# The Medical Letter®

## on Drugs and Therapeutics

Volume 64 Published online October 31, 2022

Online Article

IN THIS ISSUE

COVID-19 Update: Novavax Vaccine Authorized for Booster Immunization

The Medical Letter®
on Drugs and Therapeutics

Volume 64 Published online October 31, 2022

Online Article

IN THIS ISSUE

Novavax Vaccine Authorized for Booster Immunization ..... p 1

COVID-19 UPDATE

## Novavax Vaccine Authorized for Booster Immunization

The FDA has expanded its Emergency Use Authorization for the adjuvanted protein subunit COVID-19 vaccine manufactured by Novavax to include its use as a first booster dose in adults who completed a primary series with any COVID-19 vaccine ≥6 months previously and are unable or unwilling to receive a booster dose of a bivalent mRNA vaccine. The Novavax vaccine is not authorized for use in persons who have received a booster dose of any other COVID-19 vaccine.[1]

**CLINICAL STUDIES —** In an unpublished, open-label, longitudinal immunogenicity trial (summarized in the FDA Fact Sheet), 243 subjects who had completed a primary series with the Novavax COVID-19 vaccine ≥6 months previously and had no evidence of prior SARS-CoV-2 infection were given a booster dose of the Novavax vaccine. At 28 days after the booster dose, the geometric mean 50% anti-SARS-CoV-2 neutralizing antibody titer level was higher than it was at 14 days after completion of the primary series (5075.6 vs 1505.7; geometric mean ratio 3.4 [95% CI 2.8-4.0]), and titer levels were ≥4-fold higher than they were before booster immunization in 85% of subjects.[2]

In one cohort of a randomized, double-blind immunogenicity study in adults ≥30 years old with no evidence of prior SARS-CoV-2 infection, 232 subjects who had completed a primary series with the Pfizer/BioNTech COVID-19 vaccine *(Comirnaty)* ≥84 days previously were given either a booster dose of the Novavax vaccine or a meningococcal vaccine. The geometric mean 50% anti-SARS-CoV-2 neutralizing antibody titer level 28 days after vaccination was ~5 fold higher in the Novavax group than in the control group.[3]

**ADVERSE EFFECTS —** Adverse effects with a booster dose of the Novavax vaccine in adults appear to be similar to those with a second primary-series dose.[4] Myocarditis was reported in one patient who received a booster dose in the longitudinal study. Other serious adverse effects such as autoimmune hepatitis, local muscle edema and cellulitis, and venous thromboembolism have been reported following booster immunization with the Novavax vaccine, but causal relationships have not been established.[2]

**DOSAGE AND ADMINISTRATION —** The recommended booster dosage of the Novavax vaccine is 0.5 mL (5 mcg of vaccine with 50 mcg of adjuvant) injected intramuscularly ≥6 months after completion of a primary series with any COVID-19 vaccine.

**RECOMMENDATIONS —** CDC guidelines recommend that adults who have completed a primary series with any COVID-19 vaccine receive a booster dose of either the bivalent Pfizer vaccine or the bivalent Moderna vaccine *(Spikevax)* ≥2 months after their most recent monovalent vaccine dose.[5] The Novavax vaccine may be given as a booster dose to adults who have completed a primary series of any COVID-19 vaccine ≥6 months previously, have not received a COVID-19 vaccine booster dose of any type, and are unable or unwilling to receive a booster dose of either the bivalent Pfizer vaccine or the bivalent Moderna vaccine.[6] ■

1. FDA News Release. FDA Roundup: October 21, 2022. Available at: https://bit.ly/3FbuAC5. October 31, 2022.
2. FDA. Fact sheet for health care providers administering vaccine (vaccination providers). Emergency Use Authorization (EUA) of the Novavax vaccine, adjuvanted to prevent coronavirus disease 2019 (COVID-19). October 31, 2022. Available at: https://bit.ly/3o702aV. November 10, 2022.
3. APS Munro et al. Safety and immunogenicity of seven COVID-19 vaccines as a third dose (booster) following two doses of ChAdOx1 nCov-19 or BNT162b2 in the UK (COV-BOOST): a blinded, multicentre, randomised, controlled, phase 2 trial. Lancet 2021; 398:2258.

4. COVID-19 Update: FDA authorizes Novavax COVID-19 vaccine. Med Lett Drugs Ther 2022; 64:121.
5. COVID-19 Update: Bivalent Pfizer and Moderna COVID-19 vaccines for booster immunization. Med Lett Drugs Ther 2022; 64:159.
6. CDC. Interim clinical considerations for use of COVID-19 vaccines currently approved or authorized in the United States. October 19, 2022. Available at: https://bit.ly/3KgPdxl. October 31, 2022.