice Considerations for Care Providers

Multi-Inflammatory Syndrome in Children or in Adults (MIS-C/A) following vaccination with an mRNA COVID-19 vaccine

Children and adolescents with SARS-CoV-2 infection are at risk of multisystem inflammatory syndrome in children (MIS-C), a rare but serious syndrome that can occur several weeks following SARS-CoV-2 infection. Very rare cases of MIS-C/A (multisystem inflammatory syndrome in children and in adults) have been reported following vaccination with COVID-19 mRNA vaccines in Canada and internationally among individuals aged 12 years and older. However, on October 29, 2021, the European Medical Association Pharmacovigilance Risk Assessment Committee (EMA-PRAC) issued a statement that there is currently insufficient evidence on a possible link between mRNA COVID-19 vaccines and very rare cases of MIS-C/A.

For children with a previous history of MIS-C unrelated to any previous COVID-19 vaccination, vaccination should be postponed until clinical recovery has been achieved or until it has been ≥ 90 days since diagnosis, whichever is longer.

Bell's palsy following vaccination with an mRNA COVID-19 vaccine

Very rare cases of Bell's palsy (typically temporary weakness or paralysis on one side of the face) have been reported following vaccination with COVID-19 mRNA vaccines (Pfizer-BioNTech or Moderna) in Canada and internationally among individuals aged 12 years and older. Bell's palsy is an episode of facial muscle weakness or paralysis. The condition is typically temporary. Symptoms appear suddenly and generally start to improve after a few weeks. The exact cause is unknown. It's believed to be the result of swelling and inflammation of the nerve that controls muscles on the face.
Symptoms of Bell's palsy may include:

- uncoordinated movement of the muscles that control facial expressions, such as smiling, squinting, blinking or closing the eyelid
- loss of feeling in the face
- headache
- tearing from the eye
- drooling
- lost sense of taste on the front two-thirds of the tongue
- hypersensitivity to sound in the one ear
- inability to close an eye on one side of the face

Individuals should seek medical attention if they develop symptoms of Bell's palsy following receipt of mRNA COVID-19 vaccines. Health care providers should consider Bell's palsy in their evaluation if the patient presents with clinically

compatible symptoms after an mRNA COVID-19 vaccine. Investigations should exclude other potential causes of facial paralysis.

Allergies

See the COVID-19 Vaccine: Canadian Immunization Guide for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

Side effects

The Pfizer-BioNTech COVID-19 vaccine, like medicines and other vaccines, may cause side effects. In clinical trials, most of the side effects experienced were mild to moderate, and usually resolved within a few days. Please see the product monograph for a complete list of reported side effects.

Very common side effects	Occur in 10% or more of vaccine recipients	• Pain at injection site • Fatigue • Headache • Muscle pain • Chills • Fever (common after first dose for adults)
Common side effects	Occur in 1 to less than 10% of vaccine recipients	• Localized redness/erythema or swelling at injection site • Joint pain (very common after second dose) • Diarrhea • Nausea and/or vomiting (common after second dose for adults)
Uncommon side effects	Occur in 0.1% to less than 1% of vaccine recipients	• Enlarged lymph nodes (Lymphadenopathy)

The pediatric Pfizer-BioNTech COVID-19 vaccine, like medicines and other vaccines, may cause side effects. In clinical trials, most of the side effects experienced were mild to moderate, and usually resolved within a few days. Please see the product monograph for a complete list of reported side effects.

Very common side effects	Occur in 10% or more of vaccine recipients	• Pain, swelling and redness at injection site • Fatigue • Headache • Muscle pain
Common	Occur in 1 to less than 10% of vaccine recipients	• Chills • Fever • Vomiting • Diarrhea • Joint pain

Source: National Advisory Committee on Immunization, Appendix E: Frequency of solicited adverse events following immunization for COVID-19 vaccines in clinical trials.

See the Warnings and Precautions section above for information about the very rare reports of myocarditis and pericarditis following vaccination with mRNA COVID-19 vaccines. See the product monograph for further details on post-market adverse reactions.

Vaccine Preparation & Administration

See the Pfizer-BioNTech product monograph for step-by-step directions for administration (vial and dose verification, thawing prior to dilution, dilution, preparation) and information on packaging types and expiry dates.

