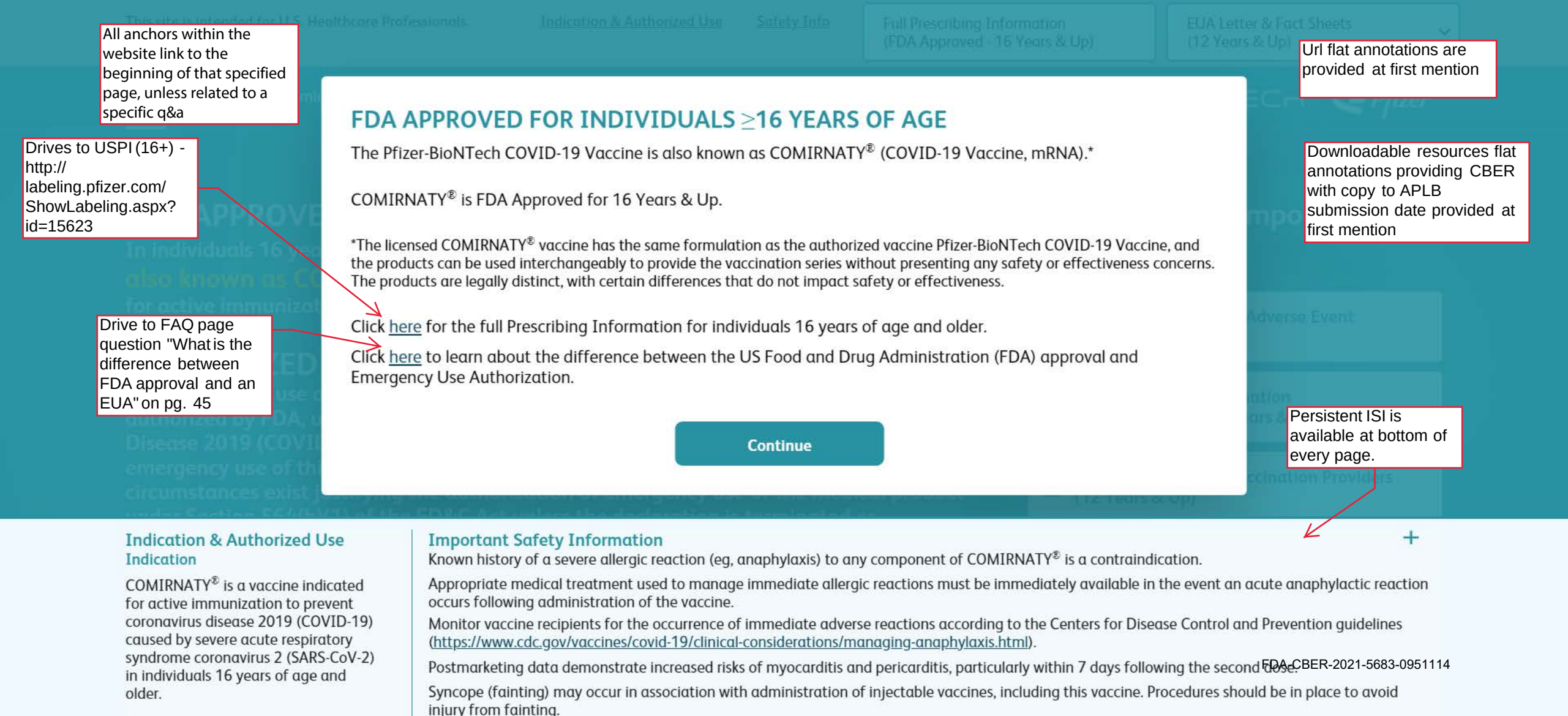

All anchors within the website link to the beginning of that specified page, unless related to a specific q&a
Drives to USPI (16+) - http://labeling.pfizer.com/ShowLabeling.aspx?id=15623
Drive to FAQ page question "What is the difference between FDA approval and an EUA" on pg. 45
Url flat annotations are provided at first mention
Downloadable resources flat annotations providing CBER with copy to APLB submission date provided at first mention
Persistent ISI is available at bottom of every page.
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.
Continue
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.
FDA-CBER-2021-5683-0951114

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.

Continue

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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.

