Updated (2023–2024 Formula) Novavax COVID-19 Vaccine

At-A-Glance

Guidance below summarizes basic storage, preparation, scheduling, and administration for 2023–24 Novavax COVID-19 Vaccine product.

Ages: 12 years of age and older
(blue cap and blue label)
Multidose Vial

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)

Vial Cap and Label Color	 Blue Cap and Blue Label
Ages	**12 years and older**
Supplied in:	Multi-dose vial (MDV): 5 doses per vial **No diluent**
Storage Temperature: Before Puncture **Do NOT freeze**	**Between:** 2°C and 8°C (36°F and 46°F) for up to 9 months.*
Storage Temperature: After 1st Puncture **Do NOT use after 12 hours**	**Between:** 2°C and 25°C (36°F and 77°F) for up to 12 hours. Discard vial and any unused vaccine after 12 hours. **Note:** The beyond-use time (12 hours) replaces the manufacturer's expiration date but NEVER extends it. Always use the earliest date. Do NOT use vaccine if the expiration date or beyond-use time has passed.

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

- Inspect the vial.
- Check the vial label to ensure the expiration date has not passed. **Note:** The beyond-use time of 12 hours replaces the manufacturer's expiration date but NEVER extends it. Always use the earliest date. **Do NOT** use vaccine after the expiration date or beyond-use time.
- Gently swirl the multi-dose vial before each dose withdrawal.
- **Do NOT** shake.
- Refer to EUA Fact Sheet for detailed instructions.
- Record the date and time of the first puncture on the vial label.

Administration

- COVID-19 vaccine may be administered at the same clinical visit as other vaccines.
- Administer intramuscularly.
- **Do NOT** "pool" vaccine from more than 1 vial to obtain a dose. If a full dose cannot be withdrawn, discard the multidose vial and any remaining vaccine.
- After the first needle puncture, hold the vial between 2°C and 25°C (36°F and 77°F).
- Discard vial 12 hours after the first puncture.

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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"*	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.

Scheduling Doses

- The number of recommended 2023–24 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

Moderate to severe acute illness, with or without fever.

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
- 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.

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

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, if receiving Novavax vaccine.
- **15 minutes:** All other persons

Documentation

Document each recipient's vaccine administration information:

- **Medical record:** The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine.
- **Vaccination record for recipient**: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or health care professional.
- **Immunization information system (IIS):** Report the vaccination to the appropriate state/local IIS.

Reporting of Vaccine Adverse Events

Adverse events (AEs) that occur in a recipient following administration of any licensed or authorized COVID-19 vaccine should be reported to VAERS, including:

- Vaccine administration errors, whether associated with an adverse event or not
- Serious AEs, irrespective of attribution to vaccination
- 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.