



SUMMARY OF NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) STATEMENT OF MARCH 17, 2022

Recommendations on the use of Moderna
Spikevax COVID-19 vaccine in children 6 to 11
years of age



OVERVIEW

- On March 17, 2022, the Public Health Agency of Canada (PHAC) released recommendations from the National Advisory Committee on Immunization (NACI) on the use of the Moderna Spikevax (50 mcg) COVID-19 vaccine in children 6 to 11 years of age. These recommendations are based on current scientific evidence and NACI's expert opinion.
- The authorized dose of the Moderna Spikevax COVID-19 vaccine in this age group is 50 micrograms (mcg) compared to the 100 mcg primary series formulation authorized for youth and adults 12 years of age and older.
- NACI reviewed the available evidence on the use of the Moderna Spikevax (50 mcg) COVID-19 vaccine in children 6 to 11 years of age to assess benefits and potential risks, as well as ethical considerations related to COVID-19 vaccination in children.

NACI recommends that:

- **A complete series with an mRNA COVID-19 vaccine should be offered to children in the authorized age groups without contraindications to the vaccine, with a dosing interval of at least 8 weeks between the first and second dose. (Strong NACI Recommendation).**

For children 6 to 11 years of age, for whom the Moderna Spikevax (50 mcg) COVID-19 vaccine primary series is now authorized:

- **Moderna Spikevax (50 mcg dose) may be offered as an alternative to Pfizer-BioNTech Comirnaty (10 mcg dose), however the use of Pfizer-BioNTech Comirnaty (10 mcg dose) is preferred to Moderna Spikevax (50 mcg dose) to start or continue the primary vaccine series.**

For the full statement, including recommendation for those children with immune compromise, please see [NACI Recommendations on the use of Moderna Spikevax COVID-19 vaccine in children 6 to 11 years of age](#).

For more information on NACI's recommendations on the use of COVID-19 vaccines, please refer to the [COVID-19 vaccine chapter](#) in the [Canadian Immunization Guide \(CIG\)](#), as well as additional statements on the [NACI web page](#).

WHAT YOU NEED TO KNOW

- On March 17, 2022, Health Canada approved the Moderna Spikevax COVID-19 vaccine (50 mcg) for use as a primary series in children 6 to 11 years of age. The authorized dose (50 mcg) is half the dose used for the primary series for youth and adults 12 years of age and older (100 mcg).

- Over the course of the pandemic, many children have been infected with the COVID-19 virus. While COVID-19 is typically mild in children, some children do experience severe disease and require hospitalization. Following infection, children are also at risk of multi-system inflammatory syndrome in children (MIS-C) and potentially post-COVID-19 condition (i.e., long COVID).
- COVID-19 vaccines are an important tool to prevent severe COVID-19 outcomes. At least 8 weeks is recommended between doses of COVID-19 vaccines in children. As seen with adults, longer intervals between doses could provide more robust protection and improve vaccine effectiveness for children.
- When developing these recommendations, NACI reviewed clinical trial data on the safety, efficacy, and immune response generated by the Moderna Spikevax (50 mcg) COVID-19 vaccine, as well as ethical considerations on the use of this vaccine in the current context of the pandemic.
- Clinical trial data showed that Moderna Spikevax (50 mcg) had a good safety profile and had good efficacy against symptomatic COVID-19 disease (88%) in children 6 to 11 years of age. No data on the efficacy of the vaccine against the Omicron variant is available at this time, as clinical trials were conducted before the emergence of this variant.
- Any side effects were typically mild and resolved within a few days. No cases of myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the lining on the outside of the heart) or any other serious safety concerns were identified in the Moderna Spikevax COVID-19 vaccine (50 mcg) for 6 to 11 year olds trial.
- As with all vaccines, more information may also be needed to determine the rate of any rare or very rare side effects, as rare adverse events may not be detected in clinical trials this size.
- Current safety data from the United States show the risk of myocarditis and/or pericarditis following Pfizer-BioNTech (10 mcg) may be much lower in children 5 to 11 years of age compared to adolescents, who received the 30 mcg formulation.
- Pfizer-BioNTech Comirnaty is preferred to start or continue the primary vaccines series in children given the currently unknown risk of myocarditis and/or pericarditis for the Moderna Spikevax (50 mcg) in children 6 to 11 years of age, and the known higher risk of myocarditis/pericarditis for the Moderna (100 mcg) than with Pfizer-BioNTech Comirnaty (30 mcg) among individuals 12 to 29 years of age when used for the primary series.
- The Moderna Spikevax (50 mcg) COVID-19 vaccine as a 3-dose primary series may be considered for some immunocompromised children 6 to 11 years of age, with each dose provided 4 to 8 weeks apart.
- Health Canada, the Public Health Agency of Canada and NACI will continue to monitor the safety and effectiveness of Moderna Spikevax (50 mcg) COVID-19 vaccine very

closely, both in Canada and internationally, and will provide any relevant updates as data continue to emerge.

For the full statement, please see NACI Statement: [Recommendations on the use of the Moderna Spikevax COVID-19 vaccine in children 6 to 11 years of age.](#)

For more information on NACI's recommendations on the use of COVID-19 vaccines, please refer to the [COVID-19 vaccine chapter](#) in the [Canadian Immunization Guide \(CIG\)](#), as well as additional statements on the [NACI web page](#).

QUOTES

“NACI continues to recommend that children should be vaccinated for protection from COVID-19. The committee has reviewed the available evidence on the newly authorized use of the Moderna Spikevax COVID-19 vaccine in children 6 to 11 years of age. Clinical trials have shown that this vaccine has a good safety profile and has good efficacy to protect children from COVID-19. Pfizer-BioNTech Comirnaty is preferred for the primary series in children 5 to 11 years, consistent with recommendations for those who are 12 to 29 years old and based upon its safety profile, but Moderna Spikevax is an option for children 6 to 11 years old that may be used. NACI will continue to monitor the real-world use of this vaccine and provide updated recommendations as appropriate.”

- Dr. Robyn Harrison, NACI Vice-chair

“A COVID-19 vaccine primary series for children following the recommended 8 week interval between doses continues to be important as we move into the next stage of the pandemic. I am pleased to see COVID-19 vaccines being made available to different age groups, and I thank NACI for continuing to provide expert advice about which vaccine options are best suited for certain populations.”

- Dr. Theresa Tam, Chief Public Health Officer