

Patient Education

COVID-19 Vaccine (Subunit) Novavax FDA Fact Sheet

You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information

About this topic

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE NOVAVAX COVID-19 VACCINE, ADJUVANTED TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

You are being offered the Novavax COVID-19 Vaccine, Adjuvanted to prevent Coronavirus Disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

The Novavax COVID-19 Vaccine, Adjuvanted has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) to provide a two-dose primary series to individuals 12 years of age and older.

This Fact Sheet contains information to help you understand the risks and benefits of the Novavax COVID-19 Vaccine, Adjuvanted, which you may receive because there is currently a pandemic of COVID-19. Talk to your vaccination provider if you have questions.

The Novavax COVID-19 Vaccine, Adjuvanted may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit <http://www.NovavaxCovidVaccine.com>.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE NOVAVAX COVID-19 VACCINE, ADJUVANTED?

The Novavax COVID-19 Vaccine, Adjuvanted is an unapproved vaccine that may prevent COVID-19.

The FDA has authorized the emergency use of the Novavax COVID-19 Vaccine, Adjuvanted to prevent COVID-19 in individuals 12 years of age and older under an EUA.

For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

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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
- 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 NOVAVAX COVID-19 VACCINE, ADJUVANTED?

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 INGREDIENTS IN THE NOVAVAX COVID-19 VACCINE, ADJUVANTED?

The Novavax COVID-19 Vaccine, Adjuvanted contains a recombinant form of the SARS-CoV-2 spike protein produced from baculovirus infected Sf9 (fall armyworm) insect cells 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, and water for injection. The vaccine may also contain small amounts of baculovirus and insect cell proteins and DNA.

HOW IS THE NOVAVAX COVID-19 VACCINE, ADJUVANTED GIVEN?

The Novavax COVID-19 Vaccine, Adjuvanted will be given to you as an injection in the muscle.

The Novavax COVID-19 Vaccine, Adjuvanted is administered as a two-dose series, 3 weeks apart.

HAS THE NOVAVAX COVID-19 VACCINE, ADJUVANTED BEEN USED BEFORE?

The Novavax COVID-19 Vaccine, Adjuvanted is an unapproved vaccine. In clinical trials, approximately 28,000 individuals 12 years of age and older have received two doses of the Novavax COVID-19 Vaccine, Adjuvanted.

WHAT ARE THE BENEFITS OF THE NOVAVAX COVID-19 VACCINE, ADJUVANTED?

The Novavax COVID-19 Vaccine, Adjuvanted has been shown to prevent COVID-19. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE NOVAVAX COVID-19 VACCINE, ADJUVANTED?

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

Side effects that have been reported in post-authorization use with the Novavax COVID-19 Vaccine 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 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., at the contact information provided below.

Website	Fax number	Telephone number
www.NovavaxMedInfo.com	1-888-988-8809	1-844-NOVAVAX (1-844-668-2829)

You may also be given an option to enroll in **v-safe**. **V-safe** is a voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

WHAT IF I DECIDE NOT TO GET THE NOVAVAX COVID-19 VACCINE, ADJUVANTED?

Under the EUA, it is your choice to receive or not receive the Novavax COVID-19 Vaccine, Adjuvanted. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES THE NOVAVAX COVID-19 VACCINE, ADJUVANTED?

For individuals 12 through 17 years of age, another choice for preventing COVID-19 is COMIRNATY (COVID-19 Vaccine, mRNA) an FDA-approved COVID-19 vaccine. For individuals 18 years of age and older, other choices for preventing COVID-19 are COMIRNATY (COVID-19 Vaccine, mRNA) and SPIKEVAX (COVID-19 Vaccine, mRNA), FDA-approved COVID-19 vaccines. Other vaccines to prevent COVID-19 may be available under EUA.

CAN I RECEIVE THE NOVAVAX COVID-19 VACCINE, ADJUVANTED AT THE SAME TIME AS OTHER VACCINES?

Data have not yet been submitted to FDA on administration of the Novavax COVID-19 Vaccine, Adjuvanted at the same time as other vaccines. If you are considering receiving the Novavax COVID-19 Vaccine, Adjuvanted with other vaccines, discuss your options with your healthcare provider.

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/>.

WILL THE NOVAVAX COVID-19 VACCINE, ADJUVANTED GIVE ME COVID-19?

No. The Novavax COVID-19 Vaccine, Adjuvanted does not contain SARS-CoV-2 and cannot give you COVID-19.


KEEP YOUR VACCINATION CARD

When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Novavax COVID-19 Vaccine, Adjuvanted. Remember to bring your card when you return.

ADDITIONAL INFORMATION

If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Novavax COVID-19 Vaccine website	Telephone number
www.NovavaxCovidVaccine.com 	1-844-NOVAVAX (1-844-668-2829)

HOW CAN I LEARN MORE?

- Ask the vaccination provider
- Visit CDC at <https://www.cdc.gov/coronavirus/2019-ncov/index.html>
- Visit FDA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- Contact your state or local public health department

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

CAN I BE CHARGED AN ADMINISTRATION FEE FOR RECEIPT OF THE COVID-19 VACCINE?

No. At this time, the provider cannot charge you for a vaccine dose and you cannot be charged an out-of-pocket vaccine administration fee or any other fee if only receiving a COVID-19 vaccination. However, vaccination providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient (private insurance, Medicare, Medicaid, HRSA COVID-19 Uninsured Program for non-insured recipients).

WHERE CAN I REPORT CASES OF SUSPECTED FRAUD?

Individuals becoming aware of any potential violations of the CDC COVID-19 Vaccination Program requirements are encouraged to report them to the Office of the Inspector General, U.S. Department of Health and Human Services, at 1-800-HHS-TIPS or [TIPS.HHS.GOV](https://www.hhs.gov/tips).

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?

The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

An EUA is a mechanism to facilitate the availability and use of medical products, including vaccines, during public health emergencies, such as the current COVID-19 pandemic. An EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic. A product authorized for emergency use has not undergone the same type of review by FDA as an FDA-approved product.

FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the

scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

An EUA is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of this product, unless terminated or revoked (after which the product may no longer be used).

Manufactured for:

Novavax, Inc., Gaithersburg, MD, 20878

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COVID-19 Vaccine FDA Fact Sheet: <https://www.fda.gov/media/159898/download>

Novavax COVID-19 Vaccine: <http://www.NovavaxCovidVaccine.com>; <http://www.NovavaxMedInfo.com>

Report vaccine side effects to FDA/CDC Vaccine Adverse Event Reporting System (VAERS): <https://vaers.hhs.gov/reportevent.html>

V-safe enrollment: <https://www.cdc.gov/vsafe>

Pregnancy exposure registry: <https://c-viper.pregistry.com/>

CDC: <https://www.cdc.gov/coronavirus/2019-ncov/index.html>

FDA: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

Immunization Information System (IIS): <https://www.cdc.gov/vaccines/programs/iis/about.html>

Suspected fraud: <https://oig.hhs.gov/fraud/report-fraud/>

Countermeasures Injury Compensation Program (CICP): <https://www.hrsa.gov/cicp/>

Consumer Information Use and Disclaimer: We want you to understand more clearly each of the health conditions and procedures you may have. This patient leaflet is a summary of useful information to help you gain a better understanding of these health topics. Other information about this condition or procedure may be important for you to know. Please talk with your healthcare provider for more information about your special health needs.

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