



SUMMARY OF NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION (NACI) STATEMENT OF JULY 14, 2022

Recommendations on the use of Moderna
Spikevax COVID-19 vaccine in children 6 months
to 5 years of age



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PARTNERSHIP, INNOVATION AND ACTION IN PUBLIC HEALTH.**

— Public Health Agency of Canada

Également disponible en français sous le titre :

Résumé de la déclaration du Comité consultatif national de l'immunisation (CCNI) du 14 juillet 2022 : Recommandations sur l'utilisation du vaccin Spikevax de Moderna contre la COVID-19 chez les enfants de 6 mois à 5 ans

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Publication date: July 2022

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Cat.: HP5-139/2-2022E-PDF
ISBN: 978-0-660-44455-0
Pub.: 220313

OVERVIEW

- On July 14, 2022, the Public Health Agency of Canada (PHAC) released recommendations from the National Advisory Committee on Immunization (NACI) regarding the use of Moderna Spikevax COVID-19 vaccine in children 6 months to 5 years of age. This guidance is based on current evidence and NACI's expert opinion.
- On July 14, 2022, Health Canada authorized Moderna Spikevax (25 mcg) mRNA COVID-19 vaccine for use as a two dose primary series in children 6 months to 5 years of age. This is the first COVID-19 vaccine authorized in Canada for use in children under the age of 5.
- NACI reviewed clinical trial data on the safety, efficacy and immune response generated by Moderna Spikevax (25 mcg) COVID-19 vaccine in children 6 months to 5 years of age, as well as the spread and severity of COVID-19 in children under 5.
- **For children 6 months to 5 years of age, NACI recommends that:**
 - 1. A primary series of two doses of Moderna Spikevax (25 mcg) COVID-19 vaccine may be offered to children 6 months to 5 years of age who do not have contraindications to the vaccine, with a dosing interval of at least 8 weeks between the first and second dose. (*Discretionary NACI recommendation*)**
 - 2. A primary series of three doses of Moderna Spikevax (25 mcg) COVID-19 vaccine may be offered to children 6 months to 5 years of age who are moderately to severely immunocompromised, with an interval of 4 to 8 weeks between each dose. (*Discretionary NACI recommendation*)**
 - 3. At this time, Moderna Spikevax (25 mcg) COVID-19 vaccine should not routinely be given concurrently (i.e., same day) with other vaccines. (*Strong NACI recommendation*)**
 - As this is a newly authorized COVID-19 vaccine in this age group, NACI recommends that Moderna Spikevax (25 mcg) COVID-19 vaccine should be given 14 days before or after a different vaccine. This will help to determine if a potential side effect is due to Moderna Spikevax (25 mcg) COVID-19 vaccine or a different vaccine. A shorter interval between the administration of Moderna Spikevax (25 mcg) vaccine and a different vaccine may be warranted in some circumstances at the discretion of a health care provider.

For the full statement, including supporting evidence and rationale, please see [NACI Statement: Recommendations on the use of Moderna Spikevax COVID-19 vaccine in children 6 months to 5 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 July 14, 2022, Health Canada authorized Moderna Spikevax (25 mcg) COVID-19 vaccine as a two dose primary series for children 6 months to 5 years of age. The dose for this age group (25 mcg) is half the dosage of Moderna Spikevax (50 mcg) COVID-19 vaccine offered to children 6 to 11 years of age. This is the first COVID-19 vaccine authorized in Canada for use in children under the age of 5.
- When developing these recommendations, NACI reviewed clinical trial data on the safety, efficacy and immune response generated by Moderna Spikevax (25 mcg) COVID-19 vaccine in children 6 months to 5 years of age, as well as the spread and severity of COVID-19 in children under the age of 5.
- Most children who get COVID-19 have mild or asymptomatic disease; however, some children experience severe disease and require hospitalization.
- Children who have had COVID-19 are at risk of experiencing multisystem inflammatory syndrome in children (MIS-C), a rare but serious complication from COVID-19 that usually requires hospitalization.
- Children who have an underlying medical condition are at higher risk of severe outcomes from COVID-19, but severe disease and MIS-C can occur in any child, even those without an underlying condition.
- Studies from British Columbia and Quebec suggest that many children under the age of 5 have had COVID-19, with the majority of infections having occurred since Omicron became the dominant variant. It is not clear if these studies are generalizable to other parts of Canada.
- Previous SARS-CoV-2 infection provides some protection but studies in adults show that vaccination following infection provides stronger and longer-lasting protection.
- The clinical trial evaluating Moderna Spikevax (25 mcg) COVID-19 vaccine in children 6 months to 5 years of age took place in Canada and the United States when Omicron was the dominant variant.
- Clinical trial findings show that a Moderna Spikevax 25 mcg dose primary series produces an immune response in children under 5 years of age equivalent to the immune response seen in young adults 18 to 25 years of age who receive the 100 mcg dose primary series.
- Preliminary efficacy of the vaccine in preventing symptomatic COVID-19 when Omicron is the dominant variant is estimated at 50.6% in children 6 to 23 months of age and 36.8% in children 2 to 5 years of age starting 14 days after the second dose.

