

# INFORMATION

## Moderna Spikevax™ COVID-19 Vaccine

**Pediatric (6 months - 5 years)** Rev. April 24, 2023

**Please read this information sheet carefully and ensure all your questions have been answered by a health care provider before receiving the vaccine.**

**COVID-19** is an infectious disease caused by a coronavirus (SARS-CoV-2). The virus that causes COVID-19 is mainly passed from an infected person to others when the infected person coughs, sneezes, sings, talks or breathes. It is important to note that infected people can spread the infection even if they have no symptoms.

Symptoms of COVID-19 can include cough, shortness of breath, fever, chills, tiredness and loss of smell or taste. Some people infected with the virus have no symptoms at all, while others have symptoms that range from mild to severe.

People who were diagnosed with COVID-19 after completing their primary vaccine series were significantly less likely to be hospitalized or to die, particularly if they received an additional dose(s) when eligible.

### How does this vaccine protect against COVID-19?

- The vaccine causes the body to produce protection (**antibodies**) to help keep us from becoming sick if we are exposed to the COVID-19 virus. The vaccine uses messenger RNA (mRNA) to help the body make protection against the virus.
- In studies where young children were given 2 doses of the vaccine, the vaccine was shown to work well at preventing them from becoming sick with COVID-19. The immunized group of children was much less likely to become sick with COVID-19 in the weeks after vaccination (51% less likely for age 6 to 23 months and 37% less likely for age 2 to 5 years) compared to the group that did not receive the vaccine.

### Who can receive this COVID-19 vaccine?

- This vaccine is authorized for use in children age 6 months to 5 years.

### Who should not have this COVID-19 vaccine?

Do not attend a public immunization clinic if your child has any new or worsening respiratory symptoms (fever, cough, sore throat, runny nose).

Check with a healthcare provider or a public health nurse before getting this vaccine if your child:

- has an allergy to any of the vaccine ingredients
- has had a severe or unusual side effect after this vaccine or one like it
- is younger than 6 months of age or older than 5 years
- has received a monoclonal antibody or convalescent plasma for treatment or prevention of COVID-19
- has any symptoms that could be due to COVID-19. In this case, your child should not go out to get vaccinated because they

could spread the infection to others. Talk with their healthcare provider, or call 811, about their symptoms and getting a COVID-19 test. Their healthcare provider will advise when they are able to receive the vaccine.

- has a history of myocarditis (inflammation of the heart) or pericarditis (inflammation of the outer lining of the heart) after a previous mRNA vaccine dose.

Contact a health care provider to determine the optimal time to receive the COVID-19 vaccine if your child:

- is receiving treatment with immunosuppressive medications, or
- has an autoimmune disease that affects the neurological system.

Always tell a healthcare provider if your child has allergies or if they have had a side effect from a vaccine, medication or other product in the past.

### How is the vaccine administered?

- Depending on the child’s age, the vaccine is given as a needle in the muscle of the upper arm or outer thigh.

### What are common reactions to this vaccine?

- Side effects can develop up to 3 days after receiving the vaccine. Although these side effects are not serious to your child’s health, they may make them feel unwell for a day or two.
- These side effects are expected and can indicate the vaccine is working to produce protection. In the study, side effects included:

» pain, redness, swelling where the needle was given	» joint pain
» enlarged lymph nodes in the underarm or groin	» loss of appetite
» muscle aches/stiffness	» fever, chills
» nausea/vomiting	» tiredness
	» headache
	» irritability/crying

- There have been reports of myocarditis and/or pericarditis in those aged 12 years and older after immunization with mRNA COVID-19 vaccines. Cases of myocarditis and/or pericarditis occur more often in adolescents and adults 12 to 29 years of age, more often in males than in females, and more often after a second dose of an mRNA vaccine than after a first dose. In the Moderna clinical trials for age 6 months to 5 years no cases of myocarditis and/or pericarditis were identified.

