

Pfizer says COVID shot 100% effective in adolescents after 4 months

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A boy receives the first dose of the Pfizer/BioNTech COVID-19 vaccine in Tegucigalpa, Honduras.

Pfizer and BioNTech said Monday their COVID-19 vaccine remained 100 percent effective in children 12 to 15 years old, four months after the second dose.



The companies said that the new data, which involved 2,228 trial participants, will help support their applications for full approval in the United States and worldwide.

No serious safety concerns were observed in individuals with at least six months of follow-up after the second dose.

"As the global health community works to increase the number of vaccinated people around the world, these additional data provide further confidence in our vaccine's safety and effectiveness profile in adolescents," said Pfizer CEO Albert Bourla in a statement.

"This is especially important as we see rates of COVID-19 climbing in this age group in some regions, while vaccine uptake has slowed. We look forward to sharing these data with the FDA and other regulators."

The vaccine was granted "emergency use authorization" for adolescents by the US in May and the companies plan to soon seek full approval. The vaccine is currently only fully approved in people aged 16 and older.

Among the 2,228 participants, there were 30 confirmed symptomatic COVID cases without evidence of prior infection, all in the <u>placebo</u> group.

This corresponds to a <u>vaccine efficacy</u> of 100 percent. Efficacy was consistently high across gender, race, obesity levels and comorbidity status.

The main safety concern among this age group is <u>vaccine</u>-linked myocarditis (heart inflammation) in males.

But such cases are very rare, and the benefits of vaccination continue to strongly outweigh the risks, data has shown. COVID itself can cause



myocarditis, both more often and a more severe form.

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