

Url flat annotations are provided at first mention

FDA APPROVED FOR INDIVIDUALS ≥16 YEARS OF AGE

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

COMIRNATY® is FDA Approved for 16 Years & Up.

*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.

Click [here](#) for the full Prescribing Information for individuals 16 years of age and older.

Click [here](#) to learn about the difference between the US Food and Drug Administration (FDA) approval and Emergency Use Authorization.

EUA Fact Sheet for Vaccination Providers Update: Effective 8/23/21 and 9/1/21

Click [here](#) to view the updated Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers). Changes include (but are not limited to) the following sections:

Drives to USPI (16+) - <http://labeling.pfizer.com/ShowLabeling.aspx?id=15623>

Drive to <https://www.cvdvaccine-us.com/faqs#diff-fda-eua>

Drives to <http://labeling.pfizer.com/ShowLabeling.aspx?id=14471&format=pdf>

Indication & Authorized Use Indication

COMIRNATY® is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

Important Safety Information

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication. Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine. Monitor 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>). Postmarketing data demonstrate increased risks of myocarditis and pericarditis, particularly within 7 days following the second dose. Syncope (fainting) may occur in association with administration of injectable vaccines, including this vaccine. Procedures should be in place to avoid injury from fainting.

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19 HOW SUPPLIED/STORAGE AND HANDLING

Frozen Vials Prior to Use

Cartons and vials of Pfizer-BioNTech COVID-19 Vaccine with an expiry date of May 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as approved storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained. Updated expiry dates are shown below.

Printed Expiry Date	Updated Expiry Date
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Continue

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Syncope (fainting) may occur in association with administration of injectable vaccines, including this vaccine. Procedures should be in place to avoid injury from fainting.

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.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.

Vaccination Storage & Dry Ice Safety Handling

The vaccine should be preferably stored in an ultra-low-temperature (ULT) freezer between -90°C to -60°C (-130°F to -76°F) until the expiry date printed on the label. Alternatively, vials may be stored or transported frozen at temperatures of -25°C to -15°C (-13°F to 5°F) for up to 2 weeks and may be returned one time to ultra-low-temperature storage. Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should not exceed 2 weeks.¹

The vaccine is provided in either 25-pack or 195-pack cartons. The thermal shipping container included with the 25-pack cartons should be returned within 10 days of delivery and should not be used as temporary storage.³ Please refer to the storage and temperature guidelines available on this page, as well as in the [Q&A](#) section of this website.

If an ultra-low-temperature freezer is not available for the 195-pack cartons, the thermal shipping container in which the vaccine arrives may be used as temporary storage for up to 30 days from delivery, when consistently re-filled with dry ice. Refer to the dry ice replenishment guidelines. The thermal shipping container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.¹

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](#).



Updated as of
6/10/2021

Checklist for Storage, Handling, and
Preparation of the Pfizer-BioNTech
COVID-19 Vaccine

 Download 



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

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Updated as of
5/20/2021

Dry Ice Replenishment Sheet

Information on dry ice replenishment, pellet size, and pack-out instructions for dry ice replenishment of thermal packaging.



Download



Safety and Storage

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](#).



Updated as of
2/16/2021



FDA-CBER-2021-5683-0951532

Safety and Storage

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](#).



Updated as of
2/16/2021

Safe Handling Guidelines for Dry Ice

Facts about dry ice, general safety guidance, and disposal procedures.

 Download 



Dry Ice Safety Data Sheet

Access the Dry Ice Safety Data Sheet.

 Click here



Product Safety Data Sheet

Access the Pfizer-BioNTech COVID-19 Vaccine Product Safety Data Sheet.


 Click here

Returning Your Thermal Shipping Container

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](#).



Returning Your Thermal Shipping Container

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](#).



Updated as of
6/16/2021

**Instructions for Returning Real-Time
Temperature Monitor and Thermal
Shipping Container**

 **Download** 

Storage and Handling³

- Storage times and transfer times between storage environments are the same for both 25-pack and 195-pack cartons
- Do not open vial cartons until there is a need to remove vials for transfer, thawing, or use
- Upon delivery:
 - Inspect the thermal shipping container to confirm ordered vial cartons were received
 - Do not stack or place anything on top of the thermal shipping container
- **Vial carton and vial handling between storage environments**

- Vial carton and vial handling between storage environments

When possible, to protect the vials that will remain in the freezer, keep the vial carton in the frozen environment while transferring the vials to a secondary container. If vial cartons must be removed, limit to the transfer times indicated below.

Once an individual vial is removed from a vial carton at room temperature, it should not be returned to frozen storage and should be thawed for use. **Do not refreeze thawed vials.**

Originating Temperature Environment	Maximum Time at Room Temperature (up to 25°C or up to 77°F) During Storage or Transfer		Time Required to Stay in Frozen Environment After Room Temperature Exposure During Transfer	Number of Times Vial Cartons May Be Transferred to the Preferred ULT Freezer Storage Condition
	Unopened Vial Cartons	Opened Vial Cartons		
<p>From ULT Freezer -90°C to -60°C (-130°F to -76°F)</p> <p>Or</p> <p>From Thermal Shipping Container* -90°C to -60°C (-130°F to -76°F)</p>	Up to 5 minutes	Up to 3 minutes	At least 2 hours before they can be removed again	N/A
<p>From Freezer -25°C to -15°C (-13°F to 5°F)</p>	Up to 3 minutes	Up to 1 minute [†]	No specified time before they can be taken out again	<p>Limit ONE return to ULT Freezer;</p> <p>Total cumulative time vials are stored at -25°C to -15°C (-13°F to 5°F) should be</p>

Or From Thermal Shipping Container* -90°C to -60°C (-130°F to -76°F)	Up to 5 minutes	Up to 3 minutes	At least 2 hours before they can be removed again	N/A
From Freezer -25°C to -15°C (-13°F to 5°F)	Up to 3 minutes	Up to 1 minute [†]	No specified time before they can be taken out again	Limit ONE return to ULT Freezer; Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks

*The thermal shipping container should not be opened for more than 3 minutes at a time.

