

Moderna Spikevax COVID-19 Vaccine

What you need to know to address patient concerns

(Note: This tool contains information regarding monovalent COVID-19 vaccines only. Information about bivalent COVID-19 vaccines are beyond the scope of this resource.)

What is the Moderna Spikevax COVID-19 Vaccine?

Moderna Spikevax COVID-19 vaccine is a monovalent mRNA vaccine approved for use in Canada for individuals 6 months of age and older as part of the primary series or as a booster for patients 18 years of age and older. In clinical trials, the efficacy of Moderna Spikevax beginning two weeks after the second dose was:

| Age Group | Efficacy |
|--------------------------------|--|
| 6 – 23 months old [†] | 51% [^] |
| 2 – 5 years old [†] | 37% [^] |
| 6 – 11 years old [#] | Comparable immune response to young adults 18 – 25 years old |
| 12 – 17 years old | 100% |
| ≥18 years old | 94.1% |

[†] Clinical trial with children 6 months – 5 years of age was conducted when Omicron was the dominant variant in Canada and the United States.
[^] Percentage represents efficacy against confirmed symptomatic COVID-19 infection.
[#] Clinical trial with children 6-11 years of age was conducted when Delta was the dominant variant in Canada and the United States.

Why is it important to be vaccinated against COVID-19 and are the vaccines safe?

Vaccination is the best defense against COVID-19. Vaccines have been shown to be very effective and significantly help in preventing infection, illness, hospitalization, and death from COVID-19. NACI preferentially recommends that a complete primary series with a monovalent (original) mRNA vaccine approved for the intended age group should be offered to all individuals 5 years of age and older without contraindications to the vaccine. For children 6 months to 5 years of age, NACI recommends that a complete primary series with Moderna Spikevax COVID-19 vaccine may be offered to those who do not have contraindications to the vaccine. These recommendations also apply to individuals who have previously been infected with COVID-19 as there is variability in the robustness and durability of protection from a previous infection. It is important that individuals stay up to date with their COVID-19 vaccinations which means receiving all recommended doses (primary series doses and any booster dose(s) when eligible), within the last six months. For more information, refer to the Ministry of Health's [COVID-19 Vaccine Guidance](#).

Prior to being approved for use in Canada, Health Canada conducts a comprehensive review of the scientific and medical evidence to ensure vaccines are safe and effective and that the benefits of use outweigh the risks. In addition, the use and safety of COVID-19 vaccines continue to be monitored on an ongoing basis by the Public Health Agency of Canada, Health Canada, and provincial and territorial health authorities.

Who can get the Moderna vaccine?

Administration of the Moderna Spikevax COVID-19 Vaccine in Ontario Pharmacies^a

| | Age Group | | | | |
|-------------------------------|------------------|----------------|----------------|----------------|-----------|
| | 6 months–5 years | 6–11 years | 12–17 years | 18–29 years | ≥30 years |
| Primary Series | ✓ ^b | ✓ ^b | ✓ ^b | ✓ ^b | ✓ |
| Booster(s)^c | x ^d | x ^d | ✓ ^b | ✓ ^b | ✓ |

- a Refer to question below on "Is one mRNA vaccine preferred over another?" for some additional considerations.
- b Both mRNA vaccines (Pfizer-BioNTech and Moderna) have been associated with the rare risk of myocarditis/pericarditis following vaccination. However, the Ministry of Health (based on advice from the OIAC and in alignment with NACI) has issued a preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine in those aged 5-29 years old for doses part of the primary series, or for those aged 5-17 years old as booster(s), based on an observed increase in the number of reports of myocarditis/pericarditis in Ontario following vaccination in children, adolescents and young adults (particularly among males) with Moderna compared to Pfizer-BioNTech. Please note that the risk of myocarditis/pericarditis is unknown in children 6 months-11 years of age with Moderna (25 mcg or 50 mcg), however the rare risk of myocarditis/pericarditis with Moderna (100 mcg) in a primary series in adolescents and young adults was higher than with Pfizer-BioNTech (30 mcg). Should a patient aged 6-29 wish to receive the Moderna vaccine, it may be administered with informed consent. For children 5 years of age, although Pfizer-BioNTech vaccine is preferred over Moderna, as per NACI, Moderna may be offered to this age group with informed consent and a discussion with the child's healthcare provider about the associated risks and benefits.
- c Information provided on the use of monovalent Moderna Spikevax vaccine in the context of booster(s) does not include recommendations regarding bivalent Omicron-containing mRNA COVID-19 vaccines. For recommendations regarding booster doses, refer to the Ministry of Health's [COVID-19 Vaccine Guidance](#).
- d For children 5-11 years old, currently only monovalent Pediatric Pfizer-BioNTech (10 mcg) is authorized to be used as a booster.

Contraindications: individuals who are hypersensitive to the active ingredient or to any ingredients in the formulation, including any non-medicinal ingredient, or component of the container, e.g., polyethylene glycol (PEG), tromethamine (trometamol or Tris). (There is a potential cross-reactive hypersensitivity between PEG and polysorbates.) Note: Patients who experience a severe immediate allergic reaction (e.g., anaphylaxis) after a first dose of an mRNA vaccine may be able to safely receive future doses of the same or another mRNA COVID-19 vaccine, however, they must first consult with an appropriate physician/nurse practitioner for an assessment.

