Q&A for Comirnaty (COVID-19 Vaccine mRNA)

Español (https://www.fda.gov/vaccines-blood-biologics/preguntas-y-respuestas-sobre-comirnaty-vacuna-de-arnm-contra-el-covid-19)

How did the FDA arrive at the decision to approve Comirnaty (COVID-19 Vaccine mRNA)? What is different now when compared to the December 2020 authorization of Pfizer-BioNTech COVID-19 Vaccine?

FDA conducted a thorough evaluation of the data and information submitted in the Biologics License Application (BLA) for Comirnaty before making a determination that the vaccine is safe and effective in preventing COVID-19 in individuals 16 years of age and older.

The EUA (/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19) for the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 years of age and older was based on safety and effectiveness data from a randomized, controlled, blinded ongoing clinical trial in approximately 18,000 individuals who received the vaccine and approximately 18,000 who received a placebo. The vaccine was 95% effective in preventing COVID-19 disease among these clinical trial participants with eight COVID-19 cases in the vaccine group and 162 in the placebo group. The duration of safety follow-up for the vaccinated and placebo participants was a median of two months after receiving the second dose.

Follow-up data from this ongoing clinical trial was analyzed by FDA to determine the safety and effectiveness of Comirnaty. The updated analysis to determine effectiveness for individuals 16 years of age and older included approximately 20,000 Comirnaty and 20,000 placebo recipients who did not have evidence of SARS-CoV-2 infection through seven days after the second dose. Overall, the vaccine was 91% effective, with 77 cases of COVID-19 occurring in the vaccine group and 833 COVID-19 cases in the placebo group.

The safety was evaluated in approximately 22,000 Comirnaty and 22,000 placebo recipients 16 years of age and older. More than half of the vaccine and placebo recipients were followed for safety for at least four months after the second dose. After issuance of the EUA, participants were unblinded in a phased manner over a period of months to offer placebo participants Comirnaty. Overall, in blinded and unblinded follow-up, approximately 12,000 Comirnaty recipients have been followed for at least 6 months.

How safe and effective is Comirnaty (COVID-19 Vaccine mRNA)?

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.

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle pain, chills, joint pain and fever.

The FDA conducted a rigorous evaluation of post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of Pfizer-BioNTech COVID-19 Vaccine and determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes. The Comirnaty Prescribing Information (/media/151707/download) includes a warning about these risks.

What are the most commonly reported side effects by those who received Comirnaty (COVID-19 Vaccine mRNA)?

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever.

How long will Comirnaty provide protection?

Data are not yet available to inform about the duration of protection that the vaccine will provide.

Can people who have already had COVID-19 get Comirnaty?

Yes. Among the participants in the study that the FDA evaluated for the December 2020 authorization, relatively few confirmed COVID-19 cases occurred overall among clinical study participants with evidence of SARS-CoV-2 infection prior to vaccination.

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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.

Does Comirnaty protect against asymptomatic SARS-CoV-2 infection (i.e. the individual is infected with SARS-CoV-2, but does not have signs or symptoms of COVID-19)?

It is not known if Comirnaty protects against asymptomatic SARS-CoV-2 infection.

If a person has received Comirnaty, will the vaccine protect against transmission of SARS-CoV-2 from individuals who are infected despite vaccination?

Most vaccines that protect from viral illnesses also reduce transmission of the virus that causes the disease by those who are vaccinated. While it is hoped this will be the case, the scientific community does not yet know if Comirnaty will reduce such transmission.

Can Comirnaty cause infertility in women?

There is no scientific evidence to suggest that the vaccine could cause infertility in women. In addition, infertility is not known to occur as a result of natural COVID-19 disease, further demonstrating that immune responses to the virus, whether induced by infection or a vaccine, are not a cause of infertility. Reports on social media have falsely asserted that the vaccine could cause infertility in women and the FDA is concerned that this misinformation may cause women to avoid vaccination to prevent COVID-19, which is a potentially serious and life-threatening disease. SARS-CoV-2 is the virus that causes COVID-19. The symptoms of COVID-19 vary and are unpredictable; 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. Comirnaty is a mRNA vaccine. It contains a piece of the SARS-CoV-2 virus's genetic material that instructs cells in the body to make the virus's distinctive "spike" protein. After a person is vaccinated, their body produces copies of the spike protein, which does not cause disease, and triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2. Contrary to false reports on social media, this protein is not the same as any involved in the formation of the placenta.

After FDA granted the emergency use authorization of the Pfizer BioNTech COVID-19 Vaccine were clinical trial participants unblinded so that the placebo recipients could be offered the vaccine?

Yes. After issuance of the EUA, clinical trial participants were unblinded in a phased manner over a period of months to offer the authorized Pfizer-BioNTech COVID-19 Vaccine to placebo participants. These participants were followed for safety outcomes. Overall, in blinded and unblinded follow-up, approximately 12,000 Pfizer-BioNTech COVID-19 Vaccine recipients have been followed for at least 6 months.

Does the emergency use authorization (EUA) for Pfizer-BioNTech COVID-19 Vaccine remain in effect after the approval?

Yes. Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use and is available under the EUA as a two dose primary series in individuals 5 years of age and older, as a third primary series dose for individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise, and as a single booster dose for individuals 12 years of age and older at least 5 months after completing a primary series of the Pfizer-BioNTech COVID-19 Vaccine or Comirnaty.

The Pfizer-BioNTech COVID-19 Vaccine is also authorized for use as a heterologous (or "mix and match") single booster dose for individuals 18 years of age and older following completion of primary vaccination with a different authorized COVID-19 vaccine.

How is Comirnaty (COVID-19 Vaccine, mRNA) related to the Pfizer-BioNTech COVID-19 Vaccine authorized for emergency use?

The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the FDA-emergency use authorized Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under EUA to administer the vaccination series as if the doses were the licensed vaccine. For

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purposes of administration, doses distributed under the EUA are interchangeable with the licensed doses. The Vaccine Information Fact Sheet for Recipients and Caregivers (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine#additional) provides additional information about both the approved and authorized vaccines.

Can Comirnaty and the Pfizer-BioNTech COVID-19 Vaccine be used interchangeably?

The FDA-approved Comirnaty (COVID-19 Vaccine, mRNA) and the two EUA-authorized formulations of the Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older when prepared according to their respective instructions for use, can be used interchangeably.

The formulation of the Pfizer-BioNTech COVID-19 Vaccine authorized for use in children 5 through 11 years of age differs from the formulations authorized for older individuals. The Pfizer-BioNTech COVID-19 Vaccine authorized for use in children 5 through 11 years of age should not be used interchangeably with Comirnaty.

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