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Take CME Exams

COVID-19 Update

Novavax Vaccine for 2024-2025

A 2024-2025 formulation of the Novavax adjuvanted protein subunit COVID-19 vaccine that more closely targets currently circulating SARS-CoV-2 variants is available now under an FDA Emergency Use Authorization (EUA) for use in persons ≥12 years old.[1,2] The 2024-2025 formulations of the mRNA COVID-19 vaccines manufactured by Pfizer/BioNTech *(Comirnaty)* and Moderna *(Spikevax)* were licensed by the FDA last month for use in persons ≥12 years old and made available under EUAs for use in persons 6 months to 11 years old.[3]

THE NEW FORMULATION — The 2024-2025 formulation of the Novavax vaccine contains the spike protein of the JN.1 Omicron strain of SARS-CoV-2. Currently prevalent "FLiRT" variants (e.g., KP.2, KP.2.3, KP.3, KP.3.1.1, LB.1) are descended from the JN.1 strain.[4,5] The Pfizer and Moderna 2024-2025 vaccines code for the spike protein of the KP.2 strain.[3]

EFFECTIVENESS — As with the mRNA COVID-19 2024-2025 vaccines, no clinical studies evaluating the immunogenicity or effectiveness of the 2024-2025 Novavax vaccine are available. Authorization of the new formulation was based on the immunogenicity, safety, and efficacy of previous vaccine formulations.[1,2]

Observational studies suggest that all of the 2023-2024 formulations of the COVID-19 vaccines available in the US were effective in reducing the incidence of COVID-19, but data specific to the Novavax vaccine are limited. In a case-control analysis of 14,860 COVID-19 nucleic acid amplification tests administered at

Table 1. Recommendations for 2024-2025 COVID-19 Vaccines[1,2]

Age	Dose/Vial Color	Not Previously Vaccinated	Previously Vaccinated
Pfizer/BioNTech Vaccine *(Comirnaty)* – mRNA vaccine			
6 months-4 years	3 mcg/0.3 mL; yellow cap and label	Three 3-mcg doses: 1st at week 0, 2nd at week 3, and 3rd ≥8 weeks after dose 2[3,4]	**1 previous Pfizer dose:** One 3-mcg dose ≥3 weeks later and 1 dose ≥8 weeks after dose 2[4] **≥2 previous Pfizer doses:** One 3-mcg dose ≥8 weeks after last dose
5-11 years	10 mcg/0.3 mL; blue cap and label	One 10-mcg dose	One 10-mcg dose ≥2 months after last dose of any mRNA COVID-19 vaccine
≥12 years	30 mcg/0.3 mL; gray cap and label	One 30-mcg dose	One 30-mcg dose ≥2 months after last dose of any COVID-19 vaccine
Moderna Vaccine *(Spikevax)* – mRNA vaccine			
6 months-4 years	25 mcg/0.25 mL; dark blue cap/green label	Two 25-mcg doses 1 month apart[3]	**1 previous Moderna dose:** One 25-mcg dose ≥1 month after last dose **≥2 previous Moderna doses:** One 25-mcg dose ≥2 months after last dose
5-11 years	25 mcg/0.25 mL; dark blue cap/green label	One 25-mcg dose	One 25-mcg dose ≥2 months after last dose of any mRNA COVID-19 vaccine
≥12 years	50 mcg/0.5 mL; dark blue cap/blue label	One 50-mcg dose	One 50-mcg dose ≥2 months after last dose of any COVID-19 vaccine
Novavax Vaccine – adjuvanted protein subunit vaccine			
≥12 years	5 mcg (plus 50 mcg adjuvant)/0.5 mL; blue cap and label	Two 5-mcg doses 3 weeks apart[5]	One 5-mcg dose ≥2 months after last dose of any COVID-19 vaccine

1. The 2024-2025 vaccines contain a monovalent component that corresponds to the KP.2 (Pfizer and Moderna) or JN.1 (Novavax) Omicron variant of SARS-CoV-2.
2. For immunocompetent persons. Persons with moderate or severe immunocompromise may receive additional doses of the 2024-2025 COVID-19 vaccines based on the clinical judgement of a healthcare provider, personal preference of the patient, and other circumstances; additional doses should be given ≥2 months after the last 2024-2025 COVID-19 vaccine dose.
3. All doses should be from the same manufacturer.
4. In children who turn 5 years old before completion of the vaccination series, instead administer one 10-mcg Pfizer vaccine dose ≥2 months after the last 3-mcg dose.
5. According to the CDC, an 8-week interval between doses might be optimal for some patients, especially adolescent and young adult males, to reduce the risk of myocarditis and pericarditis (https://bit.ly/3KgPdxl).

community pharmacies to immunocompetent adults with COVID-like symptoms between September 2023 and May 2024, receipt of any 2023-2024 COVID-19 vaccine at least 7 days before the test was associated with a decreased incidence of SARS-CoV-2 infection. The estimated adjusted vaccine efficacy was 45%; it was 58% for infections likely caused by the XBB.1.5 variant, which the 2023-2024 vaccines targeted, and 37% for infections likely caused by the JN.1 variant.[6,7]

In similar analyses of tests administered to adults with COVID-like illness within 10 days before or 3 days after an emergency department/urgent care visit (n=245,504) or a hospitalization (n=77,103) between September 2023 and May 2024, receipt of any 2023-2024 COVID-19 vaccine at least 7 days before the test was associated with a decreased incidence of COVID-19 requiring an emergency department/urgent care visit (estimated adjusted vaccine efficacy 36%) or hospitalization (estimated adjusted vaccine efficacy 42%). Among hospitalized immunocompetent persons, the estimated adjusted vaccine efficacy against critical illness was 58%.[6,8]

ADVERSE EFFECTS — Adverse effects of previous formulations of the Novavax vaccine have included injection-site pain/tenderness, fatigue/malaise, myalgia, arthralgia, headache, nausea, and vomiting. Hypersensitivity reactions, myocarditis, and pericarditis have occurred rarely; the incidence of myocarditis and pericarditis is highest in adolescent and young adult males.[9]

DOSAGE RECOMMENDATIONS — The 2024-2025 Novavax COVID-19 vaccine is indicated for use in persons ≥12 years old. Generally, persons who have not been vaccinated against COVID-19 previously should receive 2 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. Additional doses, each given ≥8 weeks after the previous dose, can be considered for persons with immunocompromise (solid-organ transplant recipients and equivalent).[2,10]

CDC RECOMMENDATIONS — The CDC recommends that all persons ≥6 months old be immunized with a 2024-2025 COVID-19 vaccine formulation. Persons ≥12 years old can receive a Pfizer, Moderna, or Novavax vaccine. Persons 6 months to 11 years old should receive a Pfizer or Moderna vaccine.[10] ■

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