FDA APPROVED FOR INDIVIDUALS ≥16 YEARS OF AGE[1]

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 immunizaton to prevent COVID-19 caused by SARS-CoV-2.[1]

AUTHORIZED FOR EMERGENCY USE[2]

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. [2]

***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 certain differences that do not impact safety or effectiveness.**

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Download and print the resources below. View the full Prescribing Information for 16 Years & Up and EUA Fact Sheet for Vaccination Providers for 12 Years & Up.

Full Prescribing Information (FDA Approved - 16 Years & Up)	EUA Fact Sheet for Vaccination Providers (12 Years & Up)	How to Prepare and Administer the Vaccine Poster	Low Dead-Volume (LDV) Syringe and/or Needles Information Sheet
Current full Prescribing Information	Current Fact Sheet	Updated as of 6/28/2021	Updated as of 9/22/2021

Dosing and Administration[1]

Vaccine is administered as a series of 2 doses three weeks apart*

Day 0	Day 21
30 mcg (0.3 mL) Intramuscular Injection	30 mcg (0.3 mL) Intramuscular Injection

***According to the Emergency Use Authorization Fact Sheet for Vaccination Providers, a third dose of the vaccine (0.3 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.[2]**

Multiple Dose Vial – Six Doses

After dilution, vials of the vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume
- Do not pool excess vaccine from multiple vials

Description

The vaccine is a sterile suspension for injection for intramuscular use. It is supplied as a frozen suspension in multiple dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP prior to use to form the vaccine. Each dose of the vaccine contains 30 mcg of a nucleoside-modified messenger RNA (mRNA) encoding the viral spike (S)-glycoprotein of SARS-CoV-2.

Each 0.3 mL dose of the vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediylbis(hexane-6,1-diyl)bis(2-hexyldecanoate), 0.05 mg 2-[(polyethylene glycol 2000)-N,N-ditetradecylacetamide, 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.2 mg cholesterol), 0.01 mg potassium chloride, 0.01 mg monobasic potassium phosphate, 0.36 mg sodium chloride, 0.07 mg dibasic sodium phosphate dihydrate, and 6 mg sucrose. The diluent (0.9% Sodium Chloride Injection, USP) contributes an additional 2.16 mg sodium chloride per dose.

The vaccine does not contain preservative.

The vial stoppers are not made with natural rubber latex.

Dosing and Schedule

The vaccine is administered intramuscularly as a series of 2 doses (0.3 mL each) 3 weeks apart.

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[2]

There are no data available on the interchangeability of the vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received 1 dose of the vaccine should receive a second dose of the vaccine to complete the vaccination series.

According to the Emergency Use Authorization Fact Sheet for Vaccination Providers, a third dose of the vaccine (0.3 mL) administered at least 28 days following the second dose of this vaccine is authorized for administration to individuals at least 12 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.[2]

Dose Preparation

- The Multiple Dose Vial contains a volume of 0.45 mL, supplied as a frozen suspension **that does not contain preservative.** Each vial must be thawed and diluted prior to administration
- Vials may be thawed in the refrigerator [2°C to 8°C (35°F to 46°F)] or at room temperature [up to 25°C (77°F)]
- **Prior to dilution,** the thawed suspension may contain white to off-white opaque amorphous particles
- The contents of the vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP to form the vaccine
- After dilution, the vial contains 6 doses of 0.3 mL of vaccine
- 0.9% Sodium Chloride Injection, USP is not packaged with the vaccine and must be sourced separately. **Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Do not add more than 1.8 mL of diluent.** Please see the Q&A section for more information on dose preparation
- **After dilution,** the vaccine will be an off-white suspension. **Inspect vials to confirm there are no particulates and no discoloration is observed**
- **Strict adherence to aseptic techniques must be followed**

Thawing Prior to Dilution

- Thaw vial(s) of the vaccine before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month
  - Allowing vial(s) to sit at room temperature [up to 25°C (77°F)] for 30 minutes
- Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours

Invert

- Before dilution invert vaccine vial gently 10 times
- **Do not shake**
- Inspect the liquid in the vial prior to dilution. The liquid is a white to off-white suspension and may contain white to off-white opaque amorphous particles
- Do not use if liquid is discolored or if other particles are observed