This site is intended for U.S. Healthcare Professionals. Indication & Authorized Use Safety Info Full Prescribing Information (FDA Approved - 16 Years & Up) EUA Letter & Fact Sheets (12 Years & Up)

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Drives to pg 26

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 immunization 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

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- Safety Information & Adverse Event Reporting
- Full Prescribing Information (FDA Approved - 16 Years & Up)
- EUA Fact Sheet for Vaccination Providers (12 Years & Up)

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

FDA-CBER-2021-5683-0951116

This site is intended for U.S. Healthcare Professionals. Indication & Authorized Use Safety Info

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

EUA Letter & Fact Sheets (12 Years & Up)

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BIONTECH Pfizer

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Drives to Page 91

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 immunization 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

Quick Access to Important Information

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

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.

Authorized Use

COMIRNATY® (COVID-19 Vaccine, mRNA) is also authorized for emergency use in individuals 12 through 15 years and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 12 years of age and older, and provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of

Important Safety Information

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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.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

The vaccine may not protect all vaccine recipients.

In clinical studies of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥10%) were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).

In clinical studies of participants 56 years of age and older, the most commonly reported adverse reactions (≥10%) were pain at the injection site (78.2%), fatigue (56.9%), headache (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).

In a clinical study, adverse reactions in adolescents 12 through 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

Before administration of the vaccine, please see full Prescribing Information (16+ years of age) and EUA Fact Sheet for Vaccination Providers (12+ years of age).

Patients should always ask their healthcare providers for medical advice about adverse events. You are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit https://vaers.hhs.gov/reportevent.html or call 1-800-822-7967.

Indication & Authorized Use

Authorized Use

COMIRNATY® (COVID-19 Vaccine, mRNA) is also authorized for emergency use in individuals 12 through 15 years and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 12 years of age and older, and provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

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.

Important Safety Information

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

The vaccine may not protect all vaccine recipients.

In clinical studies of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥10%) were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).

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Before administration of the vaccine, please see full Prescribing Information (16+ years of age) and EUA Fact Sheet for Vaccination Providers (12+ years of age).

Patients should always ask their healthcare providers for medical advice about adverse events. You are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit https://vaers.hhs.gov/reportevent.html or call 1-800-822-7967.

This site is intended for U.S. Healthcare Professionals. Indication & Authorized Use Safety Info

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

EUA Letter & Fact Sheets (12 Years & Up)

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BIONTECH Pfizer

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

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 immunization 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.

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

FDA-CBER-2021-5683-0951120

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.

Authorized Use

COMIRNATY® (COVID-19 Vaccine, mRNA) is also authorized for emergency use in individuals 12 through 15 years and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 12 years of age and older, and provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

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.

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EUA Fact Sheet for Vaccination Providers (12 Years & Up)