It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Refer to the Canadian Immunization Guide, Table 3: Needle selection guidelines for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.

Information on vaccine storage, stability and disposal can be found in the COVID-19: Vaccine Storage and Handling Guidance document.

Chapter 2: Moderna COVID-19 Vaccine

Considerations for Administration

In alignment with NACI's recommendations, the Ministry of Health has made a **preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine for individuals 5-29 years of age.** This recommendation stems from an observed increase in the number of reports of myocarditis/pericarditis following vaccination with Moderna relative to Pfizer-BioNTech in adolescents and young adults, particularly among males, in Ontario, Canada, and internationally.

As per NACI, Moderna (50 mcg dose) may be offered as an alternative to Pfizer-BioNTech for **6-11 year olds**, however the use of Pfizer-BioNTech is preferred to Moderna (50 mcg) to start or continue the primary series. Although risk of myocarditis/pericarditis with the Moderna (50 mcg) in children 6 to 11 years of age is unknown, with a primary series in adolescents and young adults the rare risk of myocarditis/pericarditis with Moderna (100 mcg) was higher than with Pfizer-BioNTech (30 mcg).

Indirect data from adult populations (≥18 years of age) suggests Moderna (100 mcg) may result in higher vaccine effectiveness after a 2-dose primary series compared to Pfizer-BioNTech (30 mcg) and is associated with a higher seroconversion rate among adult immunocompromised patients (NACI, 2022). Given this potential benefit, administration of the Moderna (50 mcg) vaccine as a 3-dose primary series may be considered for some moderately to severely immunocompromised individuals 6 to 11 years of age, as outlined in the product monograph.

Should individuals aged 6 to 29 years of age request Moderna, they can access it with informed consent, which should include awareness of the possible elevated risk of myocarditis/pericarditis. Children 6 to 11 years of age should receive the 50 mcg dose of the Moderna vaccine, whereas adolescents 12 years of age and older should continue to receive the 100 mcg dose of the Moderna vaccine.

See the COVID-19 Vaccine Booster Dose Guidance for additional information on the use of Moderna as a booster dose.

Warnings & Precautions

Myocarditis & Pericarditis

See section above on myocarditis and pericarditis and the Canadian Immunization Guide for information.

Multi-Inflammatory Syndrome in Children or in Adults (MIS-C/A) following vaccination with an mRNA COVID-19 vaccine

See section above on MIS-C/A and the Canadian Immunization Guide for information.

Bell's palsy following vaccination with an mRNA COVID-19 vaccine

See section above on Bell's palsy following vaccination with an mRNA COVID-19 vaccine and the Canadian Immunization Guide for information.

Allergies

See the COVID-19 Vaccine: Canadian Immunization Guide for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

Side effects

The Moderna COVID-19 vaccine, like medicines and other vaccines can cause side effects. In clinical trials, most of the 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	Occur in 10% or more of vaccine recipients	• Pain at injection site • Lymphadenopathy/ axillary swelling and tenderness (enlarged lymph nodes) • Fatigue • Headache • Joint pain • Muscle pain • Chills
Common side effects	Occur in 1 to less than 10% of vaccine recipients	• Localized redness/erythema and swelling at injection site (very common after second dose) • Nausea and/or vomiting (very common after second dose)
Uncommon side effects	Occur in 0.1% to less than 1% of vaccine recipients	• Fever (very common after second dose)

Source: National Advisory Committee on Immunization, Appendix E: Frequency of solicited adverse events following immunization for COVID-19 vaccines in clinical trials.

For 6 to 11 year olds who received the Moderna vaccine, in clinical trials, most of the side effects experienced were mild to moderate, and usually resolved within a few days.

Very common side effects	Occur in 10% or more of vaccine recipients	• Pain, swelling, redness at injection site • Axillary (or groin) swelling or tenderness • Fatigue • Headache • Muscle pain • Chills • Nausea or Vomiting
Common	Occur in 1 to less than 10% of vaccine recipients	• Fever (very common after second dose) • Joint pain (very common after second dose)

Source: National Advisory Committee on Immunization, Appendix B: Frequency of solicited adverse events following immunization for COVID-19 vaccines in clinical trials.

