

Novavax/Nuvaxovid™

COVID-19 Vaccine Information for Adults

Public Health Factsheet

March 2022

Manitoba 

Immunization is one of the most important accomplishments in public health. Over the past 50 years, immunization has led to the elimination, containment and control of diseases that were once very common in Canada.¹ Vaccines help our immune system recognize and fight bacteria and viruses that cause diseases.

After vaccination, continue to focus on the fundamentals. Go to manitoba.ca/covid19/fundamentals/focus-onthe-fundamentals.html for more information.

How do protein subunit vaccines work?

Novavax/Nuvaxovid™ is a COVID-19 protein subunit vaccine approved and available in Manitoba and is different from the COVID-19 mRNA vaccines (Pfizer/Comirnaty™ or Moderna/Spikevax™) and COVID-19 viral vector vaccines (AstraZeneca/Vaxzevria™ and Janssen).

Protein subunit vaccines contain harmless and purified pieces (proteins) of the virus, which have been specifically selected for their ability to trigger an immune response. Protein subunit vaccines are already used for other diseases. An example of an existing protein subunit vaccine is the one for hepatitis B. **Subunit vaccines cannot cause COVID-19 because they only contain small purified pieces of proteins and not the live COVID-19 virus.**

To make subunit vaccines, a small piece of the virus's genetic code is inserted into another cell (it could be a bacterial, yeast, mammalian or insect cell). The code contains instructions for this cell to start building the virus protein. In this case, the genetic code is the COVID-19 'spike' protein, which is known to stimulate immune cells.

The cells in which the genetic code is inserted act like factories, building large quantities of the protein. The protein is removed, purified and used as the active ingredient in the vaccine. Some protein subunit vaccines including Novavax/Nuvaxovid™, have adjuvants. An adjuvant is a substance that helps the body make a stronger and longer-lasting immune response. They have been used safely for decades in a number of vaccines.

Once vaccinated, our immune system recognizes that the proteins don't belong in the body and begins making T-lymphocytes and antibodies (immune response). If we're ever infected in the future, the body will recognize and fight the virus.

Novavax/Nuvaxovid™ vaccine is given by injection (needle) into a muscle of the upper arm.

Clinical trials showed that beginning a week after the second dose, Novavax/Nuvaxovid™ was very effective (approximately 90 per cent) in protecting against circulating strains of COVID-19 in the short-term.

Novavax/Nuvaxovid™ was in clinical trials prior to the emergence of Omicron and other variants of concern. It is therefore unknown how well Novavax/Nuvaxovid™ works against Omicron.

Is the vaccine safe?

Health Canada conducted a rigorous scientific review of the available medical evidence to assess the safety of the COVID-19 protein subunit vaccine. Health Canada approved two-doses of Novavax/Nuvaxovid™ for adults 18 years and older under normal regulatory processes (i.e., The Food and Drug Regulations) on February 17, 2022. **(Use outside of this indication—e.g., a booster dose—is not approved by Health Canada and is considered off-label at this time).**

Health Canada did not identify any major safety concerns during its assessment and approval process, and continues to monitor post-marketing studies.

¹ The Public Health Agency of Canada

The protein pieces in the vaccine are incapable of causing disease and the manufacturing technology is well established. Protein subunit vaccines are already used for other diseases. An example of an existing protein subunit vaccine is the one for hepatitis B.

Overall, Novavax/Nuvaxovid™ was well tolerated. As with other vaccines and medicines, some people may experience common reactions or side effects that are generally not serious and should go away on their own within a day or two after getting the vaccine.

The rare reaction of myocarditis/pericarditis (inflammation of the heart muscle/lining around the heart) has been reported following vaccination with the with the Novavax/Nuvaxovid™ vaccine including in two teenage males shortly after receiving a second dose of the vaccine. Both teenage males fully recovered. Public health officials in Manitoba and Canada continue to closely monitor the situation to detect and investigate possible safety concerns including myocarditis/pericarditis, to take appropriate action as needed.

Who should get Novavax/Nuvaxovid™ and when should I get vaccinated?

A COVID-19 mRNA vaccine (Pfizer/Comirnaty™ or Moderna/Spikevax™) is the preferentially recommended COVID-19 vaccine product for all adults in Manitoba. Novavax/Nuvaxovid™ may be offered to adults aged 18 years and older who are unable or unwilling to receive a COVID-19 mRNA vaccine:²

- as a first dose; **AND/OR**
- as a second dose eight weeks after the last COVID-19 vaccine. Based on individual circumstances, first and second doses can be given 28 days apart. **AND/OR**
- as a booster dose six months after the last COVID-19 vaccine.³ For current booster dose information and recommendations, go to www.manitoba.ca/covid19/vaccine/eligibility-criteria.html.

Adults who are moderately to severely immunocompromised are recommended to receive a total of four doses. Your doctor can provide more information about when is the best time to get immunized, based on a review of your medical history and individual circumstances. You can also find **Information for Individuals who are Immunosuppressed and/or have an Autoimmune Condition** here www.manitoba.ca/asset_library/en/covidvaccine/immunisuppressed-autoimmune-vaccine-factsheet.pdf.

