

Novavax and Serum Institute of India Receive Expanded Emergency Use Authorization for Novavax' COVID-19 Vaccine in Thailand in Adolescents Aged 12 Through 17

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Novavax today announced that the Thailand Food and Drug Administration (Thai FDA) has granted expanded emergency use authorization (EUA) for Novavax' protein-based vaccine for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adolescents aged 12 through 17. The vaccine, also known as NVX-CoV2373, is manufactured and marketed by the Serum Institute of India under the brand name Covovax™.

The expanded EUA is based on data from the ongoing [pediatric expansion](#) of the Phase 3 PREVENT-19 trial of 2,247 adolescents aged 12 through 17 years across 73 sites in the U.S., to evaluate the safety, effectiveness (immunogenicity), and efficacy of the Novavax COVID-19 vaccine. In the trial, the vaccine achieved its primary effectiveness endpoint and demonstrated 80% clinical efficacy overall at a time when the Delta variant was the predominant circulating SARS-CoV-2 strain in the U.S.

Preliminary safety data from the trial showed that serious and severe adverse events were low in number and balanced between vaccine and placebo groups, and not considered related to the vaccine. Local and systemic reactogenicity was generally lower than or similar to adults, after the first and second dose. The most common adverse reactions observed were injection site tenderness/pain, headache, myalgia, fatigue, and malaise. There was no increase in reactogenicity in younger (12 to <15 years old) adolescents compared to older (15 to <18 years old) adolescents. No new safety signal was observed through the placebo-controlled portion of the study.

The Thai FDA granted EUA for the vaccine in [April 2022](#) for use in adults aged 18 and older.

Authorized Use of Novavax' COVID-19 Vaccine in Thailand

The Thai FDA has issued EUA for Covovax /Recombinant Spike Protein of SARS-CoV-2 Virus 5 mcg to induce immunity against SARS-CoV-2 to prevent COVID-19 for individuals 12 years old and above.

For additional information on Covovax, please visit the following websites:

- [Serum Institute of India](#)
- [Thai FDA](#)