See the Warnings and Precautions section above for information about the very rare cases of myocarditis and pericarditis that have been reported following vaccination with mRNA COVID-19 vaccines.

Vaccine Preparation

Detailed information on vaccine preparation and transport can be found in the product monograph and the COVID-19: Vaccine Storage and Handling Guidance.

- For guidance on what to do when there is leftover solution in the vial or if more than the stated number of doses can be obtained, please see the COVID-19: Vaccine Storage and Handling Guidance document.

Vaccine Administration

See the Moderna product monograph for step-by-step directions for administration (vial and dose verification, thawing prior to dilution, dilution, preparation).

It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Refer to the Canadian Immunization Guide, Table 3: Needle selection guidelines for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.

Information on vaccine storage, stability and disposal can be found in the COVID-19: Vaccine Storage and Handling Guidance document.

Chapter 3: AstraZeneca COVID-19 Vaccine

Considerations for Administration

As per NACI, the AstraZeneca COVID-19 vaccine may be offered to individuals who have contraindications to all other authorized COVID-19 vaccines. Individuals that received AstraZeneca COVID-19 vaccine for their first and second doses are recommended to receive an mRNA COVID-19 vaccine for their booster dose(s).

- In Ontario, viral vector COVID-19 vaccines are currently only available to individuals with contraindications to all other authorized COVID-19 vaccines as identified by an appropriate physician or nurse practitioner.
- Regardless of which product is offered, it is important that individuals receive all recommended doses (including booster doses) of a COVID-19 vaccine.
- For guidance on booster doses of a COVID-19 vaccine, please consult the COVID-19 Vaccine Booster Dose Recommendations.

Contraindications

AstraZeneca COVID-19 vaccine is contraindicated in individuals who have experienced venous and/or arterial thrombosis with thrombocytopenia following vaccination with a viral vector COVID-19 vaccine.

As per NACI, the AstraZeneca COVID-19 vaccine is contraindicated in individuals who have previously experienced episodes of capillary leak syndrome (CLS) (related or not to vaccination).

Warnings & Precautions

As per NACI, anyone receiving any authorized viral vector COVID-19 vaccine should be informed of the risks associated with viral vector vaccines including Thrombosis with Thrombocytopenia Syndrome (TTS) including Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), Capillary Leak Syndrome (CLS), Immune thrombocytopenia (ITP), Venous thromboembolism (VTE) and Guillain-Barré syndrome (GBS) following viral vector COVID-19 vaccines (NACI, 2022) and be advised to seek medical attention if they develop signs and symptoms suggestive of these conditions.

See the COVID-19 Vaccine: Canadian Immunization Guide for more information on precautions and contraindications for the AstraZeneca COVID-19 vaccine.

Allergies

See the COVID-19 Vaccine: Canadian Immunization Guide for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

Side Effects

The AstraZeneca COVID-19 vaccine, like medicines and other vaccines can cause side effects. In clinical trials, most of the side effects experienced were mild to moderate and on average resolved within a few days. Please see the product monograph for AstraZeneca COVID-19 vaccine for a complete list of reported side effects/adverse reactions.

Very common side effects	Occur in 10% or more of vaccine recipients	• Pain and tenderness at the injection site • Localized redness/erythema, warmth and pruritus (common after first dose) • Fatigue • Chills (common after first dose) • Headache • Muscle pain • Nausea (common after first dose) • Joint pain
Common side effects	Occur in 1 to less than 10% of vaccine recipients	• Localized swelling at the injection site • Induration • Vomiting (very common/common after first dose) • Fever/ feverishness (feverishness very common after first dose)
Uncommon side effects	Occur in 0.1% to less than 1% of vaccine recipients	• Enlarged lymph nodes (Lymphadenopathy)

Source: National Advisory Committee on Immunization, Appendix E: Frequency of solicited adverse events following immunization for COVID-19 vaccines in clinical trials.

Vaccine Preparation & Administration

- See the AstraZeneca product monograph for step-by-step directions for administration (vial and dose verification, thawing prior to dilution, dilution, preparation) and information on packaging types and expiry dates.
- It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Refer to the Canadian Immunization Guide, Table 3: Needle selection guidelines for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.

