U.S. CDC and ACIP Recommend Additional COVID-19 Vaccine Dose for Older Individuals and Those Who Are Immunocompromised

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The U.S. Centers for Disease Control and Prevention (CDC) has endorsed the CDC Advisory Committee on Immunization Practices' (ACIP) recommendations for:

1. A second dose of 2024-2025 COVID-19 vaccine for adults aged 65 years and older six months after the first dose.
2. A second dose of 2024-2025 COVID-19 vaccine for people aged six months and older who are moderately or severely immunocompromised six months after the first dose.
3. Additional doses (i.e., three or more) for people who are moderately or severely immunocompromised in consultation with a healthcare provider.

Doses of the Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula) (NVX-CoV2705) are currently available at more than 30,000 locations, including major pharmacy retailers, regional grocers and independent pharmacies across the U.S. Doses are also available at physicians' offices and public health clinics, through Vaccines for Children, Federally Qualified Health Centers, Indian Health Services and the U.S. Department of Defense, and through agreements with Group Purchasing Organizations. The best source for finding our vaccine is us.novavaxcovidvaccine.com/vaccine-finder.

While the recommendations focus on additional protection for older individuals and those who are immunocompromised, vaccination continues to be the best source for protection against COVID-19 for all those who are eligible.

AUTHORIZED USE IN THE U.S.

Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula) has not been approved or licensed by the U.S. Food and Drug Administration (FDA) but has been authorized for emergency use by the FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older. Refer to the full Fact Sheet for information about the Novavax COVID-19 Vaccine, Adjuvanted.

The EUA of this product will remain in effect for the duration of the COVID-19 EUA declaration justifying emergency use of the product, unless the authorization is revoked sooner.

VACCINE AUTHORIZATION (U.S.)

Novavax COVID-19 Vaccine, Adjuvanted (2024-2025 Formula) is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

IMPORTANT SAFETY INFORMATION

Contraindications

- Do not administer the Novavax COVID-19 Vaccine, Adjuvanted to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the Novavax COVID-19 Vaccine, Adjuvanted.

Warnings and Precautions

- Management of Acute Allergic Reactions: Appropriate medical treatment must be immediately available to manage potential anaphylactic reactions following administration of the Novavax COVID-19 Vaccine, Adjuvanted.
- Myocarditis and Pericarditis: Clinical trials data provide evidence for increased risks of myocarditis and pericarditis following administration of Novavax COVID-19 Vaccine, Adjuvanted.
- Syncope (fainting): may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.
- Altered Immunocompetence: Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Novavax COVID-19 Vaccine, Adjuvanted.

- Limitations of Vaccine Effectiveness: The Novavax COVID-19 Vaccine, Adjuvanted may not protect all vaccine recipients.

Adverse Reactions

Solicited adverse reactions included: Injection site pain/tenderness, fatigue/malaise, muscle pain, headache, joint pain, nausea/vomiting, injection site redness, injection site swelling and fever.

Reporting Adverse Events and Vaccine Administration Errors

The vaccination provider is responsible for mandatory reporting of certain adverse events to the Vaccine Adverse Event Reporting System (VAERS) online at https://vaers.hhs.gov/reportevent.html, by calling 1-800-822-7967 or send an email to info@vaers.org.