Moderna Spikevax COVID-19 vaccination for children under five: Summary for Health Care Providers

Last updated August 16, 2022

On July 14, 2022 Health Canada authorized the Moderna COVID-19 vaccine for children six months to under five years of age. Ontario launched vaccination for this age group on July 28, 2022.

The dose for children under five receiving Moderna is lower than other ages

- A two-dose primary series of 25 micrograms each, with the second dose to be administered eight weeks after the first dose is recommended.
- Children six months to five years of age receive quarter the dose of Moderna authorized for people over 12 years of age (100 micrograms).
- Children with underlying medical conditions are strongly encouraged to complete the entire series. If a child is immunocompromised, a three dose primary series should be completed.

Children who turn five are advised to receive the same mRNA COVID-19 vaccine they got for their first dose, but may receive the other to avoid delay.

- Children under five who receive Moderna for their first dose and **turn five** before to completing their primary series are recommended to receive Moderna to complete their primary series.
- If the same vaccine product is not readily available, another age-appropriate mRNA vaccine product may be given and series considered complete.
- More information can be found on the Ministry of Health's guidance (see Chapter 2: Moderna COVID-19 Vaccine)

The COVID-19 vaccine for children under five is effective and protects against severe outcomes

- Vaccination is one of the most effective ways to protect children, families, and communities against COVID-19.
- Evidence indicates that the vaccines used in Canada are very effective at preventing severe illness, hospitalization and death from COVID-19.
- Studies show that the immune response from the COVID-19 vaccine for children 6 months to 5 years of age was comparable to that seen in people 18 to 25 years of age. This efficacy was assessed when Omicron was the predominant variant of COVID-19 circulating in the U.S. and Canada.
- The clinical trial that Health Canada based their regulatory decision on included thousands of participants aged six months to five years of age (see table 1)

Cohort	One dose		Two doses	
	Moderna	Placebo	Moderna	Placebo
6 months to < 2 years	1,760	590	1,574	530
2 years to 5 years	3,031	1,007	2,960	970

Table 1. Number of participants involved in the clinical trial by cohort (age) and doses.

- The results of the clinical trial showed that the immune response to Moderna in children six months to five years of age and (two doses; 25 mcg each dose) was comparable to that seen in subjects 18 to 25 years of age (two doses; 100 mcg each dose). Therefore, the benefit-risk profile of Moderna is considered favourable for use as a two dose series (25 mcg each dose) in children six months to five years of age, especially in children at higher risk of severe COVID-19.
- The clinical trial showed the vaccine efficacy for preventing symptomatic COVID-19 14 days or more after the second dose was 50.6% for children six months to less than two years of age and 36.8% for children two to five years of age.
- These results were also consistent with vaccine efficacy estimates observed in adults during the period when the B.1.1.529 (Omicron) variant was the predominant variant in circulation.

The COVID-19 vaccine for children under five is safe with mild to moderate adverse reactions resolving within a few days

- A thorough independent scientific review of the evidence was completed and Health Canada determined that the benefits of this vaccine for children between six months and five years of age outweigh the potential risks.
- The clinical trial showed that the vaccine was well tolerated and no safety signals were identified from the trial.
- For the clinical trial participants the most frequently reported adverse reactions were:

Common adverse reactions	6 months to < 2 years	2 years to 5 years
irritability or crying	64.3%	54.3%
pain at the injection site	46.2%	71.4%
sleepiness	35.1%	36.0%
loss of appetite	32.1%	30.5%

- Other less common reactions included:
  - fever;
  - redness and swelling at the injection site;
  - nausea or vomiting;
  - swollen or tender lymph nodes under the arm;
  - headaches (in older children); and
  - muscle and/or joint aches.

- The adverse reactions were usually mild or moderate resolving within a few days of vaccination.

- There were no deaths, and no cases of myocarditis or pericarditis reported during the study period.

- Three cases of anaphylaxis were documented, all occurring more than 14 days after vaccination, and were attributed to causes unrelated to the vaccine including concurrent medication and food allergies.

- Health Canada has terms and conditions that require Moderna to continue providing information to Health Canada on the safety and efficacy of the vaccine in this younger age group. This additional data from ongoing studies and real-world use will inform us if the benefits of the vaccine continue to outweigh any risks, as well as detect any potential new safety signals in any age group.

The risk of myocarditis and pericarditis for children 6 months to 5 years is expected to be low.

- During clinical trials of the paediatric Moderna vaccine, no participants reported myocarditis and pericarditis.
- As real-world evidence on the use of this vaccine in this age group is not yet available, the risk of myocarditis and pericarditis is unknown, but expected to be very rare.

Vaccination after infection is safe and recommended for better protection from COVID-19

- Public Health Agency of Canada (PHAC) and the National Advisory Committee on Immunization (NACI) recommend that individuals with previous infection should get all recommended doses of COVID-19 vaccine to protect from the severe outcomes of the virus.
- While infection alone provides some protection, vaccination after infection helps improve the immune response and may provide better and longer-lasting protection against COVID-19 and its variants.
- It is safe to get the COVID-19 vaccine if you have previously been infected by COVID-19.
- NACI recommends that most children wait eight weeks after a COVID-19 infection before getting their COID-19 vaccine. The eight weeks should be counted from the day symptoms began or the day of the first positive test. Waiting may give children better long-term protection, as this allows time for the immune response to mature in breadth and strength and for circulating antibodies to decrease, thus avoiding immune interference when the vaccine is administered.

- Children who are moderately to severely immunocompromised, and with no previous history of multisystem inflammatory syndrome (MIS-C) should receive the vaccine dose four to eight weeks after a COVID-19 infection.
- Children with a history of MIS-C should wait at least 90 days to be vaccinated.

Children under five experienced hospitalizations more than other people under 20

- Over 1,000 children under five in Ontario have been hospitalized from COVID-19
- Children under five have the highest number of hospitalizations among youth due to COVID-19 infection (see table below using Public Health Ontario data)

Age	Hospitalizations in Ontario as of July 2, 2022
0-4	1,068
5-11	258
12-19	472
Total	**1,798**

Additional Resources

- Halton Region, COVID-19 vaccines for children
- Health Canada, Vaccines for children: COVID-19
- Science Up First, Don’t give up! - ScienceUpFirst
- SickKids, Frequently Asked Questions
- University of Waterloo, What are the reasons to vaccinate my young child against COVID-19?
- University of Waterloo, Timing of COVID-19 vaccines for young children (Aged 6 months and older)
- Ministry of Health, COVID-19 Vaccine Administration