Information on vaccine storage, stability and disposal can be found in the COVID-19: Vaccine Storage and Handling Guidance document.

Chapter 4: Janssen (Johnson & Johnson) COVID-19 Vaccine

Considerations for Administration

As per NACI, the Janssen COVID-19 vaccine may be offered to individuals who have contraindications to all other authorized COVID-19 vaccines.

- In Ontario, viral vector COVID-19 vaccines are currently only available to individuals with contraindications to all other authorized COVID-19 vaccines as identified by an appropriate physician or nurse practitioner.
- Regardless of which product is offered, it is important that individuals receive all recommended doses (including booster doses) of a COVID-19 vaccine.
- Individuals that received Janssen COVID-19 vaccine for their first dose are recommended to receive an mRNA COVID-19 vaccine for their booster dose(s). For guidance for booster doses of a COVID-19 vaccine, please consult the COVID-19 Vaccine Booster Dose Recommendations.

Contraindications

The Janssen COVID-19 vaccine is contraindicated in individuals who have experienced venous and/or arterial thrombosis with thrombocytopenia following vaccination with a viral vector COVID-19 vaccine. Individuals with a history of capillary leak syndrome (related or not to previous vaccination) should not receive the Janssen COVID-19 vaccine, as per NACI.

Warnings & Precautions

As per NACI, anyone receiving any authorized viral vector COVID-19 vaccine should be informed of the risks associated with viral vector vaccines: Thrombosis with Thrombocytopenia Syndrome (TTS) including Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT), Capillary Leak Syndrome (CLS), Immune thrombocytopenia (ITP), Venous thromboembolism (VTE) and Guillain-Barré syndrome (GBS) following viral vector COVID-19 vaccines (NACI, 2022) and be advised to seek medical attention if they develop signs and symptoms suggestive of these conditions.

See the COVID-19 Vaccine: Canadian Immunization Guide for more information on precautions and contraindications for the Janssen COVID-19 vaccine.

Allergies

See the COVID-19 Vaccine: Canadian Immunization Guide for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

Side effects

The Janssen COVID-19 vaccines, like medicines and other vaccines can cause side effects. In clinical trials, most of the side effects experienced were mild to moderate and on average did not last longer than three days. Please see the product monographs for Janssen COVID-19 vaccine for a complete list of reported side effects/ adverse reactions.

Very common side effects	Occur in 10% or more of vaccine recipients	• Headache • Nausea • Muscle pain • Pain at injection site • Fatigue • Nausea and/or vomiting (after first dose)
Common	Occur in 1 to less than 10% of vaccine recipients	• Fever • Localized redness/swelling at injection site

Source: National Advisory Committee on Immunization, Appendix E: Frequency of solicited adverse events following immunization for COVID-19 vaccines in clinical trials.

Vaccine Preparation & Administration

This is a single dose vaccine; protection will be attained only after 2 weeks following administration of the vaccine.

- See the Janssen product monograph for step-by-step directions for administration (vial and dose verification, thawing prior to dilution, dilution, preparation) and information on packaging types and expiry dates.
- It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Refer to the Canadian Immunization Guide, Table 3: Needle selection guidelines for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as

required under O. Reg. 474/07 made under the Occupational Health and Safety Act.

Information on vaccine storage, stability and disposal can be found in the COVID-19: Vaccine Storage and Handling Guidance document.

Chapter 6: Novavax COVID-19 Vaccine

Considerations for Administration

Health Canada authorized the Novavax COVID-19 vaccine for use in a primary series in people 18 years of age and over on February 17, 2022. The Novavax vaccine is the first recombinant protein subunit COVID-19 vaccine authorized for use in Canada.

Novavax consists of a purified full-length SARS-CoV-2 recombinant spike (S) protein nanoparticle administered as a co-formulation with the adjuvant Matrix-M™. Matrix-M™ is a novel saponin-based adjuvant that facilitates activation of the cells of the body's innate immune system, which enhances the magnitude and duration of the S protein-specific immune response. Matrix-M™ has been used in Novavax clinical trials and in pre-licensure studies targeting other pathogens, but has not previously been used in any licensed vaccine.