- There were no deaths or cases of severe COVID-19 or MIS-C among trial participants that received Moderna Spikevax (25 mcg) COVID-19 vaccine. As such, it was not possible to evaluate efficacy against severe COVID-19 or MIS-C.
- Real world evidence shows that in older age groups, mRNA COVID-19 vaccines are highly effective at preventing severe COVID-19 outcomes. Efficacy estimates of Moderna Spikevax (25 mcg) vaccine against symptomatic disease during the Omicron wave in children aged 6 months to 5 years are consistent with efficacy of Pfizer-BioNTech Comirnaty (10 mcg) vaccine among children 5 to 11 years of age during the Omicron wave. mRNA vaccines are also highly effective at preventing hospitalization due to MIS-C in adolescents.
- Clinical trial data show that Moderna Spikevax (25 mcg) COVID-19 vaccine was well tolerated in children 6 months to 5 years of age. No safety signals were reported in the trial. It is important to note that due to the size of the trial, it is unlikely that adverse events that occur at a frequency less often than 6 in 10,000 people would be detected. NACI, Health Canada and PHAC will continue to closely monitor real world data from the use of this vaccine for potential rare and very rare side effects.
- For children who have already had COVID-19, NACI suggests waiting 8 weeks after the start of COVID-19 symptoms or a positive COVID-19 test before beginning or continuing the primary series. This interval may be shortened to 4 weeks for children who are moderately to severely immunocompromised.
- Both Moderna Spikevax (25 mcg) COVID-19 vaccine and Pfizer-BioNTech Comirnaty COVID-19 vaccine (10 mcg) are authorized for children who are 5 years of age. Please see the [full statement](#) and the [COVID-19 vaccine chapter in the Canadian Immunization Guide](#) for guidance on vaccines that are recommended for children who are 5 years of age and for children who turn 6 after the first dose of their primary series.
- NACI will continue to monitor the safety and effectiveness of Moderna Spikevax (25 mcg) COVID-19 vaccine in children 6 months to 5 years of age and will update guidance as needed.

For the full statement, including supporting evidence and rationale, please see [NACI Statement: Recommendations on the use of Moderna Spikevax COVID-19 vaccine in children 6 months to 5 years of age](#).

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QUOTES

“NACI is further expanding COVID-19 vaccine recommendations to include children six months to 5 years of age. While most children in this age group have relatively mild disease, some do experience severe illness, especially those with underlying medical conditions. NACI has carefully reviewed the available evidence, and recommends that vaccine may be offered to these young children using a similar approach as older age groups in terms of interval between doses, or interval between infection and doses. We expect that these recommendations will come as a relief to many parents who have been waiting for these vaccines to become available to protect their youngest children.

- Dr. Shelley Deeks, NACI Chair

“I welcome this advice from NACI on the use of the Moderna Spikevax COVID-19 vaccine for children aged 6 months to 5 years. Most children who are infected with the SARS-CoV-2 virus that causes COVID-19 have mild or no symptoms of the illness. However, some children experience severe COVID-19 disease and require hospitalization. Children who get COVID-19 can also develop a rare but serious condition called multisystem inflammatory syndrome in children (MIS-C) and while evidence in this age group is limited, may be at risk of post-COVID-19 condition (also known as long COVID). The availability of the Moderna Spikevax COVID-19 vaccine for children aged 6 months to 5 years provides families with a vaccine option to help protect their young children from COVID-19. It is very important that all children and their caregivers are supported during the decision-making process and that their decisions related to COVID-19 vaccination are respected. Health Canada, the Public Health Agency of Canada and the National Advisory Committee on Immunization will closely monitor the domestic and international rollout of the vaccine in young children.”

- Dr. Theresa Tam, Chief Public Health Officer