

# The Medical Letter<sup>®</sup>

## on Drugs and Therapeutics

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Advance  
Release  
Article

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COVID-19 Update: Novavax Vaccine for 2024-2025

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### 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  $\geq 12$  years old.<sup>1,2</sup> 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  $\geq 12$  years old and made available under EUAs for use in persons 6 months to 11 years old.<sup>3</sup>

**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.<sup>4,5</sup> The Pfizer and Moderna 2024-2025 vaccines code for the spike protein of the KP.2 strain.<sup>3</sup>

**Table 1. Recommendations for 2024-2025 COVID-19 Vaccines<sup>1,2</sup>**

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

**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.<sup>1,2</sup>

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 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.<sup>6,7</sup>

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%.<sup>6,8</sup>

**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.<sup>9</sup>

**DOSAGE RECOMMENDATIONS** — The 2024-2025 Novavax COVID-19 vaccine is indicated for use in persons  $\geq 12$  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  $\geq 2$  months after their last COVID-19 vaccine dose. Additional doses, each given  $\geq 8$  weeks after the previous dose, can be considered for persons with immunocompromise (solid-organ transplant recipients and equivalent).<sup>2,10</sup>

**CDC RECOMMENDATIONS** — The CDC recommends that all persons  $\geq 6$  months old be immunized with a 2024-2025 COVID-19 vaccine formulation. Persons  $\geq 12$  years old can receive a Pfizer, Moderna, or Novavax vaccine. Persons 6 months to 11 years old should receive a Pfizer or Moderna vaccine.<sup>10</sup> ■

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