



Novavax COVID-19 Vaccine, Adjuvanted (NVX-CoV2373): Information on Fetal Cell/Fetal Tissue

Novavax Medical Information is providing you this information in response to your request for medical information. You requested information regarding the use of fetal tissue or fetal cell lines in the development, confirmation, or production stages of the Novavax COVID-19 vaccine, Adjuvanted (NVX-CoV2373).

Novavax COVID-19 Vaccine Development

The Novavax COVID-19 Vaccine, Adjuvanted (NVX-CoV2373) vaccine is a recombinant protein vaccine, comprised of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike glycoproteins and a saponin based Matrix-M™ adjuvant.¹ The Novavax NVX-CoV2373 is produced in insect cells, not mammalian cells.

No animal or human fetal-derived cell lines/tissue are used in the manufacturing, testing or production of the Novavax COVID-19 vaccine (NVX-CoV2373) administered in the clinical trials.

Authorized Use

The Novavax COVID-19 Vaccine, Adjuvanted has not been approved or licensed by the US Food and Drug Administration (FDA), but has been authorized for emergency use by FDA, under an Emergency Use Authorization (EUA) to provide a two-dose primary series to individuals 18 years of age and older.

The emergency use of the Novavax COVID-19 Vaccine, Adjuvanted is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

IMPORTANT SAFETY INFORMATION

What should you mention to your vaccination provider before you get the Novavax COVID-19 Vaccine, Adjuvanted?

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- 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
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Please see additional Important safety information on next page.

Creating tomorrow's vaccines today.

IMPORTANT SAFETY INFORMATION (continued)

What should you mention to your vaccination provider before you get the Novavax COVID-19 Vaccine, Adjuvanted? (continued)

Tell your vaccination provider about all of your medical conditions, including if you:

- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine
- have ever fainted in association with an injection

Who should not get the vaccine?

You should not get the Novavax COVID-19 Vaccine, Adjuvanted if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

What are the risks of the vaccine?

There is a remote chance that the Novavax COVID-19 Vaccine, Adjuvanted could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Novavax COVID-19 Vaccine, Adjuvanted. For this reason, your vaccination provider may ask you to stay at the place where you received your 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 the vaccine. In most of these people, symptoms began within 10 days following vaccination. The chance of having this occur is very low. You should seek medical attention right away if you 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 the Novavax COVID-19 Vaccine 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

Please see additional important safety information on next page.

IMPORTANT SAFETY INFORMATION (continued)

What are the risks of the vaccine? (continued)

- Allergic reactions such as hives and swelling of the face
- Swollen lymph nodes

Side effects that have been reported in post-authorization use in countries outside of the United States with the Novavax COVID-19 Vaccine include:

- Severe allergic reactions
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the lining outside the heart)

These may not be all the possible side effects of the Novavax COVID-19 Vaccine, Adjuvanted. Serious and unexpected side effects may occur. The Novavax COVID-19 Vaccine, Adjuvanted is still being studied in clinical trials.

What should I do about side effects?

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

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to the FDA and the Centers for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS). The VAERS toll-free number is 1-800-822-7967 or report online to <https://vaers.hhs.gov/reportevent.html>. Please include "Novavax COVID-19 Vaccine, Adjuvanted EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Novavax, Inc., using the following contact information: Website: www.NovavaxMedInfo.com, Fax Number: 1-888-988-8809, Telephone Number: 1-844-NOVAVAX (1-844-668-2829).

What if I am pregnant or breastfeeding?

If you 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 the Novavax COVID-19 Vaccine, Adjuvanted during pregnancy. Women who are vaccinated with the Novavax COVID-19 Vaccine, Adjuvanted during pregnancy are encouraged to enroll in the registry by visiting <https://c-viper.pregistry.com>.

[Please click to see conditions of use, including the approved Fact Sheets.](#)

REFERENCE(S):

1. [Recombinant Nanoparticle Vaccine Technology](https://www.novavax.com/science-technology/recombinant-protein-based-nanoparticle-vaccine-technology). Novavax. <https://www.novavax.com/science-technology/recombinant-protein-based-nanoparticle-vaccine-technology> Accessed July 21, 2022