†If possible, opened cartons should be left in the -25°C to -15°C (-13°F to 5°F) environment when removing vials for use. If the carton must be removed from the freezer, return to freezer in less than 1 minute.

- **If using the thermal shipping container for storage (195-pack cartons only)**

To help maintain the level of dry ice and the temperature of the vaccine product:

- **24 hours:** The thermal shipping container must be replenished with dry ice within 24 hours of receipt
- **2x/Day:** It is recommended that the thermal shipping container not be opened more than **2 times a day**
- **3 Minutes:** The thermal shipping container should not be opened more than **3 minutes at a time**
- **5 Days:** The thermal shipping container should be replenished with dry ice **every 5 days**

- Dry Ice can be hazardous. Take necessary precautions by reviewing the [Dry Ice Safety Data Sheet](#), and consult with your Occupational Health Department. Ensure there is proper ventilation and wear safety goggles or safety glasses with side shields and waterproof insulated gloves when handling dry ice

Frozen Vials Prior to Use¹

- Vials must be kept frozen and protected from light, in the original cartons, until ready to use
- Vial cartons of the Multiple Dose Vials arrive in thermal shipping containers with dry ice. Once received, remove the vial cartons immediately from the thermal shipping container and preferably store in an ultra-low-temperature freezer between -90°C to -60°C (-130°F to -76°F) until the expiry date printed on the label. This information in the package insert supersedes the storage conditions printed on the vial cartons
- Cartons and vials of the vaccine with an expiry date of May 2021 through February 2022 printed on the label may remain in use for 3 months beyond the printed date as long as approved storage conditions between -90°C to -60°C (-130°F to -76°F) have been maintained. Updated expiry dates are shown below²

Printed Expiry Date²

May 2021

June 2021

July 2021

August 2021

September 2021

October 2021

November 2021

December 2021

January 2022

February 2022

Updated Expiry Date²

August 2021

September 2021

October 2021

November 2021

December 2021

January 2022

February 2022

March 2022

April 2022

May 2022

- If not stored between -90°C to -60°C (-130°F to -76°F), vials may be stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks. Vials stored at -25°C to -15°C (-13°F to 5°F) for up to 2 weeks may be returned one time to the recommended storage condition of -90°C to -60°C (-130°F to -76°F). Total cumulative time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and should not exceed 2 weeks
- If an ultra-low-temperature freezer is not available for the 195-pack carton, the thermal shipping container in which the vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. **Refer to the dry ice replenishment guidelines packed in the original thermal shipping container for instructions regarding the use of the thermal shipping container for temporary storage.** The thermal shipping container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition.

- If an ultra-low-temperature freezer is not available for the 195-pack carton, the thermal shipping container in which the vaccine arrives may be used as temporary storage when consistently re-filled to the top of the container with dry ice. **Refer to the dry ice replenishment guidelines packed in the original thermal shipping container for instructions regarding the use of the thermal shipping container for temporary storage.** The thermal shipping container maintains a temperature range of -90°C to -60°C (-130°F to -76°F). Storage of the vials between -96°C to -60°C (-141°F to -76°F) is not considered an excursion from the recommended storage condition

Transportation of Frozen Vials¹



Thawed Vials Before Dilution¹



Transportation of Thawed Vials¹



Vials After Dilution¹



For a visual guide to storage options for the vaccine, refer to "[How is the vaccine stored?](#)" in the Q&A section.

Safely Dispose^{1,3}

Discard vaccine vials that:

- Have been fully discharged and used to administer vaccinations
- Are more than 6 hours from time of dilution

Discard vaccine vials in a sharps container as medical waste to ensure they are permanently destroyed. Discard vial cartons as medical waste so they cannot be reused.

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 professional¹
 - The vaccine is not taken orally and is not available in a capsule or tablet form¹
- 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 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](tel: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. McCurry 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](tel:1-800-879-3477).

Medical Information

Visit PfizerMedicalInformation.com or call [1-800-438-1985](tel:1-800-438-1985).

General Product Inquiries

Call [1-877-829-2619](tel:1-877-829-2619).

Shipment Support

US Trade Customer Service

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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.

This site is intended only for U.S. healthcare professionals. The products discussed in this site may have different product labeling in different countries. The information provided is for educational purposes only.

FDA-CBER-2021-5683-0951541

All mobile content reflects a responsive design to desktop

All annotations from desktop apply to mobile

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[Indication & Authorized Use](#)

[Safety Info](#)

Full Prescribing Information (FDA Approved - 16 Years & Up)

EUA Letter & Fact Sheets (12 Years & Up)



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Quick Access to Important Information

 [Safety Information & Adverse Event Reporting](#)

 [Full Prescribing Information \(FDA Approved - 16 Years & Up\)](#)

 [EUA Fact Sheet for Vaccination Providers \(12 Years & Up\)](#)

 [EUA Fact Sheet for Recipients and Caregivers \(12 Years & Up\)](#)

 [Product Storage & Dry Ice](#)

 [Website for Recipients and Caregivers](#)

References

1. COMIRNATY[®] (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech; 2021.
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