To assess the individual risks and benefits of getting a booster dose, consider:

- **your risk of getting sick from COVID-19 and experiencing complications.** Emerging evidence suggests that overall the risk of serious illness from Omicron are lower compared to other variants of concern. Based on past experience, some groups of people continue to be at increased risk of experiencing serious illness from Omicron.
- **your risk as it pertains to vaccine safety.**
- **what is known and unknown at this time** (e.g., it is unknown what future variants of concern may emerge, and how the vaccine will work against them).
- **the evolving and limited evidence on the effectiveness of a booster dose.** Current evidence suggests a booster dose improves protection from Omicron among adults. It is currently unknown how long protection from a third dose will last.

Speak with your immunizer or health care provider if you have questions about your individual risks and benefits of getting a booster dose.

² Individuals who are unable or unwilling to receive an mRNA COVID-19 vaccine or a protein subunit COVID-19 vaccine should talk to their doctor about the risks and benefits of vaccination with a viral vector vaccine (AstraZeneca/Vaxzevria™ and Janssen).

³ Novavax/Nuvaxovid™ is not currently authorized for use as a booster dose in Canada.

Who should not get Novavax/Nuvaxovid™?

Anyone 17 years old or younger should not be given Novavax/Nuvaxovid™.

Anyone who is allergic to an active substance or any ingredients of Novavax/Nuvaxovid™ vaccine, or if you have had a severe allergic reaction after the first dose of a protein subunit COVID-19 vaccine, should receive an allergy referral and assessment before receiving this vaccine product. An allergic reaction can be life-threatening. For information about any of the COVID-19 vaccine ingredients, please review the vaccine manufacturer's product monograph at manitoba.ca/vaccine or speak with your health care provider.

Allergic reactions generally happen shortly after the vaccine is administered. **You must be observed for a minimum of 15 minutes after immunization.**

You can be immunized if you have allergies not related to the vaccine, such as allergies to foods, insect stings or seasonal/environmental allergies. Talk to your immunizer or health care provider about all of your allergies before vaccination.

If you were infected with COVID-19 (e.g., confirmed by a positive PCR test), you're recommended to wait two to three months after your infection before getting your next dose of vaccine. But at minimum, you need to wait until your symptoms are gone and your period of isolation is over.

If you were previously infected with COVID-19 and received a monoclonal antibody treatment (e.g., Sotrovimab, Casirivimab, Imdevimab), wait 90 days before getting the COVID-19 vaccine.

What are some of the possible side effects of Novavax/Nuvaxovid™?

In general, the side effects observed during the clinical trials were similar to those of other vaccines. The side effects were generally mild or moderate, and went away a few days after vaccination.

They included:

- pain, redness and swelling at the site of injection
- body chills
- feeling tired and feverish
- headache
- muscle and joint pain
- nausea and vomiting

These are common side effects of the vaccines and are not a risk to your health. Over-the-counter medicines like acetaminophen (e.g., Tylenol®) or ibuprofen (e.g., Advil®) may be considered to help manage these adverse events (like pain or fever, respectively), if they occur **after vaccination**.

For a full list of possible side effects, please review the vaccine manufacturer's product monograph at: manitoba.ca/vaccine or speak with your health care provider.

As with all vaccines, more serious side effects such as allergic reactions are possible. However, these are rare.

The signs and symptoms of myocarditis/pericarditis can include shortness of breath, chest pain, or the feeling of a rapid or abnormal heart rhythm. If you experience any of these symptoms, go to the nearest emergency department or health centre.

It is important to stay in the immunization clinic for 15 minutes after getting any vaccine in the unlikely event of a severe allergic reaction. You may need to stay in the clinic for 30 minutes if you have had a serious allergic reaction to a vaccine in the past. This can include hives, difficulty breathing, or swelling of the throat, tongue or lips. This can happen up to an hour after you get vaccinated. If this happens after you leave the immunization clinic, call 911 or go to the nearest emergency department or health centre for immediate attention.

Report any serious or unexpected adverse reactions to a health care provider, or call Health Links – Info Santé at 204-788-8200 or 1-888-315-9257 (toll free in Manitoba).

Your record of protection

All immunizations, including the COVID-19 vaccine, are recorded on your immunization record in Manitoba's immunization registry. This registry:

- allows health care providers to find out which immunizations you (or the people you care for) have received or need to have.
- may be used to produce immunization records or notify you or your health care provider if a particular immunization has been missed.
- allows Manitoba Health and public health officials, to monitor how well vaccines work in preventing disease.

The Personal Health Information Act protects your information and the information for any people you provide care for. You can choose to have this personal health information hidden from health care providers. For additional information, please contact your local public health office or speak with a health care provider.

For information and to obtain your Manitoba Immunization Card, Manitoba immunization record or Pan-Canadian Proof of Vaccination Credential (PVC), go to manitoba.ca/covid19/vaccine/immunizationrecord/residents.html.

Where can I find more information?

For more information about COVID-19 or the COVID-19 vaccines, talk to your health care provider. You can also call Health Links – Info Santé in Winnipeg at **204-788-8200** or **1-888-315-9257** (toll free in Manitoba).

Or visit

Manitoba Government: manitoba.ca/covid19/index.html

Government of Canada: canada.ca/en/public-health/services/diseases/coronavirus-disease-covid-19.html
