

Novavax COVID-19 vaccine, adjuvanted (2024-2025 formula) – Emergency Use Authorization

- On August 30, 2024, the <u>FDA granted</u> emergency use authorization (EUA) for <u>Novavax's Novavax</u> <u>COVID-19 vaccine, adjuvanted (2024-2025 formula)</u>, 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 who have been vaccinated with a prior formula of a COVID-19 vaccine from another manufacturer or with two or more doses of a prior formula of the Novavax COVID-19 vaccine are eligible to receive a single dose of the updated Novavax COVID-19 vaccine at least 2 months after the last dose of a COVID-19 vaccine
 - Individuals 12 years of age and older who have never been vaccinated with any COVID-19 vaccine are eligible to receive two doses of this updated vaccine, 3 weeks apart.
 - Individuals 12 years of age and older who have been vaccinated only with one dose of any Novavax COVID-19 vaccine are eligible to receive one dose of the updated Novavax COVID-19 vaccine at least 3 weeks after the previous dose.
- Novavax COVID-19 vaccine, adjuvanted (2024-2025 formula) is protein-based and includes a monovalent component that corresponds to the Omicron variant JN.1 strain of SARS-CoV-2.
- The FDA had previously <u>approved/authorized</u> Pfizer/BioNTech and Moderna's mRNA COVID-19 vaccines (2024-2025 formula) for individuals 6 months of age and older on August 22, 2024.
 - The Pfizer/BioNTech and Moderna vaccines include a monovalent component that corresponds to the Omicron variant KP.2 strain of SARS-CoV-2.
- The <u>Centers for Disease Control and Prevention's (CDC) Director</u> already adopted the Advisory Committee on Immunization Practices (ACIP)'s recommendations for use of 2024 – 2025 COVID-19 vaccines when authorized or approved by the FDA in people ages 6 months and older.

What's Next?

 Novavax will begin shipping the updated 2024 – 2025 vaccines to pharmacies and other care settings immediately.



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