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COVID-19 Update

Novavax Vaccine Authorized for Adolescents 12-17 Years Old

The FDA has expanded its Emergency Use Authorization for the adjuvanted protein subunit COVID-19 vaccine manufactured by Novavax to include use of the vaccine as a two-dose primary series in adolescents 12-17 years old.[1] The vaccine was authorized for primary immunization of adults in July 2022.[2]

CLINICAL STUDIES — Expansion of the EUA was based on the results of a study (summarized in the FDA Fact Sheet) comparing the immunogenicity of two Novavax vaccine doses given 3 weeks apart in 390 adolescents 12-17 years old with that in 415 adults 18-25 years old. At 14 days after the second dose, the geometric mean anti-SARS-CoV-2 neutralizing antibody titer level was higher in the adolescent group than among the young adults (3859.6 vs 2611.8; geometric mean ratio 1.47 [95% CI 1.26-1.72]), and 99% of adolescents had experienced a seroresponse.[3]

In an observer-blind trial (PREVENT-19 expansion; summarized in the FDA Fact Sheet), 2247 adolescents 12-17 years old were randomized 2:1 to receive the Novavax vaccine or placebo at 0 and 3 weeks. Immunocompromised persons and those with a history of SARS-CoV-2 infection were excluded. In a descriptive per-protocol efficacy analysis in 1799 adolescents, PCR-confirmed COVID-19 with onset ≥7 days after the second dose was found to have occurred in 5 subjects who received the vaccine and in 11 who received placebo; the vaccine efficacy rate was 78.3% (95% CI 37.6%-92.5%). All COVID-19 cases in both groups were mild in severity, and all genetically sequenced cases were caused by the Delta variant of SARS-CoV-2.[3]

ADVERSE EFFECTS — Adverse effects of the Novavax vaccine in adolescents appear to be similar to those in adults. In the PREVENT-19 expansion, the most common severe adverse effects after the second vaccine dose were injection-site pain/tenderness (7.7%) and systemic myalgia (7.5%). Myocarditis occurred in one adolescent who received the vaccine.[3]

DOSAGE AND ADMINISTRATION — The FDA-approved dosage of the Novavax vaccine for primary immunization in adolescents is 0.5 mL (5 mcg of vaccine with 50 mcg of adjuvant) injected intramuscularly at 0 and 3 weeks, the same as that in adults.[3] According to the CDC, an 8-week interval between doses may be optimal for immunocompetent adolescents, especially males, to reduce the small risk of myocarditis/pericarditis.[4] ■

1. FDA News Release. FDA roundup: August 19, 2022. Available at: https://bit.ly/3dKGxmt. Accessed August 30, 2022.
2. COVID-19 update: FDA authorizes Novavax COVID-19 vaccine. Med Lett Drugs Ther 2022; 64:121.
3. FDA. Fact sheet for health care providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Novavax COVID-19 vaccine, adjuvanted to prevent coronavirus disease 2019 (COVID-19). August 19, 2022. Available at: https://bit.ly/3o702aV. Accessed August 30, 2022.
4. CDC. Interim clinical considerations for use of COVID-19 vaccines currently approved or authorized in the United States. August 22, 2022. Available at: https://bit.ly/3KgPdxl. Accessed August 30, 2022.

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