Dilute

- ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent
- Using aseptic technique, withdraw 1.8 mL of diluent into a transfer syringe (21-gauge or narrower needle)
- Cleanse the vaccine vial stopper with a single-use antiseptic swab
- Add 1.8 mL of 0.9% Sodium Chloride Injection, USP into the vaccine vial

Equalize

- Equalize vial pressure (release remaining low vacuum from the vial) by withdrawing 1.8 mL of air into the empty diluent syringe

Invert

- Gently invert the vial containing the vaccine 10 times to mix
- **Do not shake**
- Inspect the vaccine in the vial
- The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter

Record and Store

- Record the date and time of dilution on the vial label
- Store between 2°C to 25°C (35°F to 77°F)
- Discard any unused vaccine 6 hours after dilution

Preparation of Individual 0.3 mL Doses of the Vaccine

Cleanse

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab, and withdraw **0.3 mL** of the vaccine preferentially using low dead-volume syringes and/or needles
- Each dose must contain 0.3 mL of vaccine
- If the amount of vaccine remaining in a single vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume

Administration

Visually inspect each dose in the dosing syringe prior to administration. The vaccine will be an off-white suspension. During the visual inspection,

- verify the final dosing volume of 0.3 mL
- confirm there are no particulates and that no discoloration is observed
- do not administer if vaccine is discolored or contains particulate matter

Administer the vaccine intramuscularly.

After dilution, vials of the vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume syringes and/or needles can be used to extract six doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume
- Do not pool excess vaccine from multiple vials

Review the Product Safety Data Sheet for the vaccine. In the event of vial breakage, damage, or leakage, to prevent cuts and exposure to the vaccine, do not handle the vial with bare hands; wear protective gloves. Remove broken glass with forceps, tongs, or other appropriate tools. Dispose of the vial and vial pieces in a medical sharps container.

Ensuring the Authenticity of Pfizer-BioNTech COVID-19 Vaccine and Registered Trademark Name COMIRNATY®

- 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[3]
  - The vaccine is not taken orally and is not available in a capsule or tablet form[3]
- 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 border**[3]
- Ensure the safety of the vaccine vials by limiting access to only vaccine-trained 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 safely crush all materials so they cannot be reused. Remember, the vaccines are only available through government-authorized vaccination centers – such as doctor's offices, authorized pharmacies, outpatient clinics, community vaccination locations, and hospitals. The 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[4,5]

If you suspect the 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.

References

1. COMIRNATY® (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 Inc. New York, NY.
4. *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations – September 16, 2020 Version 1.0.* Centers for Disease Control and Prevention; 2020.
5. McCarry MC. Secure disposal of vaccine vials 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 1-800-666-7248.

Manufactured for BioNTech Manufacturing GmbH An der Goldgrube 12 55131 Mainz, Germany Marketing Authorization Holder

Manufactured by Pfizer Inc. New York, NY 10017

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

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

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

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Downloads

FDA Emergency Use Authorization Letter | EUA Fact Sheet for Vaccination Providers (12 Years & Up) | Full Prescribing Information (FDA Approved - 16 Years & Up) | EUA Fact Sheet for Recipients and Caregivers (12 Years & Up) | Important Lot Information

Updated as of 6/28/2021

How to Prepare and Administer the Vaccine Poster

Download

Updated as of 9/22/2021

Checklist for Storage, Handling, and Preparation

Download

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Updated as of 5/19/2021

25-pack Pfizer-BioNTech COVID-19 Vaccine Shipping and Handling Guidelines

Download

Updated as of 5/21/2021

195-pack Pfizer-BioNTech COVID-19 Vaccine Shipping and Handling Guidelines

Download

Updated as of 9/22/2021

Low Dead-Volume (LDV) Syringes and/or Needles Information Sheet

Download

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Updated as of 5/20/2021

Pocket Guide for Preparation and Administration

Download

Adverse Event Reporting

Report an Adverse Event to VAERS | Report an Adverse Event to Pfizer

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Helpful links

Information About COVID-19 From the CDC | Medical Information

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1. COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech; 2021.
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3. Data on File. Pfizer Inc. New York, NY.
4. *COVID 19 Vaccination Program Interim Playbook for Jurisdiction Operations September 16, 2020 Version 1.0.* Centers for Disease Control and Prevention; 2020.
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Number: 1 Author: olivia massey Subject: CalloutDate: 9/28/2021 11:55:27 AM

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Number: 2 Author: olivia massey Subject: CalloutDate: 9/28/2021 11:51:42 AM

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