

2021-041

23
August
2021PLEASE
REVIEW

Drug Information

PharmPix Clinical Department

Drug Information:

The FDA approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 vaccine, and will now be marketed as Comirnaty™, for the prevention of COVID-19 disease in individuals 16 years of age and older.

QUESTIONS

Call us at 787-522-5252-X-220

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PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate you with the latest up-to-date drug information requested.

Summary of Clinical Topic

The U.S. Food and Drug Administration approved Comirnaty (COVID-19 vaccine mRNA), which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

Clinical Information

After the evaluation of the data and information submitted in the Biologics License Application (BLA) for Comirnaty, the FDA determined the vaccine is safe and effective in preventing COVID-19 in individuals 16 years of age and older.

Comirnaty™ is administered intramuscularly as a series of 2 doses 3 weeks apart.

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 common side effects were pain, redness and swelling at the injection site, fatigue, headache, muscle pain, chills, joint pain, and fever. The vaccine is contraindicated in individuals with known history of a severe allergic reaction (e.g., anaphylaxis) to any component of Comirnaty.

The FDA evaluated the post-authorization safety surveillance data pertaining to myocarditis and pericarditis following the administration of the Pfizer-BioNTech COVID-19 vaccine and has determined that Comirnaty has an increased risk of myocarditis and pericarditis, particularly within 7 days following the second dose.

Availability and Coverage:

The vaccine also continues to be available under emergency use authorization (EUA), including individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

The EUA will continue to cover the use of the Pfizer-BioNTech COVID-19 vaccine in individuals 16 years of age and older until sufficient approved vaccine can be manufactured and distributed.

Additional information can be found at:

1. [Prescribing information](#) for Comirnaty™
2. FDA's news release: [FDA Approves First COVID-19 Vaccine](#)
3. FDA's [Q&A section for Comirnaty™](#)

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252-X-220.

Our pharmacists will help you. In addition, know that you can access our recent communications at our providers' portal: <https://www.pharmpix.com/providers/>.

PharmPix Drug Information Communication Number 041 August 2021



REFERENCES:

1. FDA Approves First COVID-19 Vaccine. U.S. Food and Drug Administration. (2021). Retrieved 23 August 2021, from <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>
2. Comirnaty™ Prescribing Information. (2021). Retrieved 23 August 2021, from <https://www.fda.gov/media/151707/download>.