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## COVID-19 Vaccine: Update #56

### Moderna Vaccine Approved for Children 6 Months to Under 5 Years

**Attention:** Physicians, Emergency Departments, Hospital CEOs, Hospital Laboratories, Infection Control Practitioners, Occupational Health Practitioners, Walk-In Clinics/Urgent Care Clinics, Nurse and Nurse Practitioners, EMS, Designated Officers, Midwives, Family Health Teams, Pharmacies, Central LHIN, NSM LHIN, Beausoleil First Nation, Moose Deer Point First Nation, Rama First Nation, Wahta First Nation, Long-term Care Homes, Retirement Homes, Hospices, Coroners, Funeral Directors, Dentists, Group Homes, Homes for Special Care, Optometrists, Corrections, Municipalities, Licensed Child Care Providers

**Date:** July 26, 2022

Health Canada approved the Moderna Spikevax (25 mcg) vaccine for children 6 months to under 5 years of age on July 14, 2022. According to the National Advisory Committee on Immunization (NACI):

- The Moderna Spikevax COVID-19 vaccine (25 mcg) **may be offered** to children 6 months to under 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).
- Children 6 months to under 5 years of age who are moderately to severely immunocompromised **may be immunized** with a primary series of three doses of the Moderna Spikevax (25 mcg) vaccine, using an interval of 4 to 8 weeks between each dose. (Discretionary NACI recommendation).

Eligibility	Dosage (mL)	Immunization Schedule	Health Canada Authorized Interval	Recommended Interval
<b>6 months to under 5 years</b>	0.25 mL  25 mcg of 0.10 mg/mL formulation	2 doses	28 days	At least 8 weeks after 1 <sup>st</sup> dose  (56 days)

Note: Children who have had their 5<sup>th</sup> birthday should be offered pediatric Pfizer-BioNTech COVID-19 vaccine.

Pfizer-BioNTech has submitted to Health Canada for approval for their product to be authorized for children 6 months through 4 years of age. This review is expected to be completed by September.

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NACI recommends at this time that the Moderna Spikevax (25 mcg) COVID-19 vaccine primary series for children 6 months to under 5 years of age should not routinely be given concurrently (i.e. same day) with other vaccines (live or non-live). As this is a newly authorized vaccine in this age group, evidence relating to any risk of rare or very rare adverse event following immunization (AEFI)s will be monitored. It is advised to wait 14 days between vaccine products when administering the Moderna Spikevax (25 mcg) COVID-19 vaccine and other vaccines. This could prevent erroneous attribution of an AEFI to one vaccine or the other.

	<b>Moderna Spikevax</b>
<b>Age</b>	6 months to 5 years
<b>Dose</b>	25 mcg (0.25 mL)
<b>Presentation</b>	0.10 mg/mL Royal blue vial cap
<b>Diluent</b>	None
<b>Potential allergens</b>	Polyethylene glycol (PEG), Tromethamine (trometamol or Tris) <sup>a</sup>
<b>Storage<sup>b,c</sup></b>	<ul style="list-style-type: none"> <li>• Store at temperatures of -50°C to -15°C and protect from light in original packaging</li> <li>• Vials can be thawed and stored at +2°C to +8°C for up to 30 days, or at +8°C to +25°C for up to 24 hours if unpunctured</li> <li>• Do not refreeze once thawed</li> </ul>
<b>Transport<sup>c</sup></b>	If transport at -50° to -15°C is not feasible, thawed vials in a liquid state may be transported at +2°C to +8°C for up to 12 hours.

<sup>a</sup> Tromethamine (Tris or trometamol) is used as a buffer in vaccines and medications, including those for use in children, to improve stability and prevent pH fluctuations in the solution. No safety concerns have been identified with tromethamine. While tromethamine has been identified as a potential allergen, a review of existing evidence did not identify any cases of allergic reactions to tromethamine in children (27)

<sup>b</sup> Regardless of storage condition, vaccines should not be used after date of expiry printed on the vial and cartons.

<sup>c</sup> Frozen is -25°C to -15°C; Refrigerated is +2°C to +8°C; Room temperature is +15°C to +25°C.

Our [COVID-19 Vaccine Order Form](#) has been updated to include this vaccine. The vaccine comes in a 10-dose vial, no mixing is required.

As NACI, the majority of children with COVID-19 have mild or asymptomatic disease; however, some children get severe disease and require hospitalization. Population level estimates of hospitalization and ICU admission in pediatric populations have increased since Omicron became the predominant variant. For children 6 months to under 5 years of age (the age group previously ineligible for COVID-19 immunization),

the average monthly rate of hospitalization due to COVID-19 increased from 1.4 to 15.9 per 100,000, comparing March 1, 2020 - December 31, 2021 to January 1, 2022 – March 31, 2022. Children who are considered medically fragile or have an underlying condition are at higher risk of severe outcomes of COVID-19.

Children who have had COVID-19 are at risk of multisystem inflammatory syndrome in children (MIS-C), a rare but serious post-infection complication that generally requires acute care hospital admission. Out of 419 nationally reported cases of MIS-C in Canada, no deaths have been reported to date. MIS-C associated deaths have been reported in the United States; however, the generalizability of this data to the Canadian healthcare system is unknown.

Efficacy against confirmed symptomatic SARS-CoV-2 infection starting 14 days after dose 2 was estimated at 50.6% among study participants aged 6 to 23 months and 36.8% among participants aged 2 to 5 years.

Overall, the safety profile of Moderna Spikevax (25 mcg) vaccine was consistent with the known safety and reactogenicity profile of the 50 mcg and 100 mcg Spikevax formulations authorized for use in older age groups. Events reported in the vaccine group were consistent with events commonly reported for other pediatric vaccines authorized for use in children 6 months to 5 years of age.

#### **Additional COVID-19 Vaccine Information**

For more information about the rollout of COVID-19 vaccine in our area, please refer to the SMDHU [COVID-19 Vaccine and Immunization](#) webpages.

There are a number of COVID-19 resources and documents available through our Health Professional Portal at [www.smdhu.org/hpportal](http://www.smdhu.org/hpportal) as well as through [Public Health Ontario](#) and the [Government of Ontario](#).