Information about the Pfizer-BioNTech COVID-19 Vaccine

On December 11, 2020, the FDA issued an Emergency Use Authorization for the Pfizer-BioNTech COVID-19 vaccine to protect people 16 years or older from COVID-19 infection. This authorization justifies the emergency use of vaccines during the current pandemic.

This fact sheet contains information about the Pfizer vaccine that is intended to help you make the most informed decision possible about getting the vaccine to better protect yourself, your loved ones, and tribal communities, both urban and rural.

Who is the Pfizer-BioNTech COVID-19 vaccine for?

The Pfizer-BioNTech COVID-19 vaccine has been authorized for those 16 years or older. However, you should talk with your provider to discuss the risks and benefits before getting the vaccine if you:

- have any allergies.
- have a bleeding disorder or are on a blood thinner.
- are immunocompromised or are taking medication that affects your immune system.
- have a fever.
- are pregnant or plan to become pregnant.
- are breastfeeding.
- have received another COVID-19 vaccine (U.S. FDA, 2020a).

You should not get the vaccine if you have had a severe allergic reaction after a previous dose of the vaccine or if you have had a severe allergic reaction to any of the vaccine ingredients (U.S. FDA, 2020a). A list of ingredients can be found on the official Pfizer-BioNTech fact sheet (U.S. FDA, 2020a).

Is the Pfizer-BioNTech COVID-19 vaccine safe?

Over 43,000 people participated in testing this vaccine, and roughly 21,000 people received at least one dose. The clinical trial included a diverse population of participants including Natives (0.6%), people over the age of 65 (21.4%), and people with at least one condition that increases the risk of severe COVID-19 disease (46.2%) such as obesity, diabetes, and chronic pulmonary disease. Research studies are ongoing, and the Centers for Disease Control and Prevention is closely monitoring any negative side effects that occur (U.S. FDA, 2020b).

Dr. Socia Love-Thurman (Delaware, Yuchi, Cherokee)

How does the Pfizer-BioNTech COVID-19 vaccine work?

The Pfizer-BioNTech vaccine uses mRNA technology to start an immune response in our bodies that will produce antibodies to protect against future infection of COVID-19.

mRNA has been studied for decades, and Pfizer-BioNTech and other companies used this technology to assist in creating the current vaccines. More information about mRNA vaccines can be found on the CDC website (CDC, 2020).

How is the Pfizer-BioNTech COVID-19 vaccine given?

- The vaccine is given in a series of two doses given three weeks apart.
- The vaccine is injected into the muscle in your upper arm.
- After receiving the first dose, you must plan on returning within 21 days for the second dose.

Will the Pfizer-BioNTech COVID-19 vaccine prevent me from getting COVID-19?

Although clinical trials indicate that the Pfizer-BioNTech vaccine has been shown to prevent COVID-19, it may not protect everyone (U.S. FDA, 2020b). It is important to continue to practice all safety measures to help stop the spread of COVID-19, including:

- wearing a mask.
- social distancing.
- washing your hands.
- following local public health recommendations.

What are the benefits of getting vaccinated?

- We protect ourselves from serious illness and make our communities less vulnerable to infection.
- We are significantly less likely to present severe COVID-19 symptoms or fall deathly ill.

What are the risks of getting vaccinated?

Common side effects that have been reported after receiving the Pfizer-BioNTech vaccine include:

- pain, swelling, or redness at the injection site.
- tenderness and swelling of the lymph nodes in the same arm of the injection.
- headache or fatigue.
- muscle or joint pain.
- chills or fever.
- nausea or vomiting (U.S. FDA, 2020a).

These symptoms typically resolve within 24 hours. Call your provider if any side effects do not go away. In addition, you can report any side effects to Pfizer Inc. at **1–800–438–1985**.

While more serious side effects like severe allergic reactions and Bell's palsy have been reported, these side effects are generally considered rare and there is currently not enough information to determine if they were caused by the vaccine (FDA, 2020b).

If you have other concerns or questions: You can visit **www.cvdvaccine.com or call 1–877–829–2619**.

References

Centers for Disease Control and Prevention. (2020, December 18). *Understanding mRNA COVID-19 vaccines*. www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html

United States Food and Drug Administration. (2020a). *Fact sheet for recipients and caregivers: Emergency Use Authorization (EUA) of the Pfizer-BioNTech COVID-19 vaccine to prevent coronavirus disease 2019 (COVID-19) in people 16 years of age and older*. www.fda.gov/media/144414/download

United States Food and Drug Administration. (2020b, December 10). *Vaccines and Related Biological Products Advisory Committee: FDA Briefing Document*. www.fda.gov/media/144245/download