Novavax COVID-19 Vaccine

At-A-Glance



Guidance below summarizes basic storage, preparation, scheduling, and administration for Novavax COVID-19 Vaccine products.



Ages: 12 of age and older (Royal blue-capped vial) MONOVALENT

A single Novavax booster dose (instead of bivalent mRNA booster dose) may be given to persons 18 years of age or older who have not received a previous booster dose in **limited situations**.

Storage and Handling Basics

Find additional guidance on storing the vaccine properly at:

- <u>Vaccine Storage and Handling Toolkit January 2023</u> (cdc.gov) Updated with COVID-19 Vaccine Storage and Handling Information
- Novavax COVID-19 Vaccine, Adjuvanted | FDA
- Investigational Vaccine Candidate | Novavax COVID-19 Vaccine (novavaxcovidvaccine.com)

Type and vial cap color	Monovalent - Royal Blue Cap
Ages	12 years and older
Supplied in:	MDV: 5 doses per vial I No diluent
Storage Temperature: Before Puncture Do NOT freeze	Between: 2°C and 8°C (36°F and 46°F) until the expiration date. [*]
Storage Temperature: After 1st Puncture Do NOT use after 12 hours	Between: 2°C and 8°C (36°F and 46°F) for up to 12 hours. Discard vial and any unused vaccine after 12 hours.

* Check expiration date by scanning the QR on the outer carton or go to: <u>www.novavaxcovidvaccine.com</u>

Preparation and Administration Basics

Find additional guidance on preparing and administering vaccine properly at:

- Vaccine Administration Resource Library CDC
- Novavax COVID-19 Vaccine (novavaxcovidvaccine.com)
- Novavax COVID-19 Vaccine, Adjuvanted | FDA

Preparation Monovalent Vaccine

Type and vial cap color	Monovalent - Royal Blue Cap
Ages	12 years and older
Vial type	Multidose vial (MDV)
Beyond-use date/time Do NOT use after 12 hours	After 1st puncture, use within 12 hours.
	When using a multidose vial for the 1st time, record the date and time the vial was punctured. 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.

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Administration

- COVID-19 vaccine may be administered at the same clinical visit as other vaccines.
- **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 If a full dose cannot be withdrawn, discard the multidose vial and any remaining vaccine.

Recipient's Age	Vial Cap Color	Administer	Route	Needle gauge and length	Site
12 years of age and older	Monovalent Royal blue cap	Primary dose 1 & 2 5 μg rS and 50 μg of Matrix-M [™] adjuvant/0.5 mL	. IM injection	22–25 gauge, 1"	Deltoid muscle in the upper arm [*]
18 years of age and older		Booster dose 5 μg rS and 50 μg of Matrix-M™ adjuvant/0.5 mL			

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

Scheduling Doses

Doses vary by age and the presence of moderate or severe immune compromise. Review <u>CDC's Interim Clinical</u> <u>Considerations for Use of COVID-19 Vaccines Currently</u> <u>Authorized in the United States</u> and the <u>Interim COVID-19</u> <u>Immunization Schedule</u> for detailed clinical guidance when scheduling doses.

Document the Vaccine

For each vaccine recipient, record

- Both in their medical record and on their vaccination card: vaccination date and vaccine administered (product name, manufacturer, lot number)
- In their medical record: vaccination site and route, vaccinator's name and title.
- On their vaccination card: name/location of clinic or health care professional, note bivalent dose if possible.

Report the vaccination to the appropriate <u>state/local</u> <u>immunization information system (IIS)</u>

Screen for contraindications and precautions

Screen for contraindications and precautions before administering EACH dose — even if the vaccine was previously administered. Use <u>CDC's Prevaccination Checklist</u> for <u>COVID-19 Vaccination</u> to determine whether the vaccine may be administered.

Contraindications

History of:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Known diagnosed allergy to a component of the COVID-19 vaccine. See the <u>EUA fact sheet</u> for a list of vaccine components

Precautions

Moderate to severe acute illness, with or without fever History of:

- Anaphylaxis after any vaccine other than COVID-19 vaccine or after any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"])
- Non-severe, immediate (onset less than 4 hours) allergic reaction after a dose of one type of COVID-19 vaccine is a precaution to the same type of COVID-19 vaccine
- An allergy-related contraindication to one type of COVID-19 vaccine is a precaution to the other types of COVID-19 vaccines
- Moderate to severe acute illness, with or without fever
- Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A)
- Myocarditis or pericarditis after a dose of COVID-19 vaccine



At-A-Glance



Report adverse events to the Vaccine Adverse Event Reporting System (VAERS)

- While this vaccine is under <u>Emergency Use Authorization</u> (EUA), healthcare professionals are required to report to <u>VAERS</u>:
 - Vaccine administration errors (whether associated with an adverse event [AE] or not)
 - o Serious AEs (irrespective of attribution to vaccination)
 - Multisystem inflammatory syndrome (MIS) in adults or children
 - o Cases of myocarditis
 - o Cases of pericarditis
 - o Cases of COVID-19 that result in hospitalization or death
 - Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA
- Healthcare professionals are encouraged to report to <u>VAERS</u> clinically important adverse events even if unsure whether the vaccine caused the adverse event.