Clinical trial data available to date show that the Novavax vaccine is highly efficacious in preventing confirmed symptomatic COVID-19 disease in the short term. However, the duration of protection is not yet known and there is currently no data on the efficacy or effectiveness of the vaccine against the Delta or Omicron variants, as clinical trials were conducted before the emergence of these variants.

The safety and efficacy of Novavax has not been established in the following populations: individuals previously infected with SARS-CoV-2; individuals who are immunocompromised due to disease or treatment; individuals who are pregnant or breastfeeding; individuals who have an autoimmune condition.

NACI continues to preferentially recommend the use of mRNA COVID-19 vaccines due to the excellent protection they provide against severe illness and hospitalization, and their well-known safety profiles. The Novavax vaccine is a new COVID-19 vaccine option that may be offered to individuals in the authorized age group who are not able, due to contraindications, or not willing to receive an mRNA COVID-19 vaccine.

A primary series of the Novavax COVID-19 vaccine is currently considered to be two doses. People may receive two doses of the Novavax vaccine (homologous series) or a mixed (heterologous) primary series (one dose of the Novavax vaccine and one dose of another COVID-19 vaccine). If receiving a mixed primary series with the Novavax vaccine, informed consent should include a discussion of the benefits and potential risks given the currently limited data on the effectiveness and safety of mixed schedules with the Novavax vaccine.

The Novavax COVID-19 vaccine may be offered as a booster dose to people who are not willing or not able to receive an mRNA vaccine, regardless of which COVID-19 vaccines were received in the primary series. This recommendation is off-label, as the Novavax COVID-19 vaccine is not currently authorized for use by Health Canada as a booster dose in Canada. Informed consent should include a discussion about what is known and unknown about the benefits and potential risks of the use of the Novavax vaccine as a booster dose, including the off-label status of this recommendation.

For individuals with serious polyethylene glycol (PEG) allergy or previous serious allergic reaction to an mRNA vaccine precluding vaccination with mRNA vaccines, Novavax may be the preferred product for vaccination, based on consultation with an allergist or other appropriate physician or nurse practitioner.

Warnings & Precautions

As per NACI, individuals who refuse mRNA vaccines should be made aware of the long term effectiveness and safety data that are available for mRNA products as compared to other vaccines as part of informed consent before offering Novavax.

At the time of approval, there are no known serious warnings or precautions associated with the Novavax vaccine.

Allergies

See the COVID-19 Vaccine: Canadian Immunization Guide for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

Side effects

The Novavax COVID-19 vaccine, like medicines and other vaccines, can cause side effects. In clinical trials, most of the side effects experienced were mild to moderate and generally, resolved in 1-2 days. They occurred more frequently after the second dose and were more common in adults 18 to 64 years of age compared to older adults ≥ 65 years old. Please see the product monographs for Novavax COVID-19 vaccine for a complete list of reported side effects/ adverse reactions.

		Dose 1	Dose 2
Very common side effects	Occur in 10% or more of vaccine recipients	• Headache • Muscle pain • Pain or tenderness at injection site • Fatigue • Nausea and/or vomiting (more frequent after second dose)	• Pain or tenderness at injection site • Fatigue • Headache • Muscle pain • Joint pain • Vomiting
Common	Occur in 1 to less than 10% of vaccine recipients	• Joint pain • Vomiting • Localized redness at injection site	• Localized redness/swelling at injection site • Fever

Source: National Advisory Committee on Immunization, Appendix A: Frequency of solicited adverse events following immunization for COVID-19 vaccines in clinical trials.

Vaccine Preparation & Administration

See the Novavax product monograph for step-by-step directions for administration (vial and dose verification, thawing prior to dilution, dilution, preparation) and information on packaging types and expiry dates.

It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Refer to the Canadian Immunization Guide, Table 3: Needle selection guidelines for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.

Information on vaccine storage, stability and disposal can be found in the COVID-19: Vaccine Storage and Handling Guidance document.

Chapter 7: Medicago COVID-19 Vaccine

Considerations for Administration

Health Canada authorized the Medicago COVID-19 vaccine for use in a primary series in people 18-64 years of age on February 24, 2022.

