Novavax's Protein-based Non-mRNA COVID-19 Vaccine Available Now as Additional Dose for Individuals Aged 65 and Older Following U.S. CDC Advisory Committee Recommendation

February 28, 2024

Today, the U.S. Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) voted in favor (11 to 1; 1 abstain) to recommend that individuals aged 65 and older should receive an additional dose of 2023-2024 Formula COVID-19 vaccine at least four months after the initial 2023-2024 COVID-19 dose. ACIP's recommendation was subsequently endorsed by the CDC. Doses of the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) (NVX-CoV2601) are available at major retail pharmacies nationwide and can be ordered through one of our distribution partners for physician use in the non-retail setting.

While today's recommendation focuses on protection for older adults who are at increased risk of COVID-19, information shared at today's ACIP meeting also reinforces the ongoing benefit of vaccination for all those who are eligible. Data from clinical trials continue to show broad long-lived neutralization responses to currently circulating forward-drift variants including JN.1 and JN.4 for our protein-based non-mRNA COVID-19 vaccine, while maintaining a favorable side effect profile. Peer-reviewed real-world effectiveness data is being published that shows the immune responses seen in our trials translates into COVID-19 prevention in the real world.[1,2]

Those interested in a non-mRNA protein-based vaccine should ask their pharmacists about Novavax at major retail pharmacies nationwide including, but not limited to, Albertsons, Costco, CVS Pharmacy, Publix and Rite Aid. Doses can be located on us.novavaxcovidvaccine.com or vaccines.gov.

AUTHORIZED USE IN THE U.S.

Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an EUA to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older. Refer to the full Fact Sheet for information about the Novavax COVID-19 Vaccine, Adjuvanted.

The emergency use of this product 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 or your child get 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

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

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 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 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., 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 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.

Please see the Fact Sheet for Recipients and Caregivers for more information.

Reporting Adverse Events and Vaccine Administration Errors

- ·Adverse events can also be reported to Novavax, Inc. using the following contact information or by providing a copy of the VAERS form to Novavax, Inc. Website: https://www.novavaxmedinfo.com/, Fax Number: 1-888-988-8809, Telephone Number: 1-844-NOVAVAX (1-844-668-2829).

References:

1. Link-Gelles R, et al. Early Estimates of Updated 2023–2024 (Monovalent XBB.1.5) COVID-19 Vaccine Effectiveness Against Symptomatic SARS-CoV-2 Infection Attributable to Co-Circulating Omicron Variants Among Immunocompetent Adults — Increasing Community Access to Testing Program, United States, September 2023–January 2024. MMWR. 2024; accessed online February 28, 2024, at https://www.cdc.gov/mmwr/volumes/73/wr/mm7304a2.htm?s_cid=mm7304a2_w
2. Mateo-Urdiales A, et al. Estimated Effectiveness of a Primary Cycle of Protein Recombinant Vaccine NVX-CoV2373 Against COVID-19. JAMA Netw Open. 2023;6(10):e2336854. doi:10.1001/jamanetworkopen.2023.36854