

COVID-19 Vaccine Information Brief

July 22, 2022

Changes to the document from the previous version are highlighted in yellow.

NEW COVID-19 Vaccine Information - Novavax COVID-19 Vaccine, Adjuvanted

- ACIP Recommends Novavax COVID-19 Vaccine, Adjuvanted for Individuals 18 Years of Age and Older
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ACIP Recommends Novavax COVID-19 Vaccine, Adjuvanted for Individuals 18 Years of Age and Older

CDC's independent advisory committee, the Advisory Committee on Immunization Practices (ACIP) voted July 19, 2022 to recommend a two-dose Novavax COVID-19 vaccine, Adjuvanted as a COVID-19 primary series for individuals 18 years of age and older. This follows FDA's emergency use authorization (EUA) for Novavax on July 13, 2022. The Novavax COVID-19 vaccine is the first COVID-19 protein subunit vaccine recommended for use in the United States. Having multiple types of vaccines offers more options and flexibility for people receiving COVID-19 vaccines, as well as vaccine providers.

- **Novavax COVID-19 Vaccine, Adjuvanted for Individuals 18 Years of Age and Older is anticipated to be available for the July 25, 2022, vaccine allocation survey.**







Resources

- [Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States](#)
- [Fact Sheet for Healthcare Providers Administering Vaccine](#)
- [Fact Sheet for Recipients and Caregivers](#)
- [Letter of Authorization](#)
- Updated web pages for the public including:
 - [Novavax COVID-19 Vaccine Overview and Safety | CDC](#)
 - [Understanding Protein Subunit COVID-19 Vaccines](#)

- [Stay Up to Date with Your COVID-19 Vaccines | CDC](#)
- [COVID-19 Vaccines for People who are Moderately or Severely Immunocompromised | CDC](#)
- Updated CDC [COVID-19 booster tool](#)
- [COCA call](#) - July 28, 2022; 1pm

Novavax COVID-19 Vaccine, Adjuvant for Individuals 18 Years and Older

- **Novavax Vaccine Dosage**
 - The Novavax COVID-19 Vaccine, Adjuvanted is authorized for emergency use to provide a two-dose primary series to individuals 18 years of age and older.
 - The primary series of the Novavax COVID-19 Vaccine, Adjuvanted, is two doses (0.5 mL each) given 3 weeks apart as an IM injection.
 - Novavax COVID-19 Vaccine, Adjuvanted vaccine formulation is supplied in multiple-dose vials which contain 10 doses of 0.5mL and **DOES NOT** require diluent.

 <p>Age indication: 18 years and older</p>	 <p>Dose: 5 mcg SARS-CoV-2rS 50 mcg Matrix-M™ adjuvant</p>	 <p>Injection volume: 0.5 mL</p>
 <p>Preparation: Do not dilute</p>	 <p>Doses per vial: 10 doses</p>	 <p>Injection route/site: Intramuscular/deltoid</p>

Novavax Vaccine Storage and Handling

- **Shipping**
 - The Novavax COVID-19 Vaccine, Adjuvanted is supplied in a carton containing 10 multiple-dose vials
 - Each multiple-dose vial contains a maximum of 10 doses of 0.5 mL each

- **Storage of Unpunctured Vials**
 - **Do Not Freeze**
 - Store the unpunctured multi-dose vial in a refrigerator between 2° to 8°C (36° to 46°F)
 - Unpunctured vials may be stored refrigerated between 2°C to 8°C (36°F to 46°F) until expiration

Novavax Label²



- **Storage after First Puncture of Vials**
 - After the first needle puncture, hold the vial between 2° to 25°C (36° to 77°F) for up to 6 hours
 - **Discard the vial 6 hours after the first puncture**
 - The vaccine is preservative free and does not require reconstitution or dilution
- **Additional Storage and Handling Requirements**
 - The Novavax COVID-19 vaccine, Adjuvanted vial and carton do not have an expiration date
 - To find the expiration date, access [NovavaxCovidVaccine.com](https://www.novavax.com/US/Healthcare/Professionals/FAQs), navigate to the United States Healthcare Professional section of the website, and enter the lot number printed on the carton or vial into the “Expiry Date Checker” tool¹

¹ CDC. Novavax COVID-19 Vaccine Adjuvanted FAQs for CDC.

² Drugs.com. COVID-19 Vaccine Novavax. <https://www.drugs.com/pro/covid-19-vaccine-novavax.html> Accessed July 7, 2022

Storage:
Refrigerator 2° to 8°C
(36° to 46°F)