Is one mRNA vaccine preferred over another?

There are two monovalent (original) mRNA COVID-19 vaccines approved for use in Canada: Moderna Spikevax and Pfizer-BioNTech Comirnaty. In a primary series, subsequent doses started with an mRNA COVID-19 vaccine should be with the same vaccine product. However, in alignment with guidance on interchangeability of mRNA COVID-19 vaccines, if the same vaccine product is not readily available (i.e., easily available at the time of vaccination without delay or vaccine wastage), is not known, or is no longer authorized for the age group, another mRNA COVID-19 vaccine product recommended for use in the same age group can be considered interchangeable. Note: As at the date of revision, only the Moderna vaccine is available in Ontario pharmacies for use in children 6 months to under 5 years of age. For more information, including information about boosters, refer to the Ministry of Health's [COVID-19 Vaccine Guidance](#).

Both monovalent mRNA COVID-19 vaccines approved for use in Canada are safe and effective. Although there have been reports of myocarditis/pericarditis following vaccination with mRNA vaccines, these are rare and in most cases mild and resolve within a few days with rest and treatment. Conversely, a report from the Centers for Disease Control and Prevention in the US, which analyzed data from March 2020 to January 2021, found that the risk for myocarditis was 16 times higher for those with COVID-19 infection compared to those without. As such, the benefits of vaccination to protect against COVID-19 illness (which may include complications such as myocarditis/pericarditis) continue to outweigh the potential harms of experiencing an adverse reaction following vaccination. However, based on an observed increase in reports of myocarditis/pericarditis in Ontario following vaccination in children, adolescents and young adults (particularly among males) with Moderna compared to Pfizer-BioNTech, the Ministry of Health (based on advice from the OIAC and in alignment with NACI) has issued a preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine in those aged 5-29 years old for doses part of the primary series, or for those aged 5-17 years old as booster(s). Please note that the risk of myocarditis/pericarditis is unknown in children 6 months-11 years of age with Moderna (25 mcg or 50 mcg), however the rare risk of myocarditis/pericarditis with Moderna (100 mcg) in a primary series in adolescents and young adults was higher than with Pfizer-BioNTech (30 mcg). Should a patient aged 6-29 wish to receive the Moderna vaccine, it may be administered with informed consent. For children 5 years of age, although Pfizer-BioNTech vaccine is preferred over Moderna, as per NACI, Moderna may be offered to this age group with informed consent and a discussion with the child's healthcare provider about the associated risks and benefits.

For children who receive Moderna (25 mcg) and turn 5 prior to completing their primary series, it is recommended to complete the primary series with Moderna (25 mcg). If a child receives Moderna (25 mcg) and turns 6 prior to completing their primary series, it is recommended to complete the primary series with Moderna (50 mcg). However, the dose should still be considered valid and the series complete if Moderna (25 mcg) or Pfizer-BioNTech (10 mcg) is used.

For some children 6 to 11 years of age who are moderately to severely immunocompromised, consideration may be given to administration of Moderna (50 mcg) as a 3-dose primary series. This is based on the potential benefit of Moderna as indirect data from individuals 18 years of age and older suggest that after a 2-dose primary series, Moderna (100 mcg) may result in higher vaccine effectiveness in comparison to Pfizer-BioNTech (30 mcg) and is associated with a higher seroconversion rate among adult immunocompromised patients.

Can the Moderna vaccine be given with other vaccines?

For individuals 5 years of age or older, COVID-19 vaccines can be given at the same time, or any time before or after, other non-COVID-19 vaccines. When administering multiple vaccines at a single visit:

- Use different injection sites and separate needles and syringes for each vaccine
- Ensure the patient understands the benefits and risks as there is limited data on simultaneous, or shortly before or after, administration of COVID-19 vaccines with other vaccines, or whether there is increased reactogenicity of COVID-19 vaccines when administered concomitantly with other vaccines; but so far, no specific safety concerns have been identified (safety and immunogenicity studies on concurrent administration are ongoing)

For children 6 months to 5 years of age, it is recommended to space out administration of the Moderna COVID-19 vaccine and other vaccines by at least 14 days before or after. However, based on clinical discretion, simultaneous administration or a shortened interval may be warranted in some situations.

Additional Counselling Tips

Adverse Reactions

Common side effects of Moderna are usually mild to moderate and resolve within a few days:

- Local: redness, swelling and/or pain at the injection site, localized axillary (or groin) swelling and tenderness (lymphadenopathy)
- Systemic: fatigue, headache, muscle pain, chills, joint pain, nausea/vomiting, fever
- Specific to children 6-36 months: irritability/crying, sleepiness, loss of appetite

Potential rare severe adverse events include myocarditis and/or pericarditis, Bell's palsy, and anaphylaxis. Patients who develop signs and symptoms associated with these conditions should be advised to seek immediate medical attention.

These are not all the possible side effects and patients should be instructed to contact a healthcare professional if they experience any symptoms that are new, persistent, concerning or worsening.

