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Novavax COVID-19 vaccine, adjuvanted – Booster dose emergency use authorization

- On October 19, 2022, Novavax announced the FDA has granted emergency use authorization (EUA) of Novavax's COVID-19 vaccine, adjuvanted, to provide a first booster dose to individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Novavax COVID-19 vaccine because they would otherwise not receive a booster dose of a COVID-19 vaccine.

  — This booster dose is the same composition as the primary series of Novavax COVID-19 vaccine, adjuvanted.

- The recommended booster dose of Novavax COVID-19 vaccine is given intramuscularly as 0.5 mL at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine, including mRNA COVID-19 vaccines from Moderna and Pfizer/BioNTech.

- The Novavax COVID-19 vaccine is also authorized under EUA to provide a two-dose primary series to individuals 12 years of age and older.

- The FDA EUA decision was based on data from the Prevent-19 clinical trial and from the U.K.-sponsored COV-BOOST trial. In the Prevent-19 trial, a single booster dose of the Novavax COVID-19 vaccine was administered to healthy adult participants aged 18 and older approximately eight or 11 months after their primary series.

  — Following a booster dose, antibody levels increased significantly relative to pre-boost levels. Neutralizing antibodies also increased by 34- to 27-fold vs. pre-boost levels when boosted at eight or 11 months.
  — In the COV-BOOST trial, the Novavax COVID-19 vaccine increased antibody titers when used as a third dose following initial dosing with another authorized COVID-19 vaccine (heterologous boosting).

- The most common adverse reactions with Novavax COVID-19 vaccine booster use were injection site pain/tenderness, fatigue/malaise, muscle pain, headache, joint pain, nausea/vomiting, injection site swelling, injection site redness, and fever.

- The U.S. government has already purchased Novavax COVID-19 vaccine. The vaccine has been distributed by the government and available for free to appropriate individuals.

  — The Novavax COVID-19 vaccine is supplied as a multi-dose vial containing 10 doses of 0.5 mL each. The NDCs are 80631-100-10 and 80631-100-01.

- The Centers for Disease Control and Prevention (CDC) announced at the Advisory Committee on Immunization Practices (ACIP) meeting on October 19, 2022 that the CDC Director has already signed off on this FDA EUA for Novavax COVID-19 vaccine for booster use. Appropriate individuals may receive the booster dose at vaccination sites.

  — Updated information about the booster dose for Novavax COVID-19 vaccine will be posted on the CDC website.

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