

**FACT SHEET FOR RECIPIENTS AND CAREGIVERS**  
**EMERGENCY USE AUTHORIZATION (EUA) OF**  
**THE NOVAVAX COVID-19 VACCINE, ADJUVANTED (2023-2024 FORMULA) TO**  
**PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN**  
**INDIVIDUALS 12 YEARS OF AGE AND OLDER**

You are being offered the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This Fact Sheet contains information to help you understand the risks and benefits of the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula), hereafter referred to as Novavax COVID-19 Vaccine, Adjuvanted, which you or your child may receive because there is currently a pandemic of COVID-19. Talk to your or your child's vaccination provider if you have questions.

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

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make the Novavax COVID-19 Vaccine, Adjuvanted available during the COVID-19 pandemic (for more details about an EUA please see **“WHAT IS AN EMERGENCY USE AUTHORIZATION?”** at the end of this document). The Novavax COVID-19 Vaccine, Adjuvanted is not an FDA-approved vaccine in the United States. Read this Fact Sheet for information about the Novavax COVID-19 Vaccine, Adjuvanted.

### **WHAT IS COVID-19?**

COVID-19 is caused by a coronavirus called SARS-CoV-2. 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 leading to death. 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 a vaccine for use in individuals 12 years of age and older to prevent COVID-19.<sup>1</sup> The FDA has authorized the emergency use of the Novavax COVID-19 Vaccine, Adjuvanted under an EUA.

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

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<sup>1</sup> The Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) contains the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

## **WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU OR YOUR CHILD GETS THE NOVAVAX COVID-19 VACCINE, ADJUVANTED?**

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

- 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

## **HOW IS THE VACCINE GIVEN?**

The Novavax COVID-19 Vaccine, Adjuvanted is given as an injection into the muscle.

**Individuals previously vaccinated with one or more doses of a monovalent COVID-19 vaccine<sup>2</sup> or a bivalent COVID-19 vaccine<sup>3</sup>:** A single dose is administered at least 2 months after the last previous dose of any monovalent or bivalent COVID-19 vaccine.

**Individuals not previously vaccinated with any COVID-19 vaccine:** Two doses are administered 3 weeks apart.

### **Immunocompromised individuals 12 years of age and older**

Additional doses of Novavax COVID-19 Vaccine, Adjuvanted may be administered. For more information, talk to your child's healthcare provider.

## **WHO SHOULD NOT GET THE NOVAVAX COVID-19 VACCINE, ADJUVANTED?**

A person should not get the Novavax COVID-19 Vaccine, Adjuvanted if they had:

- a severe allergic reaction after a previous dose of any Novavax COVID-19 Vaccine, Adjuvanted
- a severe allergic reaction to any ingredient of these vaccines

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<sup>2</sup> Monovalent refers to a COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

<sup>3</sup> Bivalent refers to a COVID-19 vaccine that encodes the spike protein of the Original SARS-CoV-2 and the Omicron BA.4/BA.5 SARS-CoV-2.

## **WHAT ARE THE INGREDIENTS IN THIS VACCINE?**

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. The vaccine may also contain small amounts of baculovirus and insect cell proteins and DNA.

## **HAS THIS VACCINE BEEN USED BEFORE?**

Tens of thousands of individuals 12 years of age and older have received Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) under EUA.

In clinical trials, approximately 28,500 individuals 12 years of age and older have received at least one dose of Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent).

Approximately 1000 individuals have received at least a single dose of a Novavax monovalent or bivalent vaccine containing different spike proteins of SARS-CoV-2.

The Novavax COVID-19 Vaccine, Adjuvanted is made in the same way as the Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent), but it contains the spike protein of SARS-CoV-2 Omicron variant lineage XBB.1.5 (Omicron XBB.1.5).

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

FDA has authorized the Novavax COVID-19 Vaccine, Adjuvanted to provide protection against 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 vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose. For this reason, the 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 the face and throat
- A fast heartbeat
- A bad rash all over the 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 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 the Novavax COVID-19 Vaccine, Adjuvanted 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 the Novavax COVID-19 Vaccine, Adjuvanted 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. Serious and unexpected side effects may occur. The possible side effects are still being studied.

## **WHAT SHOULD I DO ABOUT SIDE EFFECTS?**

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

Call the vaccination provider or your healthcare provider for any side effects that bother you or your child 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 (2023-2024 Formula) 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
<a href="http://www.NovavaxMedInfo.com">www.NovavaxMedInfo.com</a>	1-888-988-8809	1-844-NOVAVAX (1-844-668-2829)

**WHAT IF I DECIDE NOT TO GET OR NOT TO HAVE MY CHILD GET THE NOVAVAX COVID-19 VACCINE, ADJUVANTED?**

Under the EUA, there is an option to accept or refuse receiving this vaccine. If you decide not to receive this vaccine or for your child not to receive this vaccine, it will not change the standard medical care.

**ARE THERE OTHER VACCINES FOR PREVENTING COVID-19 BESIDES THE NOVAVAX COVID-19 VACCINE, ADJUVANTED?**

Other vaccines for preventing COVID-19 include the FDA-approved COVID-19 vaccines, COMIRNATY (COVID-19 Vaccine, mRNA) and SPIKEVAX (COVID-19 Vaccine, mRNA), for individuals 12 years of age and older.

**CAN I OR MY CHILD 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 Novavax COVID-19 Vaccine, Adjuvanted at the same time as other vaccines. If you are considering having you or your child receive the Novavax COVID-19 Vaccine, Adjuvanted with other vaccines, discuss your options with your healthcare provider.

**WHAT IF I AM OR MY CHILD IS IMMUNOCOMPROMISED?**

Immunocompromised individuals 12 years of age and older may receive additional doses of Novavax COVID-19 Vaccine, Adjuvanted (see **HOW IS THE VACCINE GIVEN?** above).

**WHAT ABOUT PREGNANCY OR BREASTFEEDING?**

If you or your child are pregnant or breastfeeding, discuss the 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 THIS VACCINE GIVE ME OR MY CHILD COVID-19?**

No. This vaccine does not contain SARS-CoV-2 and cannot give you or your child COVID-19.

## 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.

<b>Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) website</b>	<b>Telephone number</b>
<p data-bbox="285 541 688 573"><a href="http://www.NovavaxCovidVaccine.com">www.NovavaxCovidVaccine.com</a></p> 	<p data-bbox="938 642 1166 726">1-844-NOVAVAX (1-844-668-2829)</p>

## 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 VACCINATION INFORMATION BE RECORDED?

The vaccination provider may include your or your child’s vaccination information in your state/local jurisdiction’s Immunization Information System (IIS) or other designated system. For more information about IISs, visit: <https://www.cdc.gov/vaccines/programs/iis/about.html>.

## 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/](http://www.hrsa.gov/cicp/) or call 1-855-266-2427.

## WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The FDA has made Novavax COVID-19 Vaccine, Adjuvanted available under an emergency access mechanism called an EUA. 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.

The 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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