

The Medical Letter[®]

on Drugs and Therapeutics

Volume 67

July 21, 2025

ISSUE No.
1733

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Volume 67 (Issue 1733)

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COVID-19 UPDATES

Full Approval for Novavax COVID-19 Vaccine

Nuvaxovid, the adjuvanted protein subunit COVID-19 vaccine marketed by Novavax, has received full approval from the FDA to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in all adults ≥ 65 years old and in adults 12-64 years old who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19. The vaccine was previously available under an FDA Emergency Use Authorization (EUA) for use in persons ≥ 12 years old.¹ *Nuvaxovid* is the first protein-based COVID-19 vaccine to receive full approval from the FDA; the mRNA COVID-19 vaccines *Comirnaty* and *Spikevax* are approved for use in patients ≥ 12 years old.

FORMULATION – The 2024-2025 formulation of *Nuvaxovid* contained the spike protein of the JN.1 Omicron strain of SARS-CoV-2. The Vaccines and Related Biological Products Advisory Committee has recommended that the same JN.1 lineage (preferentially the LP.8.1 strain) be used in the 2025-2026 COVID-19 vaccines.²

DOSAGE – Persons receiving *Nuvaxovid* who have not been vaccinated against COVID-19 previously should receive two 0.5-mL doses 3-8 weeks apart. Those who have been vaccinated against COVID-19 previously should receive a single 0.5-mL dose ≥ 2 months after their last COVID-19 vaccine dose. ■

1. COVID-19 update: Novavax vaccine for 2024-2025. Med Lett Drugs Ther 2024; 66:175.
2. FDA. COVID-19 vaccines (2025-2026 formula) for use in the United States beginning in fall 2025. May 22, 2025. Available at: <https://bit.ly/4jtmvcm>. Accessed July 2, 2025.

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