NOVAVAX COVID-19 VACCINE, ADJUVANTED (2024–2025 FORMULA)

At-A-Glance

Guidance below summarizes basic storage, preparation, scheduling, and administration for 2024–25 Novavax COVID-19 Vaccine product.

Ages: 12 years of age and older

Manufactured-filled syringe

Storage and Handling Basics

Find additional guidance on storing the vaccine properly at:

- CDC Vaccine Storage and Handling Toolkit
- Novavax COVID-19 Vaccine, Adjuvanted | FDA
- Investigational Vaccine Candidate | Novavax COVID-19 Vaccine (novavaxcovidvaccine.com)

Age	12 years and older
Supplied in:	Manufacturer-filled syringe (MFS)
Storage Temperature before use	**Between:** 2°C and 8°C (36°F and 46F°) until expiration date.* **Do not Freeze.** Protect from light.

* Check expiration date by scanning the QR on the outer carton or go to: www.novavax.com

Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly at:

- Interim Clinical Consideration for use of COVID-19 Vaccine | CDC
- Vaccine Administration Resource Library | CDC
- Novavax COVID-19 Vaccine, Adjuvanted | FDA
- Novavax COVID-19 Vaccine (novavaxcovidvaccine.com)

Preparation

- Check syringe label to ensure it states Novavax Covid-19 Vaccine, Adjuvanted (2024 – 2025 Formula).
- Check syringe label to ensure the expiration date has not passed.
- **Do NOT** use vaccine after the expiration date.
- Refer to EUA Fact Sheet for detailed instructions.

Administration

- COVID-19 vaccine may be administered at the same clinical visit as other vaccines.
- Administer intramuscularly.

Recipient's Age	Dosage	Route	Needle gauge and length	Site
12 years of age and older	0.5 mL/5 *µg* rS protein and 50 *µg* of Matrix-M™ adjuvant	IM injection	22–25 gauge, 1 inch†	Deltoid muscle in the upper arm‡

† See Vaccine Administration: Needle Gauge and Length chart for more details.

‡ Vastus lateralis muscle in the anterolateral thigh may be used.

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Scheduling Doses

- The number of recommended 2024–25 COVID-19 vaccine doses varies by vaccine, vaccination history, and the presence of moderate or severe immune compromise.
- Review CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States for detailed clinical guidance when scheduling doses and the Interim COVID-19 Immunization Schedule for summary information.

Contraindications, Precautions, and Post-Vaccination Observation

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered.

Contraindications

A severe allergic reaction (e.g., anaphylaxis) after previous dose or to a component of Novavax COVID-19 vaccine.*

Precautions

History of:

- A diagnosed non-severe allergy to a component of Novavax COVID-19 vaccine
- Non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of Novavax COVID-19 vaccine
- Current moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or adults (MIS-A)
- Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine

Consider observing persons after vaccination to monitor for allergic reactions and syncope:

- **30 minutes for persons with:**
  - A history of non-severe, immediate (onset within 4 hours) allergic reaction after a previous dose of Novavax COVID-19 vaccine
  - A history of a diagnosed non-severe allergy to a component of the Novavax COVID-19 vaccine
- **15 minutes:** All other persons

* See FDA fact sheet for a full list of vaccine ingredients.

Reporting of Vaccine Adverse Events

For the Novavax COVID-19 vaccine, which is given under an Emergency Use Authorization, vaccination providers are **required** to report to VAERS:

- Vaccine administration errors, whether or not associated with an adverse event (AE)
- Serious AEs, irrespective of attribution to vaccination. Serious AEs are per FDA defined as:
  - Death
  - A life-threatening AE
  - Inpatient hospitalization or prolongation of existing hospitalization
  - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
  - A congenital anomaly/birth defect
  - An important medical event that based on appropriate medical judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
- Multisystem Inflammatory Syndrome (MIS) in adults or children
- Cases of myocarditis
- Cases of pericarditis
- Cases of COVID-19 that result in hospitalization or death

Reporting is also encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event.

Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-9767.

In addition, anyone can register in V-safe after their COVID-19 vaccination to receive health check-ins via text messages or email.