The Novavax COVID-19 Vaccine, Adjuvanted

Anticipated Novavax COVID-19 Vaccine, Adjuvanted pending FDA authorization[1]:

2023-2024 Anticipated Vaccine Presentation*	Carton NDC	Vial NDC	CPT
5 multidose vial (for ages 12 years and older)	80631-0105-02	80631-0105-01	91304

*Ships in carton of 2 vials
100% returns of opened and unopened vials
Will be available to order through your dedicated distributor

One vial and one dosage strength for all authorized uses[2]

- Planning to be available in a 5 multidose vial (pending FDA authorization)[1]

Stored in a standard refrigerator[2]

Ready to use[2]

- No dilution, mixing, or thawing required

Novavax intends to deliver an XBB.1.5 protein-based monovalent vaccine for the fall, consistent with the VRBPAC's recommendation for the 2023-2024 vaccination season.[2-4]

Emergency Use Authorization

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 prevent Coronavirus Disease 2019 (COVID-19) as a primary series in individuals 12 years of age and older. The Novavax COVID-19 Vaccine, Adjuvanted is also authorized to provide a first booster dose at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine to individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, and to 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.

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.

Please see Important Safety Information on back and the Novavax COVID-19 Vaccine, Adjuvanted Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and EUA Full Prescribing Information.

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IMPORTANT SAFETY INFORMATION

Contraindications

Do not administer the Novavax COVID-19 Vaccine, Adjuvanted to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Novavax COVID-19 Vaccine, Adjuvanted.

Warnings and Precautions

Management of Acute Allergic Reactions: Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Novavax COVID-19 Vaccine, Adjuvanted. Monitor the Novavax COVID-19 Vaccine, Adjuvanted recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control (CDC) and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html).
Myocarditis and Pericarditis: Clinical trials data provide evidence for increased risks of myocarditis and pericarditis following administration of the Novavax COVID-19 Vaccine, Adjuvanted *(see Full EUA Prescribing Information)*.
Syncope (fainting): May occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
Altered Immunocompetence: Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Novavax COVID-19 Vaccine, Adjuvanted.
Limitations of Vaccine Effectiveness: The Novavax COVID-19 Vaccine, Adjuvanted may not protect all vaccine recipients.

Adverse Reactions

Adverse reactions reported in clinical trials following administration of the Novavax COVID-19 Vaccine, Adjuvanted include injection site pain/tenderness, fatigue/malaise, muscle pain, headache, joint pain, nausea/vomiting, injection site redness, injection site swelling, fever, chills, injection site pruritus, hypersensitivity reactions, lymphadenopathy-related reactions, myocarditis, and pericarditis.

Myocarditis, pericarditis, anaphylaxis, paresthesia, and hypoesthesia have been reported following administration of the Novavax COVID-19 Vaccine, Adjuvanted outside of clinical trials.

Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Novavax COVID-19 Vaccine, Adjuvanted.

Reporting Adverse Events and Vaccine Administration Errors

Vaccination providers administering the Novavax COVID-19 Vaccine, Adjuvanted must report the following information associated with the administration of the Novavax COVID-19 Vaccine, Adjuvanted of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):

- vaccine administration errors whether or not associated with an adverse event,
- serious adverse events (irrespective of attribution to vaccination),
- cases of myocarditis,
- cases of pericarditis,
- cases of Multisystem Inflammatory Syndrome (MIS), in adults and children, and
- cases of COVID-19 that results in hospitalization or death.

Complete and submit reports to VAERS online: https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS, call 1-800-822-7967. The reports should include the words “Novavax COVID-19 Vaccine, Adjuvanted EUA” in the description section of the report.

To the extent feasible, report adverse events to Novavax, Inc. using the following contact information or by providing a copy of the VAERS form to Novavax, Inc. Website: www.NovavaxMedInfo.com, Fax Number: 1-888-988-8809, Telephone Number: 1-844-NOVAVAX (1-844-668-2829).

Please see the Novavax COVID-19 Vaccine, Adjuvanted Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and EUA Full Prescribing Information.

References: 1. Data on file. Novavax, Inc. 2023. **2.** Novavax COVID-19 Vaccine, Adjuvanted EUA Fact Sheet for Healthcare Providers. Novavax, Inc.; May 2023. **3.** Dubovsky, F. Novavax data in support of 2023-2024 vaccine update. Presented at: Vaccines and Related Biological Products Advisory Committee; June 15, 2023. https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-15-2023-meeting-announcement. **4.** US Food and Drug Administration. Updated COVID-19 vaccines for use in the United States beginning in fall 2023. https://www.fda.gov/vaccines-blood-biologics/updated-covid-19-vaccines-use-united-states-beginning-fall-2023. Updated June 16, 2023. Accessed August 25, 2023.

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