

# Frequently Asked Questions about the Pfizer-BioNTech COVID-19 vaccine for Parents and Caregivers of Children 5 to 11 years old


The US Food and Drug Administration (FDA) authorized the use of the Pfizer-BioNTech COVID-19 vaccine for children 5 to 11 years under an Emergency Use Authorization (EUA) to prevent COVID-19.

This vaccine is a primary series of two shots given to these children, in an arm muscle, 3 weeks apart. The FDA has also authorized a third primary shot for children in this age group who have been determined to have certain kinds of conditions that cause their immune systems to be compromised. It is a lower dose than what is given in the vaccines for those 12 years and older.

At this time, the FDA has authorized booster shots only for those 12 and older. Children 5 to 11 who are fully vaccinated and are not immunocompromised do not need a third dose at this time. The FDA will continue to review information and communicate with the public if data emerges suggesting booster doses are needed for this group of children.

**Q: How well does the Pfizer-BioNTech/Comirnaty COVID-19 vaccine prevent COVID-19 in individuals 5 to 11 years?** 

A: Based on results from the clinical trial data, the vaccine was 91% effective in preventing COVID-19 in children.

**Q: Has the vaccine been used before?** 

A; In the United States, more than 7 million children 5 to 11 years old have received both doses of the COVID-19 vaccine since the Pfizer-BioNTech COVID-19 vaccine was authorized under the EUA. Overall, more than 300 million Pfizer vaccines have been administered, and more than 123 million people have been fully vaccinated with this vaccine. More than 52 million boosters of this vaccine have also been given.

**Q: What are the benefits of the vaccine?** 

A: The vaccine has been shown to prevent COVID-19 and to prevent severe COVID-19 that results in hospitalization or death. The duration of protection against COVID-19 is currently unknown but is being studied.

**Q: What are the risks of the vaccine?**



A: Commonly reported side effects in the clinical trial included injection site pain (sore arm), redness and swelling, fatigue, headache, muscle and/or joint pain, chills, fever, swollen lymph nodes, nausea and decreased appetite. More children reported side effects after the second dose than after the first dose. Side effects were generally mild to moderate in severity and occurred within two days after vaccination, and most went away within one to two days.

The vaccine may not protect everyone from getting COVID-19, but it is effective in preventing COVID-19 and potentially serious outcomes, including hospitalization or death.

There is a remote chance the vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the vaccine. For this reason, vaccination provider may ask your child to stay for monitoring after the vaccination. Children should not get the vaccine if they have had a severe allergic reaction after a previous dose of this vaccine or to any ingredient in this vaccine.

The chance of this occurring is very low, but some people who received the vaccine experienced myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the lining outside the heart). In most of these people, symptoms began within a few days following receipt of the second dose of vaccine.

These may not be all the possible side effects of the vaccine. Serious and unexpected side effects may occur. The possible side effects of the vaccine are still being studied in clinical trials.

It is important to note that as a general matter, while some individuals may experience side effects following any vaccination, not every individual's experience will be the same, and some people may not experience side effects.

**Q: Can the vaccine cause infertility in women?**



A: There is no scientific evidence to suggest that the vaccine causes infertility in women. Infertility is also not known to occur as a result of natural COVID-19 disease, further demonstrating that immune responses to the virus are not a cause of infertility whether induced by infection or a vaccine. Reports on social media have falsely stated the vaccine could cause infertility in women and contrary to false reports on social media, the protein in the vaccine is not the same as any involved in the formation of the placenta.

The FDA is concerned this misinformation may cause women to avoid vaccination to prevent COVID-19, a potentially serious and life-threatening disease. Many people have no symptoms or only mild disease, while some have severe respiratory disease, including pneumonia and acute respiratory distress syndrome (ARDS), leading to multi-organ failure and death.

**Q: Will the vaccine give my child COVID-19?**



A: No. The vaccine does not contain SARS-CoV-2, the virus that causes COVID-19, and cannot give your child COVID-19.

**Q: What is Emergency Use Authorization?**



A: The Emergency Use Authorization (EUA) authority allows the Secretary of the U. S. Department of Health and Human Services (HHS) to declare that EUAs are justified for medical products to respond to certain types of public health threats, including infectious diseases. EUAs are authorized only when statutory requirements are met and in appropriate circumstances that are determined to have a significant potential to affect national security, or the health and security of U.S. citizens. On February 4, 2020, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act, the HHS Secretary determined the virus that causes COVID-19 constituted such a public health emergency.