Drives to USPI (16+) http:// labeling.pfizer.co ShowLabeling.as ex? id=15623

Drive to https:// www.cvdvaccineus.com/fags#diff-fdaeua

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.

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 leadly 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

Important Safety Information

Known history of a severe allergic reaction (eq. 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 FDA-CBER-2021-5683-0951527

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

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

<u>Click here</u> to view the updated Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers). Changes include (but are not limited to) the following sections:

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

May 2021 August 2021
June 2021 September 2021
July 2021 October 2021

August 2021 November 2021 September 2021 December 2021

Octobor 2021 January 202

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 FDAsc BER-2021-5683-0951528

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





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 FDAeCBER-2021-5683-0951529

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

Dosing & Administration

Clinical Efficacy

Safety Info

Q&A

Product Storage & Dry Ice

Resources

BIONTECH



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

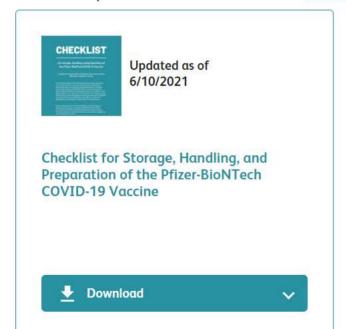
Clinical Efficacy

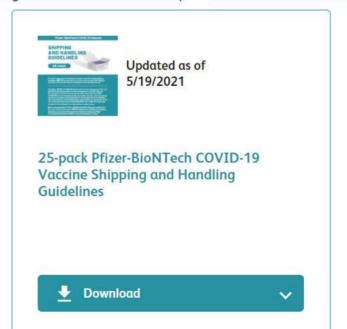
The vaccine should be preferably stored in an ultra-low-temperature (ULT) freezer between -90°C to -60°C (-130°F to -76°F) until the expiry date printed on the label. Alternatively, vials may be stored or transported frozen at temperatures of -25°C to -15°C (-13°F to 5°F) for up to 2 weeks and may be 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

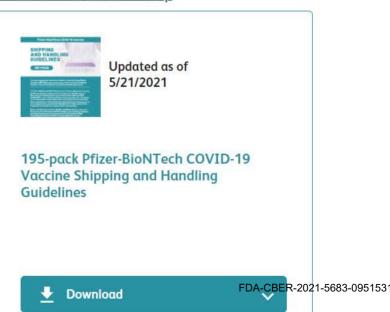
The vaccine is provided in either 25-pack or 195-pack cartons. The thermal shipping container included with the 25-pack cartons should be returned within 10 days of delivery and should not be used as temporary storage.³ Please refer to the storage and temperature guidelines available on this page, as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

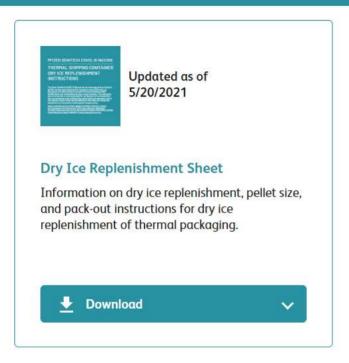
If an ultra-low-temperature freezer is not available for the 195-pack cartons, the thermal shipping container in which the vaccine arrives may be used as temporary storage for up to 30 days from delivery, when consistently re-filled with dry ice. Refer to the dry ice replenishment quidelines. The thermal 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.

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.









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.







Dosing & Administration Clinical Efficacy

Safety Info

Product Storage & Dry Ice

Q&A

Resources

Safety and Storage

Home

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

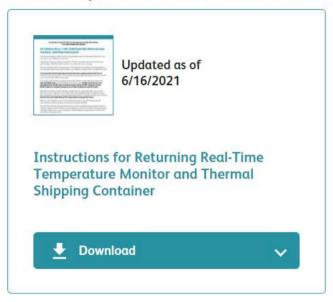
Download and print the resources below. View the full Prescribing Information for 16 Years & Up and EUA Fact Sheet for Vaccination Providers for 12 Years & Up.

Home

Clinical Efficacy

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.



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

Но	ome Dosing & Administration	Clinical Efficacy Safety Info	Q&A Product Storage & I	Dry Ice Resources BIC	ONTECH & Pfizer				
	 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	Number of Times Vial Cartons May Be Transferred to the Preferred ULT Freezer				
		Unopened Vial Cartons	Opened Vial Cartons	During Transfer	Storage Condition				
	From ULT Freezer -90°C to -60°C (-130°F to -76°F) 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 cumfinatore Rr2021 15683-0951535 vials are stored at -25°C to -15°C (-13°F to 5°F) should be				

Or From Thermal Shipping	Up to 5 minutes	Up to 3 minutes	At least 2 hours before they can be removed again	N/A
Container* -90°C to -60°C (-130°F to -76°F)				
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

