

INFORMATION FOR RECIPIENTS AND CAREGIVERS

NUVAXOVID™ (Noo-VAX-o-vid) (COVID-19 Vaccine, Adjuvanted) (2025-2026 Formula)

This summary is not intended to take the place of talking with your healthcare provider. If you have questions or would like more information, please talk with your healthcare provider.

What is NUVAXOVID?

NUVAXOVID is a vaccine to protect against COVID-19.

NUVAXOVID is for people who are:

- 65 years of age and older, or
- 12 years through 64 years of age at high risk for severe COVID-19.

Vaccination with NUVAXOVID may not protect all people who receive the vaccine.

NUVAXOVID does not contain SARS-CoV-2, the virus that causes COVID-19.

NUVAXOVID cannot give you or your child COVID-19.

Who should not get NUVAXOVID?

You or your child should not get NUVAXOVID if you or your child had:

- a severe allergic reaction after a previous dose of NUVAXOVID or Novavax COVID-19 Vaccine, Adjuvanted
- a severe allergic reaction to any ingredient of this vaccine (see **What are the ingredients in NUVAXOVID?**)

What should you tell your vaccination provider before you or your child gets NUVAXOVID?

Tell your vaccination provider about all of your or your child's medical conditions, including if you or your child:

- have any allergies
- had a severe allergic reaction after receiving a previous dose of any COVID-19 vaccine
- have had myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining outside the heart)
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system

- are pregnant or plan to become pregnant
- are breastfeeding
- have received any other COVID-19 vaccine
- have ever fainted in association with an injection

How is NUVAXOVID given?

NUVAXOVID is given as an injection into the muscle.

What are the risks of NUVAXOVID?

There is a remote chance that NUVAXOVID could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to 1 hour after getting a dose. For this reason, your vaccination provider may ask you or your child to stay at the place where you or your child received the vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

Myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart) have occurred in some people who have received NUVAXOVID or Novavax COVID-19 Vaccine, Adjuvanted. The chance of having this occur is very low. You should seek medical attention right away if you or your child have any of the following symptoms after receiving the vaccine:

- Chest pain
- Shortness of breath
- Feelings of having a fast-beating, fluttering, or pounding heart

Side effects that have been reported in clinical trials with NUVAXOVID include:

- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Injection site reactions: pain/tenderness, swelling, redness and itching
- General side effects: fatigue or generally feeling unwell, muscle pain, headache, joint pain, nausea, vomiting, fever, chills
- Allergic reactions such as hives and swelling of the face
- Swollen lymph nodes

Side effects that have been reported in post-authorization use with NUVAXOVID include:

- Severe allergic reactions
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)
- Paresthesia (unusual feeling in the skin such as tingling or a crawling feeling), hypoesthesia (decreased feeling or sensitivity, especially in the skin)

These may not be all the possible side effects of NUVAXOVID. Ask your healthcare provider about any side effects that concern you.

Report vaccine side effects to the FDA and the Centers for Disease Control and Prevention (CDC) **Vaccine Adverse Event Reporting System (VAERS)** at 1-800-822-7967 or <https://vaers.hhs.gov/reportevent.html>.

In addition, you can report side effects to Novavax, Inc., at www.Nuvaxovid.com or 1-844-NOVAVAX (1-844-668-2829).

What if you are pregnant or breastfeeding?

If you or your child are pregnant or breastfeeding, discuss your options with your healthcare provider.

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/>.

What are the ingredients in NUVAXOVID?

NUVAXOVID contains a recombinant form of the SARS-CoV-2 spike protein produced from baculovirus-infected Sf9 insect cells (derived from the fall armyworm, which is an insect related to moths and butterflies) and Matrix-M[®] adjuvant containing saponins derived from the soapbark tree (*Quillaja saponaria* Molina).

Other ingredients include:

- cholesterol
- phosphatidylcholine
- potassium dihydrogen phosphate
- potassium chloride
- disodium hydrogen phosphate dihydrate
- sodium chloride
- disodium hydrogen phosphate heptahydrate
- sodium dihydrogen phosphate monohydrate

- polysorbate 80

NUVAXOVID may also contain small amounts of baculovirus and insect cell proteins, baculovirus and cellular DNA, lentil lectin, methyl- α -D-mannopyranoside, simethicone, pluronic F-68, Triton X-100, Tergitol, and DL- α -tocopherol.

NUVAXOVID does not contain preservatives.

This Information for Recipients and Caregivers may have been updated. For the most recent Information for Recipients and Caregivers, please visit <https://dailymed.nlm.nih.gov/dailymed/>.

If you have questions, talk to your healthcare provider.



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