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](#)
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.

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

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 Upunctured Vials**
  - **Do Not Freeze**
  - Store the unpunctured multi-dose vial in a refrigerator between 2°C to 8°C (36°F to 46°F)
  - Unpunctured vials may be stored refrigerated between 2°C to 8°C (36°F to 46°F) until expiration
COVID-19 Vaccine Information Brief

July 22, 2022

- **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://NovavaxCovidVaccine.com), 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” tool

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

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Novavax COVID-19 Vaccination Schedule

<table>
<thead>
<tr>
<th>People who are <strong>NOT</strong> moderately or severely immunocompromised</th>
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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

- **mRNA**
  - Moderna
  - Pfizer-BioNTech

- **Adenovirus vector**
  - Janssen

- **Protein subunit**
  - Novavax
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)