At the time of initial posting on June 25, 2021, individuals using assistive technology may not be able to fully access the information contained in this document. A fully accessible version of the document is in preparation and will be posted as soon as it is ready. We regret any inconvenience that this may cause our readers. For assistance, please send an e-mail to ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.
FDA-authorized EUA for Pfizer-BioNTech COVID-19 Vaccine

June 23, 2021

FDA has authorized emergency use of the Pfizer-BioNTech COVID-19 vaccine for individuals 16 years of age and older.

This authorization is based on the totality of available data, including results from the Pfizer-BioNTech clinical trial that showed the vaccine is safe and effective, as confirmed by an independent data monitoring board.

The Pfizer-BioNTech COVID-19 vaccine is a messenger RNA (mRNA) vaccine. It is administered as a two-dose series, with the second dose given approximately 21 days after the first dose.

The FDA will continue to closely monitor the vaccine's safety and effectiveness and provide updates as new data become available.

For more information, visit www.fda.gov/covid-19/vaccines.

*This authorization is temporary and subject to change.*
FDA has approved Pfizer-BioNTech’s COVID-19 vaccine for emergency use. The vaccine, known as Pfizer-BioNTech COVID-19 mRNA, is designed to protect people from the virus that causes COVID-19.

The vaccine consists of RNA that codes for a specific protein found on the surface of the COVID-19 virus. When the RNA enters the body, it is translated into a protein that mimics the virus. The immune system then produces antibodies that recognize and neutralize the actual virus.

The vaccine is administered in two doses, with the second dose given approximately one month after the first. The vaccine is indicated for use in people 16 years of age and older.

The vaccine is highly effective in preventing COVID-19, with more than 95% of people who received the vaccine experiencing protection against the virus.

The vaccine is produced using a novel technology called messenger RNA (mRNA). This technology allows for the rapid development and manufacturing of vaccines against emerging pathogens.

The vaccine is being distributed through a joint federal and state program, with doses allocated based on population size.

The FDA’s approval of the Pfizer-BioNTech COVID-19 vaccine is a significant step in the global effort to combat COVID-19 and return to normalcy.

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www.cdc.gov/vsafe

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www.cvdvaccine.com

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**COVID-19 Information**

**CDC**

**1-800-HHS-TIPS**

**https://TIPS.HHS.GOV**

**What is EUA?**

EUA (Emergency Use Authorization) is a mechanism that allows the U.S. Food and Drug Administration (FDA) to authorise the use of medical products in an emergency, such as during a public health crisis. This authorisation is given when there is a determination that the potential benefits of using these products outweigh the risks.

**Who is eligible for EUA?**

EUA is available for individuals who are at high risk of COVID-19 or who are caring for someone who is at high risk.

**What are the conditions for EUA?**

The conditions for EUA include:

- The product must be considered to be safe.
- The potential benefits of using the product must outweigh the risks.
- There must be no other approved or authorised products available.

**Who can request EUA?**

EUA requests can be made by healthcare providers, hospitals, or other organisations with extensive clinical experience using the product.

**What are the next steps after EUA?**

After EUA, the FDA may seek further information or data to ensure the continued safety and efficacy of the product.

**Who can learn more?**

For more information, refer to the CDC's website or contact 1-800-HHS-TIPS.

**COVID-19 Vaccines and EUA**

- Pfizer-BioNTech COVID-19 Vaccine
- Moderna COVID-19 Vaccine

Both vaccines have been authorised under EUA by the FDA. The FDA has confirmed that these vaccines are safe and effective for use in people 16 years of age and older.

**Additional Resources**

- **FDA COVID-19 webpage:** [https://www.fda.gov/coronavirus](https://www.fda.gov/coronavirus)
FDA ერთგზა რა ინფორმაცია თანახმად თქვენ პატივს გამოაცხადე. თქვენი თავისუფლად CGR-ში იმდგომ ღირსშესანიშნავი ინფორმაცია სთავაზობთ, თუ თქვენ განაგრძოთ გრძელყოფილი ინფორმაცია ეპიზოოძებით.