Product Storage & Dry Ice

Resources

BIONTECH

Clinical Efficacy

Safety Info

Q&A

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

Home

Dosing & Administration

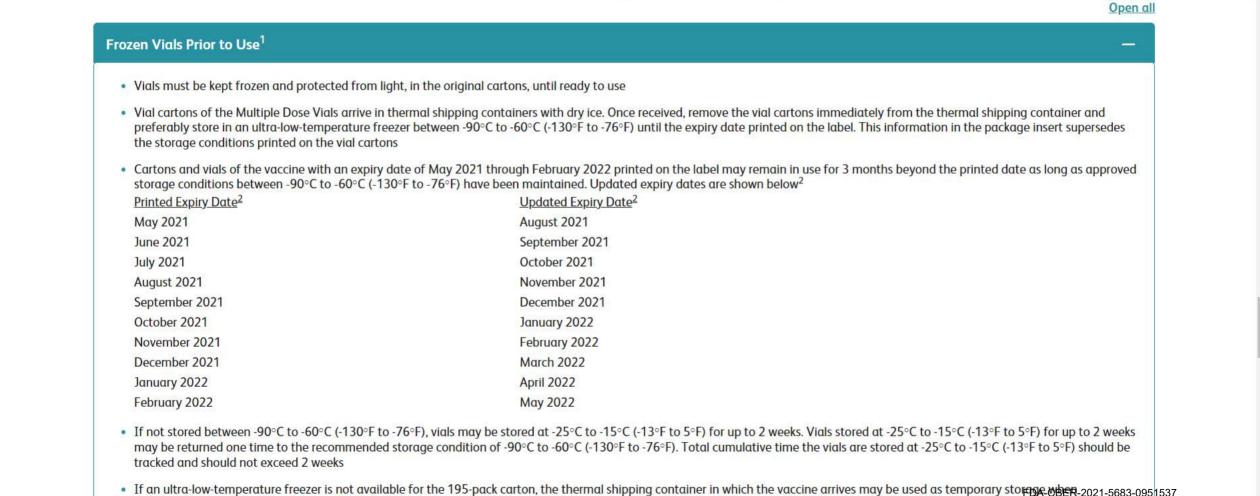
To help maintain the level of dry ice and the temperature of the vaccine product:

- 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
- o 3 Minutes: The thermal shipping container should not be opened more than 3 minutes at a time
- o 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 <u>Dry Ice Safety Data Sheet</u>, 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

¥

^{&#}x27;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.



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

0&A

Safety Info

between 06°C to 60°C (1/10°E to 76°E) is not considered an excursion from the recommended storage condition

Home

Dosing & Administration

Clinical Efficacy

Product Storage & Dry Ice

Resources

BIONTECH **Pfizer**

• 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 O&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.

Dosing & Administration Clinical Efficacy Safety Info Q&A Product Storage & Dry Ice Resources

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 1
 - The vaccine is not taken orally and is not available in a capsule or tablet form
- 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 or visit https://www.pfizer.com/products/product-contact-information.

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

References

Home

- 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.

FDA-CBER-2021-5683-0951539

BIONTECH Prizer



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.





Terms of Use | Privacy Policy | Contact Us | Site Map

© 2021 Pfizer Inc. All rights reserved. PP-CVV-USA-0408

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

Manufactured by 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.



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.





Terms of Use | Privacy Policy | Contact Us | Site Map

© 2021 Pfizer Inc. All rights reserved. PP-CVV-USA-0408

Manufactured for Manufactured by BioNTech Manufacturing GmbH Pfizer Inc. An der Goldgrube 12 New York, NY 10017 55131 Mainz, Germany Marketing 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. 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

▼ Teams



AA 🔒 com-augustupdate.dev.pfizerstatic.io



All mobile content reflects a responsive design to desktop

All annotations from desktop apply to mobile

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

Important Safety Information



Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication.









AA a com-augustupdate.dev.pfizerstatic.io



This site is intended for U.S. Healthcare

The products are legally distinct, with certain differences that do not impact safety or effectiveness.

Click <u>here</u> 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

Important Safety Information

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY[®] is a contraindication.









AA a com-augustupdate.dev.pfizerstatic.io



This site is intended for U.S. Healthcare

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:

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

Important Safety Information

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY[®] is a contraindication.









AA a com-augustupdate.dev.pfizerstatic.io



This site is intended for U.S. Healthcare

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

May 2021 August 2021

June 2021 September 2021

July 2021 October 2021

August 2021 November 2021

September 2021 December 2021

October 2021 January 2022

November 2021 February 2022

Important Safety Information

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication.









AA 🔒 com-augustupdate.dev.pfizerstatic.io



This site is intended for U.S. Healthcare

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

May 2021 August 2021

June 2021 September 2021

July 2021 October 2021

August 2021 November 2021

September 2021 December 2021

October 2021 January 2022

November 2021 February 2022

December 2021 March 2022

January 2022 April 2022

February 2022 May 2022

Continue

Important Safety Information

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® is a contraindication.







Indication & Authorized Use Safety Info Full Prescribing Information (FDA Approved -16 Years & Up) **EUA Letter & Fact Sheets** (12 Years & Up) Pfizer BIONTECH

This site is intended for U.S. Healthcare

Professionals.

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

Important Information

are legally distinct, with certain differences that do not impact safety or effectiveness.

Safety Information & Adverse Event B" Reporting **Full Prescribing Information**

(FDA Approved - 16 Years & Up)

EUA Fact Sheet for Vaccination

Quick Access to

+

(12 Years & Up) EUA Fact Sheet for Recipients and Caregivers

(12 Years & Up)

Product Storage & Dry Ice

Providers

- Website for Recipients and B. Caregivers
- COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech;

Providers). Pfizer and BioNTech; 2021.

Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination

Medical Information

or call 1-800-438-1985.

For more information

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

Visit PfizerMedicalInformation.com

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

Shipment Support US Trade Custom Call 1-800-666-7248.

Pfizer BIONTECH



Monufactured 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. © 2021 Pfizer Inc. All rights reserved. PP-CVV-USA-0408 Terms of Use

Privacy Policy

Contact Us

Site Map

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.