

Novavax COVID-19 vaccine, adjuvanted (2023-2024 formula) – Emergency Use Authorization

- On October 3, 2023, the [FDA granted](#) emergency use authorization (EUA) for [Novavax's Novavax COVID-19 vaccine, adjuvanted \(2023-2024 formula\)](#), 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.
 - Individuals 12 years of age and older previously vaccinated with any COVID-19 vaccine: administer a single 0.5 mL dose at least 2 months after receipt of the last previous dose of COVID-19 vaccine
 - Individuals 12 years of age and older not previously vaccinated with any COVID-19 vaccine: administer a series of two doses (0.5 mL each) 3 weeks apart
 - Individuals 12 years of age and older with certain kinds of immunocompromise: an additional dose of Novavax COVID-19 vaccine, adjuvanted (2023-2024 formula) may be administered at least 2 months following the last dose of a COVID-19 vaccine (2023-2024 formula). Additional doses of Novavax COVID-19 vaccine, adjuvanted (2023-2024 formula) may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances. The timing of the additional doses may be based on the individual's clinical circumstances.
- Novavax COVID-19 vaccine, adjuvanted (2023-2024 formula) is protein-based.
- The FDA had previously [approved/authorized](#) Pfizer's and Moderna's mRNA COVID-19 vaccines (2023-2024 formula) for individuals 6 months of age and older on September 11, 2023.
- As part of today's action, the Novavax COVID-19 vaccine, adjuvanted (original monovalent) is no longer authorized for use in the U.S.
- The Centers for Disease Control and Prevention's (CDC) [Advisory Committee on Immunization Practices \(ACIP\)](#) has already assessed the Novavax vaccine, and recommended at a [September 12 meeting](#) that all COVID boosters that the FDA approves or authorizes should be used in the U.S. The [CDC Director accepted](#) the recommendation, meaning that the FDA authorization for Novavax's vaccine makes it immediately available.
 - Updated recommendations for COVID-19 vaccines may be found [here](#).
- Novavax will begin shipping the vaccine to administration sites in the coming days.