This site is intended for U.S. Healthcare Professionals. Full EUA PI | Safety Info | FDA EUA Letter

EUA Fact Sheets

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The Pfizer-BioNTech COVID-19 Vaccine Was Granted Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA)

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA under an Emergency Use Authorization to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

Quick Access to Important Information

- Safety Information
- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers)
- Fact Sheet for Recipients and Caregivers
- Full EUA Prescribing Information
- Product Storage & Dry Ice
- Adverse Event Reporting

Important Safety Information

- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of

Pfizer-BioNTech COVID-19 Vaccine

Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html)

- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine
- The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients
- In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%)
- Severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine during mass vaccination outside of clinical trials

  Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine
- Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy
- Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion
- There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS call 1-800-822-7967. The reports should include the words “Pfizer-BioNTech COVID-19 Vaccine EUA” in the description section of the report
- Vaccination providers should review the Fact Sheet for *Information to Provide to Vaccine Recipients/Caregivers* and *Mandatory Requirements for Pfizer-BioNTech COVID-19 Vaccine Administration Under Emergency Use Authorization*
- Before administration of Pfizer-BioNTech COVID-19 Vaccine, please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine-us.com

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Ensuring the Authenticity of Pfizer-BioNTech COVID-19 Vaccine

- Pfizer is committed to patient safety and ensuring that people have accurate information about the investigational Pfizer-BioNTech COVID-19 Vaccine, including how it is accessed and administered. We are actively monitoring for fraudulent offers of illegitimate Pfizer-BioNTech COVID-19 Vaccines to protect patients from products that might be dangerous and lead to serious and life-threatening harm
- The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 16 years of age and older.
  - The Pfizer-BioNTech COVID-19 Vaccine is only administered intramuscularly by a healthcare professional
  - The Pfizer-BioNTech COVID-19 Vaccine is not taken orally and is not available in a capsule or tablet form
- Authentic Pfizer-BioNTech COVID-19 Vaccines, manufactured by Pfizer Inc., will include the Pfizer and

BioNTech names on the label and are dispensed in a vial with a purple cap

- Ensure the safety of the vaccine vials by limiting access to only authorized personnel. The location they are stored in must be secure and locked when not in use. To prevent counterfeits, discard vaccine vials in sharps containers and empty vial trays as medical waste or deface or safely crush all materials so they cannot be reused. Remember, Pfizer-BioNTech COVID-19 Vaccines are only available through government-authorized vaccination centers – such as hospitals, outpatient clinics, pharmacies, and community vaccination locations. The Pfizer-BioNTech COVID-19 Vaccine can only be administered by licensed healthcare professionals, or other individuals that are approved vaccinators, at government-authorized vaccination sites. Individual doses are not for sale

If you suspect the Pfizer-BioNTech COVID-19 Vaccine you have purchased may be counterfeit, contact us at 1-800-438-1985 or visit https://www.pfizer.com/products/product-contact-information.

To learn more, visit https://www.pfizer.com/counterfeiting/frequently-asked-questions.

For more information

Medical Information
Visit PfizerMedicalInformation.com
or call 1-800-438-1985.

General Product Inquiries
Call 1-877-829-2619.

Shipment Support
US Trade Customer Service
Call 1-800-666-7248.

Manufactured by
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Manufactured for
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An der Goldgrube 12
55131 Mainz, Germany
Emergency Use Authorization Holder

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech proprietary mRNA technology, was developed by both BioNTech and Pfizer.

This site is intended only for U.S. residents. The products discussed in this site may have different product labeling in different countries. The information provided is for educational purposes only and is not intended to replace discussions with a healthcare provider.