

## Nuvaxovid<sup>®</sup> (COVID-19 vaccine, adjuvanted) – New vaccine approval

- On May 19, 2025, [Novavax announced](#) the [FDA approval](#) of [Nuvaxovid \(COVID-19 vaccine, adjuvanted\)](#), for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adults 65 years and older. Nuvaxovid is also indicated for individuals 12 through 64 years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
  - Novavax COVID-19 vaccine, adjuvanted was previously available under [emergency use authorization \(EUA\)](#), for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and over.
- Nuvaxovid is the only protein-based COVID-19 vaccine.
- The FDA's [Vaccines and Related Biological Products Advisory Committee](#) will be meeting on May 22, 2025, to make recommendations on the selection of the 2025 - 2026 formula for COVID-19 vaccines.
  - Novavax in conjunction with Sanofi will be ready for commercial delivery of its Nuvaxovid 2025 – 2026 vaccine in the Fall of 2025.
- The approval of Nuvaxovid was based on previously conducted clinical trials for Novavax's COVID-19 vaccine.
- Warnings and precautions for Nuvaxovid include management of acute allergic reactions, myocarditis and pericarditis, syncope, altered immunocompetence, and limitations of vaccine effectiveness.
- The most common adverse reactions (> 10%) with Nuvaxovid use in patients ≥ 65 years of age were injection site tenderness, injection site pain, fatigue, muscle pain, headache, malaise, and joint pain.
- The most common adverse reactions (> 10%) with Nuvaxovid use in patients 18 through 64 years of age were injection site tenderness, injection site pain, muscle pain, fatigue, headache, malaise, joint pain, and nausea/vomiting.
- The most common adverse reactions (> 10%) with Nuvaxovid use in patients 12 through 17 years of age were injection site tenderness, injection site pain, headache, fatigue, muscle pain, malaise, nausea/vomiting, fever, and joint pain.
- The recommended dose of Nuvaxovid is 0.5 mL administered intramuscularly.
- Nuvaxovid 2024 – 2025 vaccine is already available in the marketplace under the previously approved EUA. Novavax plans to launch Nuvaxovid 2025 – 2026 vaccine in the Fall of 2025. Nuvaxovid will be available as a pre-filled syringe containing one dose of 0.5 mL.