- Very rare reports of Bell’s palsy (weakness or paralysis on 1 side of the face that is often temporary) following

immunization have been reported in a small number of older individuals in Canada and internationally. Symptoms usually resolve within a month.

- Rarely allergic reactions can occur after receiving a vaccine. Symptoms of an allergic reaction include hives (bumps on the skin that are often very itchy), swelling of the face, tongue or throat, or difficulty breathing. The clinic staff are prepared to manage an allergic reaction should it occur. Seek immediate medical care if your child develops any of these symptoms.
- It is important to note that your child **cannot get COVID-19 infection from the vaccine.**
- **If you have any concerns about the symptoms your child develops after receiving the vaccine, call 811. If your child received a vaccination from a pharmacist, please consult them first when possible.**

For more information please speak with the person providing the vaccine or contact your local public health office, your physician, nurse practitioner, or by calling 811.

### What measures have been put in place to safely provide immunizations during COVID-19?

Health care providers are being very careful to prevent the spread of COVID-19 when offering immunizations. Examples of extra safety measures include the following:

- You will be asked about any COVID-19 symptoms your child has upon arrival at the clinic. People with symptoms of COVID-19 should not attend the clinic.
- You and your child may be asked to wear a mask while at the clinic, as well as to clean your hands, and to stay at least 2 metres (6 feet) from others (except those you live with).
- The staff may also be wearing personal protective equipment and will be cleaning their hands before and after each client.
- Other measures may also be put in place in clinics. Be sure to read and follow any signs or instructions provided.

### What should you do after receiving the vaccine?

- Your child will need to **wait at least 15 minutes after receiving the vaccine** to be sure they are feeling well. Longer waiting times of 30 minutes may be recommended if there is concern about a possible vaccine allergy. Your child may be asked by the health care provider to wait with you in the clinic, or if you have a warm, dry place to wait (such as in a vehicle), you may be asked to wait outside of the clinic. Inform a health care provider right away if your child feels unwell while waiting. They should not leave the clinic (or clinic parking lot) for at least 15 to 30 minutes after receiving the vaccine, based on the recommendation of the health

care provider.

- **Upon leaving the clinic, call 9-1-1 right away if your child develops any serious symptoms or symptoms of an allergic reaction** such as hives (bumps on the skin that are often very itchy), swelling of the face, tongue or throat, or difficulty breathing.
- Continue to follow the recommendations of local public health officials to prevent spread of COVID-19, which may include wearing a mask, staying at least 2 metres from others and limiting/avoiding contact with others outside your household.

### When should my child return for their next dose?

- Evidence shows that an 8-week interval is optimal between doses of a primary series. This is very important to ensure the vaccine works well.
- The minimum interval of 28 days maybe provided if people choose the shorter interval for their child and vaccine supply is available.
- Ask your healthcare provider or visit <https://www.saskatchewan.ca/covid19-vaccine> for booster dose information. After the last dose in a primary series, it is recommended that people aged 5 years and older return for a booster dose after 6 months. This is very important to ensure the vaccine continues to work well.
- Your child is considered up-to-date on their vaccinations if they have received the last dose they are eligible for.

### What does Moderna Spikevax® vaccine contain?

- Medicinal ingredient: mRNA-1273 SARS-CoV-2. Non-medicinal ingredients: Acetic acid, cholesterol, DSPC (1,2-distearoyl-sn-glycero-3-phosphocholine), lipid SM-102, PEG2000-DMG (1,2-dimyristoyl-racglycerol, methoxy-polyethyleneglycol), sodium acetate trihydrate, sucrose, trometamol, trometamol hydrochloride, water for injection.



To ensure that a complete immunization record is maintained, immunizations will be documented into the electronic provincial immunization registry, known as Panorama. These immunization records may also be shared with health care professionals in order to provide public health services; assist with diagnosis and treatment; and to control the spread of vaccine preventable diseases. Panorama is a secure electronic system used in Saskatchewan to record and manage immunization records and the health information related to immunization for all Saskatchewan residents.