

Summary of Comments on pp-cvv-usa-0429.pdf

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Number: 1 Author: olivia massey Subject: CalloutDate: 9/28/2021 11:50:39 AM Upon clicking, downloads to PP-CVV-USA-0389

FDA APPROVED FOR INDIVIDUALS ≥16 YEARS OF AGE¹

In individuals 16 years of age and older, the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA),* has been approved for active immunization to prevent COVID-19 caused by SARS-CoV-2.1

AUTHORIZED FOR EMERGENCY USE²

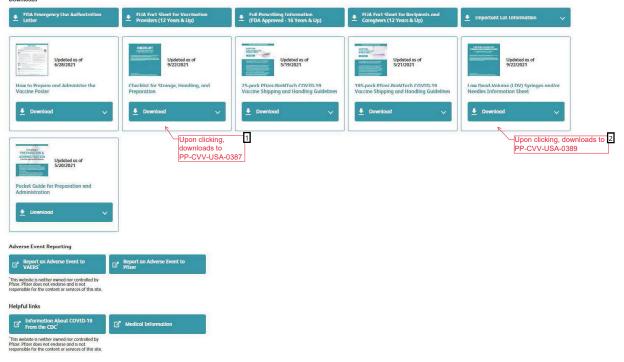
The emergency use of the product has not been approved or licensed by FDA, but has been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 12 years of age and older, and the emergency use of this product is only authorized 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.

"The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine Pfizer-BioNTech COVID-19 Vaccine, and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns. The products are legally distinct, with cortain differences that do not impact safety or effectiveness.

Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA), Resources*

 $\textbf{Download and print the resources below. View the full } \underline{\textbf{Prescribing Information for 16 Years \& Up}} \\ \underline{\textbf{and } \underline{\textbf{FUA Fact Sheet for Vaccination Providers for 12 Years \& Up}}. \\ \\$





Ensuring the Authenticity of Pfizer-BioNTech COVID-19 Vaccine and Registered Trademark Name COMIRNATY $^{\mathbb{R}}$

- Pfizer is committed to patient safety and ensuring that people have accurate information about the vaccine, including how it is accessed and administered. We are actively monitoring for fraudulent offers of illegitimate vaccines to protect patients from products that might be dangerous and lead to serious and life-threatening harm

 The vaccine is only administered intramuscularly by a healthcare professional
 The vaccine is not taken only and is not available in a capsule or tablet form
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- Authentic 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. Two versions of the vial label are in current circulation with or without a purple border³
- 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 cartons as medical waste or deface or safety crush all materials so they cannot be reused. Remember, the vaccine are only available through government-authorized vaccination centers—such as objectives of the control parameters, outpatient clinics, community vaccination is bordien, and hospitals. The vaccine can only be administered by it itemsed healthcare professionals, or other individuals that are approved vaccination, at government-authorized vaccination is also remarks and the professionals, or other individuals that are approved vaccination is a community vaccination and hospitals. The vaccine can only be administered by itemsed by itemsed and the professionals, or other individuals that are approved vaccination as a few and the professionals are also remarks.

 $If you suspect the vaccine you have purchased may be counterfeit, contact us at \underline{1-800-438-1985} \ or visit \underline{https://www.pfizer.com/products/product-contact-information.} \\$ To learn more, visit https://www.pfizer.com/counterfeiting/frequently-asked-questions.

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 1. COMINNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech: 2021.

 1. COMINNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech: 2021.

 2. Pfizer BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers). Pfizer and BioNTech: 2021.

 3. Data on File, Pfizer line. New York, Propagam Interview Playbook for Jurisdiction Operations. September 16, 2020 Version 1.0. Centers for Disease Control and Prevention; 2020.

 5. McCury MC. Secure deposal of Vaccine values and packaging recommendations. US Department of Defense; 2020.

For more information

Pfizer Customer Service Call 1-800-879-3477.

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 <u>1-800-666-7248</u>.



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