

INFORMATION Moderna Spikevax™ XBB.1.5 COVID-19 Vaccine

Read this information carefully and ensure your questions have been answered by a health care provider before receiving the vaccine. A parent/guardian must be present for the immunization of children 11 years old and younger.

- COVID-19 is an infectious disease caused by a coronavirus (SARS-CoV-2). The virus is mainly passed from an infected person to others when the infected person coughs, sneezes, sings, talks or breathes.
- 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.

How does this vaccine protect against COVID-19?

- The vaccine causes our bodies to produce protection (antibodies) to help keep us from becoming sick if we are exposed to a COVID-19 virus. The vaccine uses messenger RNA (mRNA) to help our bodies make protection against the virus, which help keep us from becoming seriously ill if we are exposed to a COVID-19 virus.
- As with any vaccine, this vaccine may not fully protect all those who receive it, especially for immunocompromised individuals and it is not known how long you / your child will be protected.
- It is important to know that **you / your child cannot get COVID-19 infection from the vaccine.**

Who can receive this COVID-19 vaccine?

- **For those five years and older**, even if they have not received a COVID-19 vaccine dose in the past, one dose is recommended six months after a previous dose.
- **For children six months to four years who have never received a COVID-19 vaccine dose**, two doses, given 4-8 weeks apart, are recommended. The longer interval is ideal for best protection.
- **For children six months to four years who have received at least one COVID-19 vaccine dose in the past**, the recommended number of doses and space between each dose depends on their vaccination history.
- Immune compromised individuals may require additional doses.

Who should not have this COVID-19 vaccine?

- Children younger than six months of age.
- **Do not attend a public immunization clinic** if you/your child have any new or worsening respiratory symptoms (fever, cough, sore throat, runny nose).
- **Check with your healthcare provider or a public health nurse before you get this vaccine if you/your child:**
 - has an allergy to any of the vaccine ingredients;
 - had a severe or unusual side effect after a COVID-19 or other vaccine;
 - received the smallpox/mpox vaccine in the past four weeks or plan to get it in the next four weeks;
 - have 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 your health care provider to determine the optimal time to receive the COVID-19 vaccine if you/your child are receiving treatment with immunosuppressive medications or have an autoimmune disease that affects the neurological system.
- Stem cell transplant recipients **must consult** their healthcare provider prior to getting immunized.
- Always tell your healthcare provider if you/your child have allergies or have had a side effect from a vaccine, medication or other product in the past.

How is the vaccine administered?

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

What are possible reactions to this vaccine?

- Side effects can develop up to three days after receiving the vaccine. Although these side effects are not serious to your/your child's health, they may make you/your child feel unwell for 1-2 days. These side effects are expected and can indicate the vaccine is working to produce protection. Expected side effects include:

» pain, redness or swelling where the needle was given (resolves in up to 7-10 days)	» nausea/vomiting
» swollen and tender lymph nodes in the underarm	» headache
» muscle aches/stiffness	» fever, chills, rash
	» tiredness
	» joint pain

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- Very rare cases of myocarditis (inflammation of the heart) and/or pericarditis (inflammation of the outer lining of the heart) following immunization with older COVID-19 vaccines were reported.

Use Acetaminophen (all ages; Tylenol®, Tempra®) or Ibuprofen (6 months & older; Advil®, Motrin®) to treat fevers and pain. Never give ASA (Aspirin®) to children younger than 18 years old because of the serious risk of Reye's syndrome.

- A skin condition called erythema multiforme is an allergic reaction that can occur following immunization with mRNA COVID-19 vaccines. Symptoms are round red, raised areas on the skin that can appear all over the body, and on the fingers and toes. These patches often look like “targets” (dark circles with purple-grey centers). The skin condition may reoccur and usually lasts for 2-4 weeks each time.
- Very rare reports of Bell's palsy (weakness or paralysis on one side of the face that is often temporary) following immunization have been reported. 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 you/your child develop any of these symptoms.
- It is important to note that you/your child cannot get COVID-19 infection from the vaccine.
- If you have any concerns about the symptoms you/your child develop after receiving the vaccine, call HealthLine 811. If you/your child (age 5-17 years old) received your 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 HealthLine 811.

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

- You/your child may be asked about any COVID-19 symptoms when you/ your child arrive at the clinic. People with symptoms of COVID-19 should not attend the clinic.

What should you/your child do after receiving the vaccine?

- It is important to stay in the clinic for 15 minutes after getting any vaccine because there is an extremely rare possibility of a life-threatening allergic reaction called anaphylaxis. This may include hives, difficulty breathing, or swelling of the throat, tongue or lips. This reaction can be treated, and occurs in less than one in one million people who get the vaccine. **If this happens after you leave the clinic, get medical attention or call 911 right away.**

Who needs another vaccine dose?

- Children six months to four years old may require additional doses depending on their vaccination history.
- Immune compromised individuals may require additional doses.

Mature Minor Consent

- It is recommended that parents/guardians discuss consent for immunization with their children. Efforts are first made to get parental/guardian consent for immunizations. However, children at least 13 years of age up to and including 17 years of age, who are able to understand the benefits and possible reactions for each vaccine and the risks of not getting immunized, can legally consent to or refuse immunizations in Saskatchewan by providing mature minor informed consent to a healthcare provider.

What does this vaccine contain?

Medicinal ingredients: Andusomeran (mRNA) encoding the pre-fusion stabilized conformation variant (K982P and V983P) of the SARS-CoV-2 Spike glycoprotein (Omicron subvariant XBB.1.5), acetic acid, cholesterol, DSPC (1,2-distearyl-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.