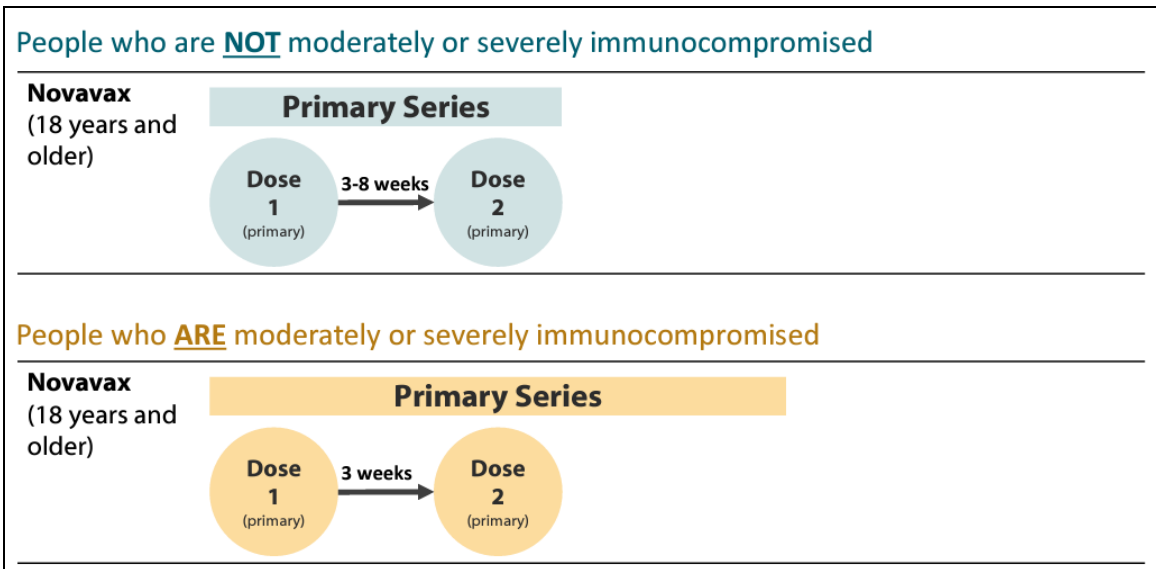
DO NOT FREEZE

Beyond use time:
6 hours after first puncture

Expiration:
No expiration date is printed on the vial or carton

www.NovavaxCovidVaccine.com

Novavax COVID-19 Vaccination Schedule



Novavax COVID-19 Vaccine Doses NOT Currently Authorized

For people receiving a Novavax COVID 19 Vaccine primary series, the following are **NOT** currently authorized:

- A third primary dose for people who are moderately or severely immunocompromised
- A booster dose using any COVID-19 vaccine is not authorized for individuals who receive a Novavax primary series.

CDC provides clinical guidance for what FDA authorizes; **once authorized**, these doses can be added to the COVID -19 vaccination schedule

COVID-19 Vaccine Mixed Primary Series

- The **same** vaccine product should be used for all doses in the primary series.
- There are limited data on the safety and efficacy of a mixed primary series composed of any combination of Moderna, Novavax, and PfizerBioNTech COVID-19 vaccines.
- If a mixed primary series is inadvertently administered:
 - The series is complete, and doses do not need to be repeated
 - **This is considered an error; report to the Vaccine Adverse Event Reporting System (VAERS)**
- If a person starts but is unable to complete the primary series with the same COVID-19 vaccine due to a contraindication, any other age appropriate COVID-19 vaccine may be administered to complete the series at a minimum interval of 4 weeks (28 days) from the last COVID dose.
 - This would not need to be reported to VAERS.

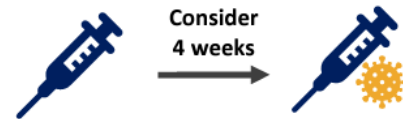
COVID-19 Vaccine Coadministration

- In general, COVID-19 vaccines may be administered without regard to timing of other vaccines.
 - ☑ Same day
 - ☑ Any time before
 - ☑ Any time after
- Routine administration of all age-appropriate doses of vaccines simultaneously is recommended for people for whom no specific contraindications exist at the time of the healthcare visit.
- There are additional considerations for orthopoxvirus vaccines.

- When deciding whether to coadminister another vaccine(s) with COVID-19 vaccine, providers may consider:
 - ✓ Whether a person is behind or at risk of becoming behind on recommended vaccines
 - ✓ Likelihood of the person returning for another vaccination
 - ✓ Person’s risk of becoming infected with a vaccine-preventable disease
 - ✓ Person’s risk for severe disease if infected
 - ✓ Reactogenicity profile of the vaccines

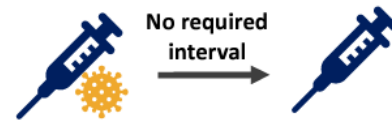
- Additional consideration for orthopoxvirus vaccination:

If orthopoxvirus vaccine administered first: Might consider waiting 4 weeks before receiving a Moderna, Novavax, or Pfizer-BioNTech vaccine



If Moderna, Novavax, or Pfizer-BioNTech administered first:

No minimum interval necessary before receiving orthopoxvirus vaccination for prophylaxis in the setting of an outbreak



Types of COVID-19 Vaccines

<p><u>mRNA</u></p> <ul style="list-style-type: none">• Moderna• Pfizer-BioNTech	<p><u>Adenovirus vector</u></p> <ul style="list-style-type: none">• Janssen	<p><u>Protein subunit</u></p> <ul style="list-style-type: none">• Novavax
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V-Safe After Vaccination Health Checker

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after an individual receives a COVID-19 vaccination. V-safe web pages feature information on how to register and complete a v-safe health check-in (including step-by-instructions with images), troubleshooting, FAQs, and contact information for technical support. These web pages will be continuously updated with additional resources.

V-safe information sheet and poster: Posted on the Vaccine webpage and available in 5 languages: English, Spanish, Korean, Vietnamese, and Simplified Chinese

[V-safe after vaccination health checker website](#)

[V-Safe Print Resources](#)

[Vaccine Adverse Event Reporting System \(VAERS\)](#)