

## Novavax COVID-19 vaccine, adjuvanted – Expanded emergency use authorization

- On August 19, 2022, the [FDA announced](#) the emergency use authorization (EUA) of the [Novavax COVID-19 vaccine, adjuvanted](#), 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.
  - The Novavax COVID-19 vaccine, adjuvanted was previously authorized under an EUA for adults 18 years of age and older.
- The Novavax COVID-19 vaccine, adjuvanted contains purified SARS-CoV-2 spike protein and Matrix-M adjuvant. Adjuvants are incorporated into some vaccines to enhance the immune response of the vaccinated individual.
- The efficacy of Novavax COVID-19 vaccine, adjuvanted was established in a randomized, observer-blinded, placebo-controlled study in 2,247 participants who were 12 to 17 years of age and did not have evidence of SARS-CoV-2 infection. Participants received two doses of the Novavax COVID-19 vaccine, adjuvanted (0.5 mL) or placebo three weeks apart.
  - Noninferior immune responses as assessed by geometric mean titers and seroconversion rates were demonstrated in a comparison of adolescents 12 through 17 years of age to participants 18 through 25 years of age.
  - Vaccine efficacy was 78.29% (95% CI: 37.55, 92.45) with 5 cases of mild COVID-19 reported in the Novavax COVID-19 vaccine group vs. 11 cases in the placebo group.
  - The delta variant was the predominant variant while the study was conducted.
- The most common adverse reactions with Novavax COVID-19 vaccine, adjuvanted use in individuals 12 to 17 years of age were injection site pain/tenderness, headache, fatigue/malaise, muscle pain, nausea/vomiting, joint pain, fever, injection site swelling, and injection site redness.
- The recommended dose of Novavax COVID-19 vaccine, adjuvanted in individuals 12 years of age and older is given intramuscularly as a primary series of two doses (0.5 mL each) 3 weeks apart.
- The [Centers for Disease Control and Prevention's Director has already recommended](#) the Novavax COVID-19 vaccine, adjuvanted be used in individuals 12 to 17 years of age. No public meetings are planned for this expanded use