INFORMATION

Novavax Nuvaxovid® COVID-19 Vaccine 12+ Years   Rev. March 28, 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 commpleting their primary vaccine series were significantly less likley to be hospitalized or die, particularly if they received an additional dose(s).

How does this vaccine protect against COVID-19?

- 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 the COVID-19 virus.
- Clinical trials showed that beginning 7 days after the second dose, the Novavax vaccine lowered the chance of getting sick by 90%, including helping to prevent people from getting seriously ill.

Who can receive Novavax COVID-19 vaccine?

- Individuals 12 years and older.

Who should not have this COVID-19 vaccine?

- Do not attend a public immunization clinic if you 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 this vaccine or one like it
- have received a monoclonal antibody or convalescent plasma for treatment or prevention of COVID-19
- If you have any symptoms that could be due to COVID-19, you should not go out to get vaccinated because you could spread the infection to others. Talk with your health care provider, or call 811, about your symptoms and getting a COVID-19 test. Your health care provider will advise you when you are able to receive the vaccine.

- If you 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.
- If you belong to one of the following groups, it is preferred you contact your health care provider prior to receiving:
  - » You are receiving treatment with immunosuppressive medications to determine the optimal time to receive the COVID-19 vaccine.
  - » All those with an autoimmune disease that affects the neurological system.
- The safety and efficacy of this vaccine have not been established in the following populations; however with informed consent the vaccine can be given to:
  - » Individuals previously infected with COVID-19.
  - » Individuals who are immunocompromised due to disease or treatment.
  - » Individuals who are pregnant or breastfeeding. 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 https://c-viper.pregistry.com/.
  - » Individuals who have an autoimmune condition.

Always tell your healthcare provider if you have allergies or if you 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. This COVID-19 vaccine can be given at the same time as other non-COVID-19 vaccines.

What are common reactions to this vaccine?

- Side effects can occur within a few days of receiving the vaccine. Although these side effects are not serious to your health, they may make you feel unwell for a day or two, and will go away on their own. These types of side effects are expected and indicate the vaccine is working to produce protection. Side effects can include:

» pain, redness or swelling where the needle was given	
» headache	» nausea and vomiting
» muscle pain, stiffness	» fever, chills
» joint pain	» tiredness

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- Myocarditis and pericarditis have been reported following NUVAXOVID administration. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis and pericarditis in general. Available data cannot determine a causal association with NUVAXOVID.

- Numbness and/or tingling in the body or face have been reported following immunization with this vaccine.

- 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 your 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 note that you **cannot get COVID-19 infection from the vaccine.**

- **If you have any concerns about the symptoms you develop after receiving the vaccine, call 811. If you 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 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 when you arrive at the clinic. People with symptoms of COVID-19 should not attend the clinic.

- You will 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 will 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?

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

Once you leave the clinic, call 9-1-1 right away if you develop any serious symptoms or symptoms of an allergic reaction such as hives (bumps on the skin that are often very itchy), swelling of your 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.

- **Keep your immunization record with information about the COVID-19 vaccine in a safe place.**

When should I return for my next vaccine dose?

- Evidence shows that an 8 week interval is optimal between first and second doses to complete a primary series. 28 days is the minimum recommended interval in Saskatchewan but an interval of 21 days may be provided if people choose the shorter interval.

- mRNA bivalent vaccine is the preferred vaccine for a booster. However, for those who are not able or willing to receive an mRNA COVID-19 vaccine as a booster dose, Novavax's Nuvaxovid may be offered to those without contraindications to the vaccine.

- You /your childe are/is considered up-to-date on your/their vaccinations if you/they have received the last dose you/they are eligible for.

- Please ask your healthcare provider for more information or visit https://www.saskatchewan.ca/covid19-vaccine.

What does Novavax COVID-19 vaccine contain?

- Medicinal ingredients: 5 micrograms of purified SARS-CoV-2 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 contains Quillaja saponaria saponins fraction-A and fraction-C) cholesterol, phosphatidylcholine, potassium dihydrogen phosphate, disodium hydrogen phosphate dihydrate, sodium chloride and potassium chloride.