Suggestions for Management of Pain/Fever

| Before or at the time of vaccination: | After vaccination: |
|---|--|
| <ul style="list-style-type: none"> Physical strategies (e.g., positioning, relaxing arm) Psychological strategies (e.g., distraction) Consider use of topical anesthetics Although not a contraindication to vaccine administration, in general, prophylactic use of oral analgesics/antipyretics for prevention of injection pain and/or systemic reactions is not recommended | <ul style="list-style-type: none"> If adverse effects (e.g., pain, fever) are experienced post-vaccination, use of oral analgesics/antipyretics may be considered Pain: cold compress on the area; movement of the vaccinated arm Fever: stay hydrated; dress lightly |

Abbreviations:

mcg: micrograms; Moderna: monovalent Moderna Spikevax COVID-19 vaccine; mRNA: messenger ribonucleic acid; NACI: National Advisory Committee on Immunization; OIAC: Ontario Immunization Advisory Committee; Pfizer-BioNTech: monovalent Pfizer-BioNTech Comirnaty COVID-19 vaccine

DISCLAIMER:

This tool was developed by the Ontario Pharmacists Association (OPA) with a grant provided by Moderna Biopharma Canada Corporation. This resource is provided to pharmacy professionals for informational purposes only and is intended to assist pharmacists during discussions with patients about Moderna Spikevax COVID-19 vaccine but does not replace professional judgment and responsibilities. It is provided without warranty of any kind by OPA and OPA assumes no responsibility for any errors, omissions or inaccuracies therein. The decision for use and application of this document is the responsibility of the user. OPA assumes no liability for such use and application or any resulting outcomes. It is the responsibility of the pharmacy professional to use professional judgment in evaluating this material in light of any relevant clinical or situational data. It is intended to supplement materials provided by regulatory authorities, and should there be any discrepancies, municipal, provincial, and federal laws, policies and guidelines shall prevail. This information is up to date as at the date of publication. Pharmacy professionals are encouraged to confirm information with additional resources.

REFERENCES:

- Government of Canada. (2022, September 1). *Moderna Spikevax COVID-19 vaccine*. Accessed September 16, 2022. <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines/moderna.html>
- Public Health Agency of Canada (2022, July 14). *An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI) Recommendations on the use of Moderna Spikevax COVID-19 vaccine in children 6 months to 5 years of age*. Government of Canada. Accessed July 22, 2022. <https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-moderna-spikevax-covid-19-vaccine-children-6-months-5-years.pdf>
- Public Health Agency of Canada (2022, March 17). *An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI) Recommendations on the use of Moderna Spikevax COVID-19 vaccine in children 6 to 11 years of age*. Government of Canada. Accessed August 30, 2022. <https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/statement-recommendations-use-moderna-spikevax-covid-19-vaccine.pdf>
- Ministry of Health. (2022, March 24). *COVID-19 Vaccine Information Sheet (age 12+)*. Government of Ontario. Accessed April 8, 2022. https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_info_sheet.pdf
- Ministry of Health (2022, September 9). *COVID-19 Vaccine Guidance*. Government of Ontario. Accessed September 16, 2022. https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/COVID-19_vaccine_administration.pdf
- Canadian Immunization Guide (2022, August 29). *COVID-19 vaccine*. Government of Canada. Accessed September 16, 2022. <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html>
- Ministry of Health (2022, September 12). *Updated: Executive Officer Notice: Administration of Publicly Funded COVID-19 Vaccines in Ontario Pharmacies – Eligibility*. Government of Ontario. Accessed September 16, 2022. (Email communication)
- Ministry of Health (2022, September 12). *Updated: Questions and Answers for Administration of Publicly Funded COVID-19 Vaccine in Ontario Pharmacies*. Government of Ontario. Accessed September 16, 2022. (Email communication)
- ModernaTX, Inc. (2022, July 14). *Spikevax Product Monograph*. Government of Canada. Accessed July 22, 2022. <https://covid-vaccine.canada.ca/info/pdf/covid-19-vaccine-moderna-pm-en.pdf>
- Boehmer, T. K., Kompaniyets, L., Lavery, A. M., Hsu, J., Ko, J. Y., Yusuf, H., Romano, S. D., Gundlapalli, A. V., Oster, M. E. & Harris, A. M. (2021). Association Between COVID-19 and Myocarditis Using Hospital-Based Administrative Data – United States, March 2020–January 2021. *MMWR. Morbidity and mortality weekly report*, 70(35), 1228–1232. <https://doi.org/10.15585/mmwr.mm7035e5>
- HelpinKids&Adults, University of Toronto, Immunize Canada. *Recommendations for Reducing Vaccine Pain in Adults*. Government of Ontario. Accessed March 15, 2022. https://www.health.gov.on.ca/en/pro/programs/publichealth/coronavirus/docs/vaccine/Reducing_Vaccination_Pain_Adults.pdf
- City and County of Denver. *COVID-19 Moderna Vaccine Fact Sheet*. Accessed March 15, 2022. https://denvergov.org/files/assets/public/moderna_community_vaccine_fact_sheets_english.pdf

Date of Revision: September 16, 2022