

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

NUVAXOVID

COVID-19 Vaccine, Adjuvanted

Read this carefully before you start taking **NUVAXOVID**. This leaflet is a summary and will not tell you everything about this vaccine. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **NUVAXOVID**.

What is NUVAXOVID used for?

NUVAXOVID is a vaccine used to prevent the coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus. It can be given to adults aged 18 years and older.

How does NUVAXOVID work?

NUVAXOVID causes the immune system (the body's natural defences) to produce antibodies and specialised white blood cells that work against the virus, to give protection against COVID-19. None of the ingredients in this vaccine can cause COVID-19.

The vaccine is given by injection with a needle in the upper arm and will require two doses given 3 weeks apart.

As with any vaccine, NUVAXOVID may not fully protect all those who receive it. Even after you have had both doses of the vaccine, continue to follow the recommendations of local public health officials to prevent spread of COVID-19.

Individuals may not be optimally protected until after receiving the second dose of the vaccine. You cannot get COVID-19 from this vaccine.

What are the ingredients in NUVAXOVID?

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 cholesterol, phosphatidylcholine, potassium dihydrogen phosphate disodium hydrogen phosphate dihydrate, sodium chloride and potassium chloride.

NUVAXOVID comes in the following dosage forms:

Colourless to slightly yellow, clear to mildly opalescent suspension provided in a clear multidose glass vial with a rubber stopper and a blue flip-off top. Each multidose vial contains 10 doses each of 0.5 mL.

Do not use NUVAXOVID if:

- you are allergic to the active substance or any of the other ingredients of this vaccine
- you have had an allergic reaction to a previous dose of NUVAXOVID
- you currently have symptoms that could be due to COVID-19. Talk with your healthcare professional about your symptoms and getting a COVID-19 test. Your healthcare professional will advise you when you are able to receive the vaccine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take NUVAXOVID. Talk about any health conditions or problems you may have, including if you:

- Have any allergies or previous problems following administration of NUVAXOVID, such as an allergic reaction or breathing problems
- Have ever fainted following any needle injection
- Have a bleeding problem, bruise easily or use a blood thinning medication
- Have a high fever or severe infection
- Have any serious illness
- Your immune system does not work properly (immunodeficiency) or you are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants, or cancer medicines)
- Are pregnant, think you may be pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

There is no information on the use of NUVAXOVID with other vaccines. Tell your healthcare professional if you have recently received any other vaccine.

How is NUVAXOVID given:

- Your doctor, pharmacist or nurse will inject the vaccine into a muscle (intramuscular injection) in your upper arm
- During and after each injection of the vaccine, your doctor, pharmacist, or nurse will watch over you for around 15 minutes to monitor for signs of an allergic reaction.

Usual dose:

NUVAXOVID will be given to you as two 0.5 mL injections. Each injection will be given on a separate visit 3 weeks apart. It is very important that you return for the second injection, or the vaccine may not work as well.

Overdose:

In the event of suspected overdose with NUVAXOVID, contact your regional poison control centre.

Missed Dose:

If you forget to go back to your healthcare professional at the scheduled time for your next dose, ask your healthcare professional for advice.

What are possible side effects from using NUVAXOVID?

Like all vaccines, NUVAXOVID can cause side effects.

The following are common or very common side effects of NUVAXOVID. Most of these side effects are mild and do not last long. Tell your doctor if you have side effects that bother you:

- headache
- feeling sick (nausea) or getting sick (vomiting)
- muscle ache
- joint pain
- tenderness or pain where the injection is given
- feeling very tired (fatigue)
- generally feeling unwell (malaise)
- redness where the injection is given
- swelling where the injection is given
- fever (> 38°C)
- chills
- pain or discomfort in the arm, hand, leg and/or foot (pain in the extremity)

These are not all the possible side effects you may have when taking NUVAXOVID. If you experience any side effects not listed here, tell your healthcare professional.

Should you develop any serious symptoms or symptoms that could be an allergic reaction, seek medical attention immediately. Symptoms of an allergic reaction include:

- feeling faint or light-headed
- changes in your heartbeat
- shortness of breath
- wheezing
- swelling of your lips, face, or throat
- hives or rash
- nausea or vomiting
- stomach pain

If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough

to interfere with your daily activities, tell your healthcare professional.

Reporting Suspected Side Effects for Vaccines

For the general public: Should you experience a side effect following immunization, please report it to your healthcare professional.

Should you require information related to the management of the side effect, please contact your healthcare professional. The Public Health Agency of Canada, Health Canada and Novavax, Inc. cannot provide medical advice.

For healthcare professionals: If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html>) and send it to your local Health Unit.

Storage:

Do not use this vaccine after the expiry date, which is stated on the label after EXP. The expiry date refers to the last day of that month.

Your doctor or pharmacist is responsible storing, supplying and administering this vaccine, as well as disposing of any unused product correctly.

Keep out of reach and sight of children.

If you want more information about NUVAXOVID:

- Talk to your healthcare professional

Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website:

(<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.NovavaxCovidVaccine.com, or by calling 1-855-239-9172.

This leaflet was prepared by Novavax, Inc.

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