

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/your child's healthcare professional about your/your child's medical condition and treatment and ask if there is any new information about **NUVAXOVID**.

What is NUVAXOVID used for?

NUVAXOVID is a protein-based vaccine used to prevent the coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus. It can be given to individuals aged 12 years and older.

How does NUVAXOVID work?

NUVAXOVID causes the immune system (the body's natural defenses) to produce antibodies and specialized white blood cells that work against the virus, to give protection against COVID-19. Protein-based vaccines use a purified recombinant protein to help our bodies protect against the virus. The addition of the Matrix-M adjuvant helps activate the immune system, which enhances the magnitude of the vaccine-specific response to the purified recombinant spike protein, which may contribute to protection against COVID-19.

The vaccine is given by injection with a needle in the upper arm.

As with any vaccine, NUVAXOVID may not fully protect all those who receive it. Even after you/your child have received a dose of the vaccine, continue to follow the recommendations of local public health officials to prevent spread of COVID-19.

You/your child cannot get COVID-19 from this vaccine.

What are the ingredients in NUVAXOVID?

Medicinal ingredients: One dose (0.5 mL) contains 5 mcg of recombinant SARS-CoV-2 spike protein (derived from Omicron JN.1 variant) 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 saponin, cholesterol, phosphatidylcholine, potassium dihydrogen phosphate disodium hydrogen phosphate dihydrate, sodium chloride and potassium chloride. NUVAXOVID does not contain mRNA, antibiotics, or preservatives; there is no gelatin added in NUVAXOVID as a stabilizer.

NUVAXOVID comes in the following dosage forms:

Colourless to slightly yellow, clear to mildly opalescent suspension provided in a single dose prefilled syringe or clear multidose glass vial with a rubber stopper and a blue flip-off top. Each prefilled syringe contains 1 dose of 0.5 mL and each multidose vial contains 5 doses of 0.5 mL.

Do not use NUVAXOVID if:

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

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

- Have any allergies or previous problems following administration of NUVAXOVID (Original, Wuhan strain) or 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
- Have previously had episodes of myocarditis (inflammation of the heart muscle) and/or pericarditis (inflammation of the lining outside the heart)
- Your/your child's immune system does not work properly (immunodeficiency) or you/your child are taking medicines that weaken the immune system (such as high-dose corticosteroids, immunosuppressants, or cancer medicines)
- Are pregnant, think you/your child may be pregnant or plan to become pregnant

- Are breastfeeding or plan to breastfeed

Tell your healthcare professional about all the medicines you/your child 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/your child's healthcare professional if you/your child 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 the 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:

Individuals 12 years of age and older who have been vaccinated with a previously or currently marketed Canadian COVID-19 vaccine series.

NUVAXOVID will be given to you/your child as a single dose (0.5 mL injection). You/your child should receive a dose of NUVAXOVID at least 6 months after the most recent dose of a Canadian marketed COVID-19 vaccine. No dose adjustment is required based on age.

Individuals 12 years of age and older who have not been vaccinated with a previously or currently marketed Canadian COVID-19 vaccine series.

NUVAXOVID will be given to you/your child 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.

You/your child should complete the vaccination course with NUVAXOVID.

Overdose:

If you think you, or a person you are caring for, have received too much NUVAXOVID, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to go back to your/your child's healthcare professional at the scheduled time for your/their next dose, ask your/your child's 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/your child's 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)
- pain or discomfort in the arm, hand, leg and/or foot (pain in the extremity)

Non-severe and severe allergic reactions, hypoaesthesia (decreased sense of touch or sensation, numbness), and paraesthesia (tingling, itching or pricking sensation) have also been reported. Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have been reported following NUVAXOVID (Original, Wuhan strain) administration.

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

Should you/your child 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/your child's heartbeat
- shortness of breath
- wheezing
- swelling of your/your child's lips, face, or throat
- hives or rash
- nausea or vomiting
- stomach pain

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

If you/your child have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your/your child's daily activities, tell your/your child's 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 Sanofi Vaccines Canada Ltd 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 (<http://www.phac-aspc.gc.ca/im/ae-fi-essi-form-eng.php>) 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/your child's healthcare professional is responsible for 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.sanofi.com/en/canada, or by calling 1-800-265-7927.

This leaflet was prepared by Sanofi Vaccines Canada Ltd.

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