

# The Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula)

## Storage and dosing



Vial is not actual size.

## Storage



### One vial, one dosage strength for all authorized uses<sup>1</sup>

- 5-dose vial
- Ships in carton of 2 vials



### Ready to use—no dilution, mixing, or thawing required<sup>1</sup>



### Stored in a standard refrigerator

- Store the unpunctured multidose vial in a refrigerator between 2 and 8 °C (36 and 46 °F) for up to 9 months<sup>1,2</sup>
- After first puncture, store the vial between 2 and 25 °C (36 and 77 °F) for up to 12 hours. Discard the vial 12 hours after the first puncture<sup>1</sup>

## EUA Statement

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 Emergency Use Authorization (EUA) to prevent coronavirus disease 2019 (COVID-19) for use in individuals 12 years of age and older.

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* starting on page 3 and the *Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) [Fact Sheet for Healthcare Providers](#) Administering Vaccine (Vaccination Providers) and EUA Full Prescribing Information*.



# Dosing

For patients aged 12 years and older<sup>1</sup>



## Previously vaccinated with any COVID-19 vaccine

- The Novavax COVID-19 vaccine is administered intramuscularly as a single 0.5 mL dose at least 2 months after receipt of the last previous dose of a COVID-19 vaccine



## Not previously vaccinated with any COVID-19 vaccine

- The Novavax COVID-19 vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 3 weeks apart



## Individuals with certain kinds of immunocompromise\*

- An additional dose of the Novavax COVID-19 vaccine may be administered at least 2 months following the last dose of a COVID-19 vaccine
- Additional doses of the Novavax COVID-19 vaccine may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances
- The timing of the additional doses may be based on the individual's clinical circumstances

\*Certain kinds of immunocompromise refers to individuals who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.<sup>1</sup>

For all mandatory requirements for the administration of the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) under EUA, please see the [Fact Sheet for Healthcare Providers Administering the Vaccine \(Vaccination Providers\)](#).

Please see Important Safety Information starting on page 3 and the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) [Fact Sheet for Healthcare Providers Administering Vaccine \(Vaccination Providers\)](#) and [EUA Full Prescribing Information](#).

## Authorized Use

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older. Individuals previously vaccinated with any COVID-19 vaccine: A single dose is administered at least 2 months after receipt of the last previous dose of COVID-19 vaccine. Individuals not previously vaccinated with any COVID-19 vaccine: Two doses are administered 3 weeks apart.

## IMPORTANT SAFETY INFORMATION

The safety data for Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) are based on studies of the Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) [no longer authorized for use in the U.S.] and of the Novavax monovalent vaccine (Omicron BA.1); bivalent vaccine (Original and Omicron BA.1); bivalent vaccine (Original and Omicron BA.5); and monovalent vaccine (Omicron BA.5) [none of which has been authorized or approved in the U.S.].

## 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, or to individuals who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a 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 Novavax COVID-19 Vaccine, Adjuvanted recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control 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 Fact Sheet*).

The CDC has published considerations related to myocarditis and pericarditis after vaccination, including for vaccination of individuals with a history of myocarditis or pericarditis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#myocarditis-pericarditis>).

**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.

Please see additional Important Safety Information on the next page.

## IMPORTANT SAFETY INFORMATION (cont'd)

**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.

### Required Reporting for Adverse Events and Vaccine Administration Errors

Vaccination providers must report the events listed below following administration of the Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) to the Vaccine Adverse Event Reporting System (VAERS):

- 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)
- 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 (2023-2024 Formula) 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](http://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 (2023-2024 Formula) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and EUA Full Prescribing Information.***

For more information, visit <https://us.novavaxcovidvaccine.com/hcp>.

**References:** 1. Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) EUA Fact Sheet for Healthcare Providers. Novavax, Inc.; October 2023. 2. Data on file. Novavax, Inc. 2023.