Frequently Asked Questions about the Pfizer-BioNTech/Comirnaty COVID-19 Vaccine

The U.S. Food and Drug Administration announced the first approval of a COVID-19 vaccine for the prevention of COVID-19 in individuals 16 years and older on August 23, 2021. The vaccine has been known as the Pfizer-BioNTech COVID-19 vaccine and is now being marketed as Comirnaty.

The vaccine is administered in a two-dose series of shots into an arm muscle given 3 weeks apart. A third primary series dose may be administered at least 4 weeks after the second dose to individuals who are determined to have certain kinds of immunocompromise.

For those 12 years and older, FDA has also authorized a single booster dose administered at least 5 months after completing a primary series of the vaccine.

Q: How effective is Pfizer-BioNTech/Comirnaty?

A: Overall, the vaccine was 91% effective in preventing COVID-19 disease, with 77 cases of COVID-19 occurring in the vaccine group and 833 COVID-19 cases in the placebo group.

Q: Has the vaccine been used before?

A: More than 300 million Pfizer-BioNTech/Comirnaty 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: Will the vaccine give me COVID-19?

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

Q: What are the risks of the vaccine?

A: The most commonly reported side effects by clinical trial participants who received the Pfizer-BioNTech/Comirnaty vaccine were pain, redness and swelling at the injection site, fatigue, headache, muscle or joint pain, chills, and fever. 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, the vaccination provider may ask you to stay for monitoring after the vaccination. You should not get the vaccine if you have had a severe allergic reaction after a previous dose of this vaccine or to any ingredient of 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 after they got the second vaccine shot, particularly within 7 days following this second dose. The risk was observed to be higher in men younger than 40 years than in women or older men. The observed risk was highest in 12- to 17-years-old boys. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some required intensive care support. Information is not yet available about potential long-term health outcomes.

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 people who have had COVID-19 already get the Pfizer-BioNTech/Comirnaty COVID-19 vaccine?

A: Yes. Current scientific evidence suggests that individuals previously infected with SARS-CoV-2, including individuals who have had COVID-19, may be at risk of reinfection and developing COVID-19 again and could benefit from vaccination. Furthermore, available data suggest that the safety profile of the vaccine in previously infected individuals is just as favorable as in previously uninfected individuals.

Q: Can you describe the mRNA technology of the Pfizer-BioNTech/Comirnaty COVID-19 Vaccine? Are there any safety concerns considering the "newness" of the technology?

A: The Pfizer-BioNTech/Comirnaty COVID-19 vaccine contains messenger RNA (mRNA), which is genetic material. The vaccine contains a synthetic piece of mRNA that instructs cells in the body to make the distinctive "spike" protein of the SARS-CoV-2 virus. When vaccinated, the body produces copies of the spike protein, which alone does not cause disease, and the immune system learns to react defensively, producing an immune response against SARS-CoV-2.

FDA scientists have expertise with this technology as it has been used to develop other preventive investigational vaccines that have been tested in human clinical trials. The FDA does not have specific safety concerns with a vaccine that utilizes this technology

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: Can pregnant or breastfeeding women receive the Pfizer-BioNTech/Comirnaty COVID-19 vaccine?

A: Yes. There is no reason pregnant or breastfeeding women should not receive this vaccine. Pregnant or breastfeeding women should discuss potential benefits and risks of vaccination with their healthcare provider.

Q: Am I currently eligible for COVID-19 vaccine boosters dose, and if so, which one?

A: If you are 18 or older and received the Pfizer-BioNTech COVID-19 vaccine, Comirnaty COVID-19 vaccine or Moderna COVID-19 vaccine for your primary vaccination series at least 5 months ago, you may receive a single booster dose of any of the currently available COVID-19 vaccines. They are:

-- Moderna COVID-19 vaccine

-- Pfizer-BioNTech COVID-19 vaccine

-- Comirnaty Vaccine

-- Janseen (J&J) COVID-19 vaccine

-- Spikevax vaccine

If you are 18 or older and received the Janssen (J&J) COVID-19 vaccine as your primary vaccination at least 2 months ago, you may receive a booster dose of any of the vaccines currently available in the US.

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.