INFORMATION Novavax Nuvaxovid® XBB.1.5 COVID-19 Vaccine

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 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 Novavax vaccine is a protein-based vaccine. It contains the spike protein that is on the surface of the coronavirus, and an adjuvant called Matrix-M, which helps create a strong immune response.
- Our body recognizes the spike protein as a threat and produces antibodies, 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. It is not known how long your child will be protected against severe illness or hospitalization.
- It is important to know that **you cannot get COVID-19 infection from the vaccine.**

Who can receive Nuvaxovid XBB.1.5 COVID-19 vaccine?

- Nuvaxovid XBB.1.5 vaccine can be used in individuals 12 years and older who do not have contraindications to the vaccine.
- **For those who have never received a COVID-19 vaccination,** one dose is acceptable; however two doses given eight weeks apart are recommended. The second dose may be given three weeks (21 days) after the first dose.
- **For those who have previously received a COVID-19 vaccination**, one dose is recommended, given at least six months after their last dose.
- Immunocompromised individuals may require additional doses.
- Novavax Nuvaxovid has been used less than other COVID-19 vaccines to date, so there is less information available about this vaccine compared to Pfizer or Moderna COVID-19 vaccines, particularly for those who are pregnant. More evidence on the use of Novavax Nuvaxovid in pregnant individuals is expected to increase over time.
- There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Nuvaxovid during pregnancy. Women who are vaccinated with Nuvaxovid during pregnancy are encouraged to enroll in the registry by visiting **c-viper.pregistry.com**

Who should not have this vaccine?

- Children younger than 12 years 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:
  - have an allergy to any of the vaccine ingredients.
  - had a severe or unusual side effect after a COVID-19 vaccine or other vaccine.
  - have a history of myocarditis (inflammation of the heart) or pericarditis (inflammation of the outer lining of the heart) after a previous COVID-19 vaccine dose.
- Contact your health care provider to determine the optimal time to receive the COVID-19 vaccine if you/ your child is receiving treatment with immunosuppressive medications or has 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 your you/ your child have allergies or has had a side effect from a vaccine, medication or other product in the past.

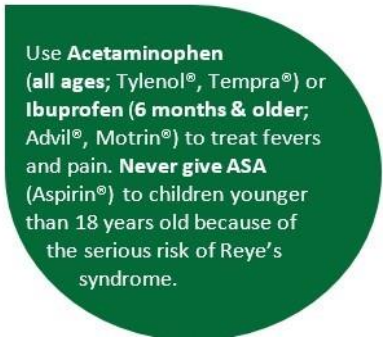
How is the vaccine administered?

The vaccine is given as a needle in the upper arm muscle.

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 health, they may make you feel unwell for 1 to 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
- headache, tiredness
- muscle pain, stiffness
- joint pain
- nausea, vomiting
- fever, chills
- tingling in body or face



- Available data suggests that the course of myocarditis and pericarditis following vaccination with the original Nuvaxovid vaccine is not different from myocarditis and pericarditis in general. Available data cannot determine a causal association with Nuvaxovid XBB.1.5.
- 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 develop any of these symptoms.
- It is important to know that you cannot get COVID-19 infection from the vaccine.
- For more information 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?

- You/ your child may be asked about any COVID-19 symptoms upon arrival 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.**

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: Purified SARS-CoV-2 XBB.1.5 recombinant spike protein as the active substance.
Non-medicinal ingredients: disodium hydrogen phosphate heptahydrate, sodium dihydrogen phosphate monohydrate, sodium chloride, polysorbate 80, sodium hydroxide, hydrochloric acid, water for injection. The Matrix-M adjuvant (Quillaja saponaria saponins fraction-A and fraction-C) contains cholesterol, phosphatidylcholine, potassium dihydrogen phosphate, disodium hydrogen phosphate dihydrate, sodium chloride and potassium chloride.

To ensure that a complete immunization record is maintained, immunizations will be documented into Panorama, the electronic provincial immunization registry. 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.

APRIL 2024