Moderna Spikevax COVID-19 Vaccine

What you need to know to address patient concerns

ONTARIO PHARMACISTS ASSOCIATION
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What is Moderna Spikevax COVID-19 Vaccine?

Moderna Spikevax COVID-19 vaccine is an mRNA vaccine approved for use in Canada for individuals 6 years 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, it has been shown to be 94.1% effective at protecting against COVID-19 in individuals 18 years of age and older, and in adolescents 12-17 years of age, it demonstrated 100% effectiveness two weeks after the second dose. Furthermore, clinical trials with individuals 6-11 years of age found that the Moderna Spikevax COVID-19 vaccine was as effective for this age cohort as it was for young adults 18-25 years of age.

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 an mRNA vaccine approved for the intended age group should be offered to all individuals without contraindications to the vaccine. This includes individuals who have previously been infected with COVID-19 as there is variability in the robustness and durability of protection from a previous infection. In addition, mRNA vaccines continue to be preferentially recommended as boosters for eligible individuals without contraindications to the vaccine.

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 Moderna vaccine?

Administration of Moderna Spikevax COVID-19 Vaccine in Ontario Pharmacies[a]

	Age Group			
	6-11 years	12-17 years	18-29 years	≥30 years
Primary Series	✓[b]	✓[b]	✓[b]	✓
Booster	✗	✓[b,c]	✓[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, Ontario has issued a preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine in those aged 5-29 based on an observed increase in reports of myocarditis/pericarditis following vaccination in 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 6-11 years of age with Moderna (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 wish to receive the Moderna vaccine, it may be administered with informed consent.

c Although Health Canada has only authorized Moderna for use as a booster for individuals 18 years of age and older, in Ontario, the OIAC has recommended that Moderna can also be used as a booster dose in adolescents 12 to 17 years of age, but there is a preferential recommendation for the use of Pfizer-BioNTech vaccine for this cohort (see note b above). For more information, refer to the Ministry's COVID-19 Vaccine Booster Recommendations.

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). (It has been reported in the literature that there may be 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 mRNA COVID-19 vaccines approved for use in Canada: Moderna Spikevax and Pfizer-BioNTech Comirnaty. NACI recommends that subsequent doses in a vaccine series started with an mRNA COVID-19 vaccine should be with the same vaccine product if readily available (i.e., easily available at the time of vaccination without delay or vaccine wastage). However, mRNA COVID-19 vaccine products recommended for use in the same age group can be considered interchangeable, therefore, if the same vaccine product is not readily available or is not known, an interchangeable product should be offered to complete the vaccine series.

Both 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. 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 following vaccination in adolescents and young adults (particularly among males) with Moderna compared to Pfizer-BioNTech, Ontario has issued a preferential recommendation for the use of Pfizer-BioNTech COVID-19 vaccine in those aged 5-29. Please note that the risk of myocarditis/pericarditis is unknown in children 6-11 years of age with Moderna (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 wish to receive the Moderna vaccine, it may be administered with informed consent.

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 suggests 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.

Furthermore, in certain situations: 1) third and/or booster doses for patients ≥30 years of age who are moderately to severely immunocompromised, 2) booster doses for individuals ≥70 years of age, and 3) booster doses for residents of long-term care homes, retirement homes or seniors in other congregate settings, either Moderna or Pfizer-BioNTech can be used, however consideration should be given to data that suggests that **Moderna (100 mcg) induces somewhat higher antibody levels compared to Pfizer-BioNTech (30 mcg) and protection (against infection and severe disease) from a primary series with Moderna (100 mcg) may be more durable than Pfizer (30 mcg)**. Additionally, there is limited evidence that suggests that in some individuals, a booster dose with Moderna produced higher antibody levels against the Beta variant in comparison to those who received a booster dose of Pfizer-BioNTech. For more information, consult the guidance on COVID-19 Vaccine Booster Recommendations.

Can Moderna vaccine be given with other vaccines?

For individuals 12 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, but so far, no specific safety concerns have been identified

For children 5-11 years of age, it is recommended to space out administration of a 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 swelling and tenderness (lymphadenopathy)
- Systemic: fatigue, headache, muscle pain, chills, joint pain, nausea/vomiting, fever

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 other side effects that are concerning or worsening.

Suggestions for Management of Pain/Fever

Before or at the time of vaccination:	*After vaccination:*
• 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	• 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

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Abbreviations:

mcg: micrograms; Moderna: Moderna Spikevax COVID-19 vaccine; mRNA: messenger ribonucleic acid; NACI: National Advisory Committee on Immunization; OIAC: Ontario Immunization Advisory Committee; Pfizer-BioNTech: 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. The information provided in this document is intended to assist pharmacists during discussions with patients about Moderna Spikevax COVID-19 vaccine but does not replace professional judgement and responsibilities. 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. The information provided in this document are current at the time of publication. 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.

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