Novavax COVID-19 Vaccine, Adjuvanted

Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) Authorized For Individuals 12 Years of Age and Older

Fact Sheets

Novavax Fact Sheet Translations

Vacunas contra el COVID-19 (https://www.fda.gov/about-fda/fda-en-espanol/vacunas-contra-el-covid-19)

On October 3, 2023, the Food and Drug Administration amended the emergency use authorization (EUA) of Novavax COVID-19 Vaccine, Adjuvanted to include the 2023-2024 formula. The Novavax COVID-19 Vaccine, Adjuvanted, a monovalent vaccine, has been updated to include the spike protein from the SARS-CoV-2 Omicron variant lineage XBB.1.5 (2023-2024 formula). The Novavax COVID-19 Vaccine, Adjuvanted (Original monovalent) is no longer authorized for use in the United States.

Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) is authorized for use in individuals 12 years of age and older as follows:

- **Individuals previously vaccinated with any COVID-19 vaccine:** one dose of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) is administered at least 2 months after receipt of the last previous dose of an original monovalent (Original) or bivalent (Original and Omicron BA.4/BA.5) COVID-19 vaccine.
- **Individuals not previously vaccinated with any COVID-19 vaccine:** two doses of Novavax COVID-19 Vaccine, Adjuvanted (2023-2024 Formula) are administered three weeks apart.
- **Immunocompromised individuals**: 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.

Fact Sheets (English)

Information	Last Updated
Fact Sheet for Healthcare Providers Administering Vaccine (/media/159897/download?attachment)	October 3, 2023
Fact Sheet for Recipients and Caregivers (/media/159898/download?attachment)	October 3, 2023

Regulatory Information (Emergency Use Authorization)

Information	Date
Letter of Authorization (/media/159902/download?attachment) (Reissued)	October 3, 2023

BioNTech-Pfizer Exhibit 1111
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

Information	Date
Decision Memo - Novavax COVID-19 Vaccine, Adjuvanted (/media/168233/download?attachment)	October 3, 2023
Advisory Committee Meeting Information (/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-7-2022-meeting-announcement)	June 7, 2022

Federal Register Notices

Title	Date
Authorization of Emergency Use of a Biological Product During the COVID-19 Pandemic; Availability (https://www.federalregister.gov/documents/2022/08/29/2022-18527/authorization-of-emergency-use-of-a-biological-product-during-the-covid-19-pandemic-availability)	August 29, 2022

Translations of the Fact Sheet for Recipients and Caregivers

接受者和护理者须知 (/media/173097/download?attachment) (October 3, 2023)	中文 (Chinese, Simplified)
환자와 의료진을 위한 정보지 (/media/173098/download?attachment) (October 3, 2023)	한국어 (Korean)
HOJA INFORMATIVA PARA RECEPTORES Y PROVEEDORES DE CUIDADO (/media/173099/download?attachment) (October 3, 2023)	Español (Spanish)
FACT SHEET PARA SA MGA TATANGGAP AT MGA TAGAPAG-ALAGA (/media/173100/download?attachment) (October 3, 2023)	Tagalog (Tagalog)
TỜ THÔNG TIN CHO NGƯỜI NHẬN VÀ NHỮNG NGƯỜI CHĂM SÓC (/media/173101/download?attachment) (October 3, 2023)	Tiếng Việt (Vietnamese)

Was this helpful? Yes No