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COVID-19 Update

New Novavax Vaccine Formulation for 2023-2024

This article was published online ahead of print on October 18, 2023.

A new 2023-2024 formulation of the adjuvanted protein subunit COVID-19 vaccine manufactured by Novavax that was developed to more closely target currently circulating SARS-CoV-2 variants has been made available in the US under an FDA Emergency Use Authorization (EUA) for use in persons ≥ 12 years old. The original formulation of the Novavax vaccine is no longer authorized for use in the US.¹ In September, updated formulations of the mRNA

COVID-19 vaccines manufactured by Pfizer/BioNTech (*Comirnaty*) and Moderna (*Spikevax*) were licensed by the FDA for use in persons ≥ 12 years old and made available under EUAs for use in persons 6 months to 11 years old.²

THE NEW FORMULATION – The 2023-2024 formulation of the Novavax vaccine contains the spike protein of the XBB.1.5 Omicron strain of SARS-CoV-2.

EFFICACY – No clinical studies evaluating the effectiveness of the 2023-2024 Novavax vaccine are available. Authorization of the new formulation was based on immunogenicity data showing that it has

Table 1. Vaccination Recommendations for Updated 2023-2024 COVID-19 Vaccines^{1,2}

Age	Dose/Vial Color	Not Previously Vaccinated	Previously Vaccinated
Pfizer/BioNTech Vaccine (<i>Comirnaty</i>) – mRNA vaccine			
6 months-4 years ³	3 mcg/0.3 mL; yellow cap and label	3 doses: 1st at week 0, 2nd at week 3, 3rd ≥ 8 weeks after dose 2	<ul style="list-style-type: none"> ▶ 1 previous Pfizer dose: 1 dose ≥ 3 weeks later and 1 dose ≥ 8 weeks after dose 2 ▶ 2 previous Pfizer doses: 1 dose ≥ 8 weeks after last dose ▶ 3 previous Pfizer doses: 1 dose ≥ 2 months after last dose
5-11 years	10 mcg/0.3 mL; light blue cap and label	1 dose	▶ 1 dose ≥ 2 months after last dose of any mRNA COVID vaccine
≥ 12 years	30 mcg/0.3 mL; gray cap and label	1 dose	▶ 1 dose ≥ 2 months after last dose of any COVID vaccine
Moderna Vaccine (<i>Spikevax</i>) – mRNA vaccine			
6 months-4 years ³	25 mcg/0.25 mL; dark blue cap/green label	2 doses 1 month apart	<ul style="list-style-type: none"> ▶ 1 previous Moderna dose: 1 dose ≥ 1 month after last vaccine ▶ ≥ 2 previous Moderna doses: 1 dose ≥ 2 months after last vaccine
5-11 years	25 mcg/0.25 mL; dark blue cap/green label	1 dose	▶ 1 dose ≥ 2 months after last dose of any mRNA COVID vaccine
≥ 12 years	50 mcg/0.5 mL; blue cap and label	1 dose	▶ 1 dose ≥ 2 months after last dose of any COVID vaccine
Novavax Vaccine – adjuvanted protein subunit vaccine			
≥ 12 years	5 mcg (plus 50 mcg adjuvant)/0.5 mL; blue cap and label	2 doses 3 weeks apart ⁴	▶ 1 dose ≥ 2 months after last dose of any COVID vaccine

1. The updated 2023-2024 formula vaccines include a monovalent component that corresponds to the Omicron variant XBB.1.5. Previous bivalent Moderna and Pfizer/BioNTech and monovalent Novavax vaccines are no longer authorized for use in the US. The Johnson & Johnson (Janssen) vaccine is no longer available in the US.
2. For immunocompetent persons. Persons with moderate or severe immunocompromise may receive additional doses of the 2023-2024 COVID-19 formula vaccines based on the clinical judgement of a healthcare provider and personal preference and circumstances; additional doses should be given ≥ 2 months after the last 2023-2024 COVID-19 vaccine dose.
3. Includes children who would turn 5 years old during the vaccination series. All doses should be from the same manufacturer.
4. 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>).

neutralization potency against currently circulating strains of the virus, including EG.5 (Eris), FL.1.5.1 (Fornax), and various XBB-lineage strains.^{1,3}

ADVERSE EFFECTS – Adverse effects of the original Novavax vaccine have included injection-site pain/tenderness, fatigue/malaise, myalgia, arthralgia, headache, nausea, and vomiting. Hypersensitivity reactions, myocarditis, and pericarditis have occurred rarely with the Novavax and mRNA vaccines; the incidence of myocarditis and pericarditis is highest in adolescent and young adult males.^{4,5}

DOSAGE RECOMMENDATIONS – The updated Novavax COVID-19 vaccine is indicated for use in persons ≥ 12 years old who have not already received another 2023-2024 COVID-19 vaccine formulation. Generally, persons who have **previously been vaccinated against COVID-19** should receive a single 0.5-mL dose ≥ 2 months after their previous COVID-19 vaccine dose. Those who have **not previously been vaccinated against COVID-19** should receive 2 doses; the product labeling recommends that they be given 3 weeks apart, but 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. Additional vaccine doses, each

given ≥ 8 weeks after the previous COVID-19 vaccine dose, can be considered for persons with **immunocompromise** (solid-organ transplant recipients and equivalent).^{4,5}

CDC RECOMMENDATIONS – The CDC recommends that all persons ≥ 6 months old be immunized with a 2023-2024 COVID-19 vaccine formulation. Persons ≥ 12 years old can receive a 2023-2024 Pfizer, Moderna, or Novavax vaccine. Persons 6 months to 11 years old should receive a Pfizer or Moderna vaccine.⁵ ■

1. FDA News Release. FDA authorizes updated Novavax COVID-19 vaccine formulated to better protect against currently circulating variants. October 3, 2023. Available at: <https://bit.ly/3Fa4Kx8>. Accessed October 18, 2023.
2. COVID-19 Update: New Pfizer and Moderna vaccine formulations for 2023-2024. *Med Lett Drugs Ther* 2023; 65:167.
3. F Dubovsky. Data in support of Novavax XBB.1.5 vaccine. ACIP. September 12, 2023. Available at: <https://bit.ly/48ILUuB>. Accessed October 18, 2023.
4. FDA. Fact sheet for healthcare providers administering vaccine: Emergency Use Authorization of Novavax vaccine, adjuvanted (2023-2024 formula), for individuals 12 years of age and older. October 3, 2023. Available at: <https://bit.ly/46M6kBa>. Accessed October 18, 2023.
5. CDC. Interim clinical considerations for use of COVID-19 vaccines in the United States. October 6, 2023. Available at: <https://bit.ly/3KgPdxl>. Accessed October 18, 2023.

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