The Medicago COVID-19 vaccine is an adjuvanted vaccine consisting of recombinant SARS-CoV-2 spike glycoproteins stabilized in the prefusion conformation that are produced by transient expression in *Nicotiana benthamiana* plants and become membrane imbedded in self-assembled enveloped virus-like particles (VLP).

Clinical trial data available to date show that the Medicago vaccine is efficacious in preventing confirmed symptomatic COVID-19 disease in the short term. However, the duration of protection is not yet known and there is currently no data on the efficacy or effectiveness of the vaccine against the Omicron variant, as clinical trials were conducted before the emergence of the Omicron variant.

The safety and efficacy of Medicago has not been established in the following populations: individuals previously infected with SARS-CoV-2; individuals who are immunocompromised due to disease or treatment; individuals who are pregnant or breastfeeding; individuals who have an autoimmune condition.

NACI continues to preferentially recommend the use of mRNA COVID-19 vaccines for most people due to the excellent protection they provide against severe illness and hospitalization, and their well-known safety profiles. The Medicago vaccine is a new COVID-19 vaccine option that may be offered to individuals who are not able to, due to contraindications, or not willing to receive an mRNA COVID-19 vaccine.

A primary series of the Medicago COVID-19 vaccine is currently considered to be two doses. People may receive two doses of the Medicago vaccine (homologous series) or a mixed (heterologous) primary series (one dose of the Medicago vaccine and one dose of another COVID-19 vaccine). If receiving a mixed primary series with the Medicago vaccine, informed consent should include a discussion of the benefits

and potential risks given the absence of data on the effectiveness and safety of mixed schedules with the Medicago vaccine.

Medicago is not currently authorized for use as a booster dose in Canada. Clinical trials of a booster dose of this vaccine are planned for Spring 2022. At the time of publication, there are no data available on the use of Medicago as a booster dose in either a homologous or heterologous schedule. Informed consent when administering a Medicago primary series should therefore include mention that this vaccine is not currently authorized for use as a booster dose in Canada. See the COVID-19 Vaccine Booster Dose Recommendations for more information.

Warnings & Precautions

As per NACI, individuals who are not willing to receive an mRNA vaccine should be made aware of the long term effectiveness and safety data that are available for the mRNA products as compared to Medicago as part of informed consent before offering Medicago, including a discussion of the benefits and risks given the limited data available on administration of the Medicago.

At the time of approval, there are no known serious warnings or precautions associated with the Medicago vaccine.

Allergies

See the COVID-19 Vaccine: Canadian Immunization Guide for information on vaccination for all individuals with allergies (including those with allergic reactions to previous doses of any COVID-19 vaccine, or vaccine components).

Side effects

The Medicago COVID-19 vaccine, like medicines and other vaccines, can cause side effects. In clinical trials, most of the side effects experienced were mild to moderate and generally, resolved in 1-2 days. Please see the product monograph for Medicago COVID-19 vaccine for a complete list of reported side effects/ adverse reactions.

		Dose 1	Dose 2
Very common side effects	Occur in 10% or more of vaccine recipients	• Pain or tenderness at injection site • Swelling at injection site • Fatigue • Headache • Muscle Pain • Joint Pain	• Pain or tenderness at injection site • Redness/swelling at injection site • Fatigue • Headache • Muscle Pain • Joint Pain
Common	Occur in 1 to less than 10% of vaccine recipients	• Redness/erythema at injection site • Fever	• Fever

Source: National Advisory Committee on Immunization, Appendix A: Frequency of solicited adverse events following immunization for COVID-19 vaccines in clinical trials.

Vaccine Preparation & Administration

See the Medicago product monograph for step-by-step directions for administration (vial and dose verification, thawing prior to dilution, dilution, preparation) and information on packaging types and expiry dates.

It is important that proper sized syringes are chosen to ensure the correct volume is accurately drawn up. Refer to the Canadian Immunization Guide, Table 3: Needle selection guidelines for assistance in selecting appropriate needle length and gauge. Safety engineered needles must be used as required under O. Reg. 474/07 made under the Occupational Health and Safety Act.

Information on vaccine storage, stability and disposal can be found in the COVID-19: Vaccine Storage and Handling Guidance document.