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.
- a first booster dose to the following individuals at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine:
    - individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent[1] COVID-19 booster vaccine is not accessible or clinically appropriate,
    - individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

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.

[1] Authorized bivalent COVID-19 vaccines encode the spike protein of the Original SARS-CoV-2 and the Omicron BA.4/BA.5 SARS-CoV-2.

WHAT IS THE NOVAVAX COVID-19 VACCINE, ADJUVANTED?

The Novavax COVID-19 Vaccine, Adjuvanted is an unapproved vaccine that may prevent COVID-19. The Novavax COVID-19 Vaccine, Adjuvanted is a monovalent vaccine that contains the spike protein of the original SARS-CoV-2.

The FDA has authorized the emergency use of the Novavax COVID-19 Vaccine, Adjuvanted as a primary series to prevent COVID-19 in individuals 12 years of age and older and as a first booster dose in individuals 18 years of age and older under an EUA. The booster dose authorization for individuals 18 years of age and older only applies to those for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, and those who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

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

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.

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

Booster Dose: The Novavax COVID-19 Vaccine, Adjuvanted may be administered as a first booster dose at least 6 months after completing primary vaccination with an authorized or approved COVID-19 vaccine.

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 at least one dose 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, 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 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 primary vaccination, other choices for preventing COVID-19 include the FDA-approved COVID-19 vaccines COMIRNATY (COVID-19 Vaccine, mRNA) for individuals 12 years of age and older and SPIKEVAX (COVID-19 Vaccine, mRNA) for individuals 18 years of age and older. Other vaccines to prevent COVID-19 may be available under EUA, including bivalent vaccines that contain an Omicron component of SARS-CoV-2.

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, Adjuvanted 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.

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).

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Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

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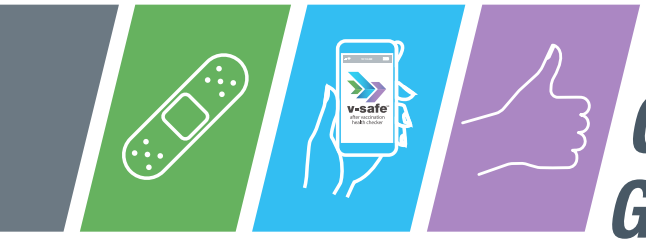

Get vaccinated. Get your smartphone. Get started with v-safe.

What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through ***v-safe***, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And ***v-safe*** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's ***v-safe*** makes a difference—it helps keep COVID-19 vaccines safe.

How can I participate?

Once you get a COVID-19 vaccine, you can enroll in ***v-safe*** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from ***v-safe*** around 2pm local time. To opt out, simply text "STOP" when ***v-safe*** sends you a text message. You can also start ***v-safe*** again by texting "START."

How long do v-safe check-ins last?

During the first week after you get your vaccine, ***v-safe*** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions ***v-safe*** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, ***v-safe*** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

Is my health information safe?

Yes. Your personal information in ***v-safe*** is protected so that it stays confidential and private.*

*To the extent ***v-safe*** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health Insurance Portability and Accountability Act of 1996 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

v-safe℠
after vaccination health checker

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.

Sign up with your smartphone's browser at vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

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How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

Register

1. Go to the ***v-safe*** website using one of the two options below:

Use your smartphone's browser to go to

vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in ***v-safe*** and click **Verify**.
5. At the top of the screen, click **Enter your COVID-19 vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2pm local time, ***v-safe*** will start your initial health check-in around 2pm that day. If you register after 2pm, ***v-safe*** will start your initial health check-in immediately after you register—just follow the instructions.

   You will receive a reminder text message from ***v-safe*** when it's time for the next check-in—around 2pm local time. Just click the link in the text message to start the check-in.

Complete a v-safe health check-in

1. When you receive a ***v-safe*** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

Troubleshooting

How can I come back and finish a check-in later if I'm interrupted?

- Click the link in the text message reminder to restart and complete your check-in.

How do I update my vaccine information after my second COVID-19 vaccine dose?

- ***V-safe*** will automatically ask you to update your second dose information. Just follow the instructions.

Need help with *v-safe*?
Call 800-CDC-INFO (800-232-4636)
TTY 888-232-6348
Open 24 hours, 7 days a week
Visit www.cdc.gov/vsafe

CAIR California Immunization Registry

Immunization Registry Notice to Patients and Parents

Immunizations or 'shots' prevent serious diseases. Tuberculosis (TB) screening tests help to determine if you may have TB infection and can be required for school or work. Keeping track of shots/TB tests you have received can be hard. It's especially hard if more than one doctor gave them. Today, doctors use a secure computer system called an *immunization registry* to keep track of shots and TB tests. If you change doctors, your new doctor can use the registry to see the shot/TB test record. It's your right to choose if you want shot/TB test records shared in the *California Immunization Registry*.

How Does a Registry Help You?

- Keeps track of all shots and TB tests (skin tests/chest x-rays), so you don't miss any or get too many
- Sends reminders when you or your child need shots
- Gives you a copy of the shot/TB record from the doctor
- Can show proof about shots/TB tests needed to start child care, school, or a new job

How Does a Registry Help Your Health Care Team?

Doctors, nurses, health plans, and public health agencies use the registry to:

- See which shots/TB tests are needed
- Remind you about shots needed
- Prevent disease in your community
- Help with record-keeping

Can Schools or Other Programs See the Registry?

Yes, but this is limited. Schools, child care, and other agencies allowed under California law may:

- See which shots/TB tests children in their programs need
- Make sure children have all shots/TB tests needed to start child care or school

What Information Can Be Shared in a Registry?

- patient's name, sex, and birth date
- parents' or guardians' names
- limited information to identify patients
- details about a patient's shots/TB tests

What's entered in the registry is treated like other private medical information. Misuse of the registry can be punished by law. Under California law, only your doctor's office, health plan, or public health department may see your address and phone number.

Patient and Parent Rights

It's your legal right to ask:

- not to share your (or your child's) registry shot/TB test records with others besides your doctor*
- not to get shot appointment reminders from your doctor's office
- to look at a copy of your or your child's shot/TB test records
- who has seen the records or to have the doctor change any mistakes

If you DO want your or your child's records in the registry, do nothing. You're all done.

If you DO NOT want your doctor's office to share your immunization/TB test information with other registry users, tell your doctor or download a "*Decline or Start Sharing/Information Request Form*" from the CAIR website (http://cairweb.org/cair-forms/) and FAX or email it to the CAIR Help Desk at 1-888-436-8320 or CAIRHelpDesk@cdph.ca.gov.

For more information, contact the CAIR Help Desk at 800-578-7889 or CAIRHelpDesk@cdph.ca.gov

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** By law, public health officials can also look at the registry in the case of a public health emergency.*