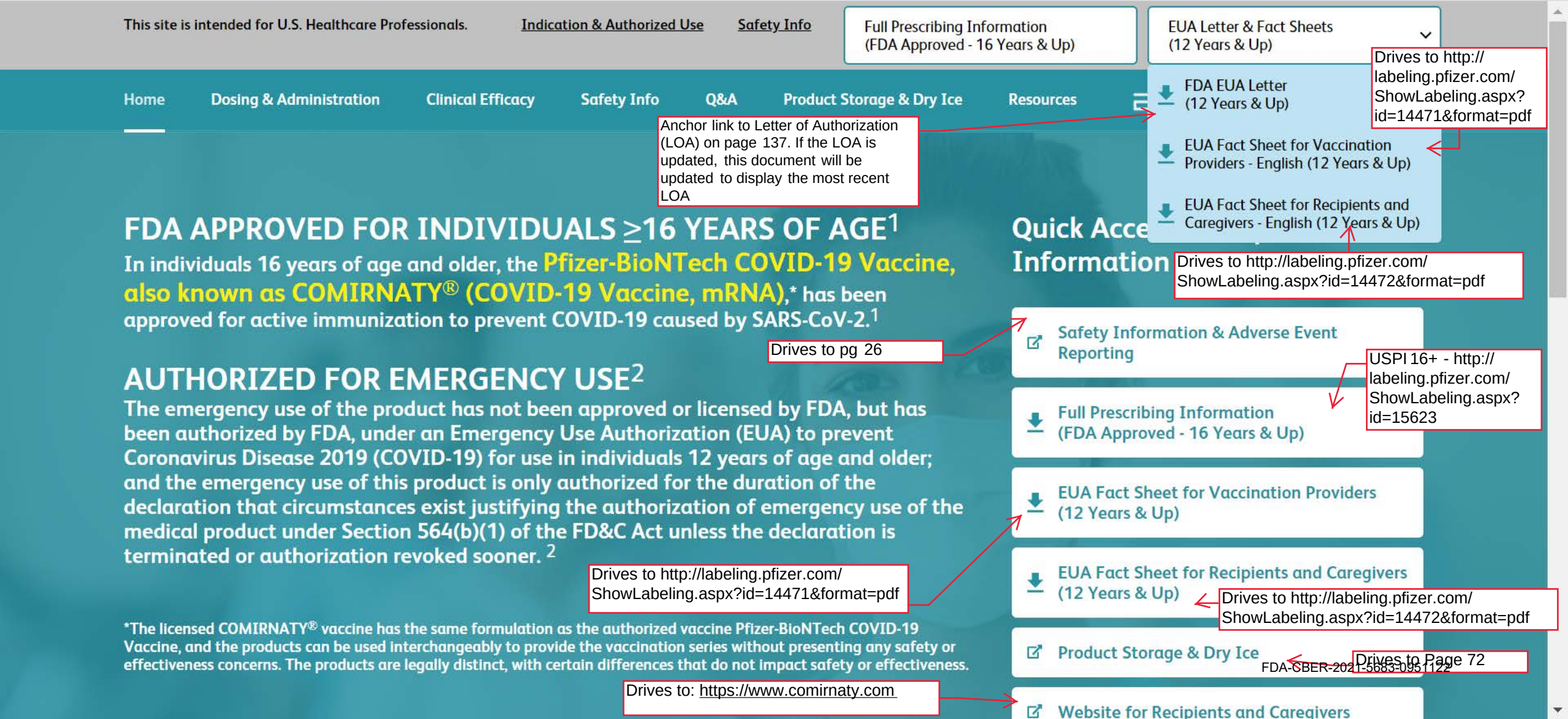
EUA Fact Sheet for Recipients and Caregivers (12 Years & Up)

Product Storage & Dry Ice

Website for Recipients and Caregivers

FDA-CBER-2021-5683-0951121

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Resources
FDA EUA Letter (12 Years & Up)
EUA Fact Sheet for Vaccination Providers - English (12 Years & Up)
EUA Fact Sheet for Recipients and Caregivers - English (12 Years & Up)
Drives to http://labeling.pfizer.com/ShowLabeling.aspx?id=14471&format=pdf
Anchor link to Letter of Authorization (LOA) on page 137. If the LOA is updated, this document will be updated to display the most recent LOA
Drives to http://labeling.pfizer.com/ShowLabeling.aspx?id=14472&format=pdf
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 immunization to prevent COVID-19 caused by SARS-CoV-2.[1]
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EUA Fact Sheet for Vaccination Providers (12 Years & Up)
Drives to http://labeling.pfizer.com/ShowLabeling.aspx?id=14471&format=pdf
EUA Fact Sheet for Recipients and Caregivers (12 Years & Up)
Drives to http://labeling.pfizer.com/ShowLabeling.aspx?id=14472&format=pdf
Product Storage & Dry Ice
Drives to Page 72
Drives to: https://www.comirnaty.com
Website for Recipients and Caregivers
FDA-CBER-2021-5683-0951122

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.



GLOBAL: Drives to https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine

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.

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

AUTHORIZED FOR EMERGENCY USE[2]

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*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.

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)

Current full Prescribing Information

EUA Fact Sheet for Vaccination Providers (12 Years & Up)

Current Fact Sheet

How to Prepare and Administer the Vaccine Poster

Updated as of 6/28/2021

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

Updated as of 5/20/2021

USPI 16+ - http://labeling.pfizer.com/ShowLabeling.aspx?id=15623

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

PP-CVV-USA-0302 submitted to CBER with copy to APLB on 6/2/21

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)	**30 mcg** (0.3 mL)
Intramuscular Injection	**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]

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

Current full Prescribing Information

EUA Fact Sheet for Vaccination Providers (12 Years & Up)

Current Fact Sheet

How to Prepare and Administer the Vaccine Poster

- English
- Español

PP-CVV-USA-0307 (English) submitted to CBER with copy to APLB on 7/13/21

PP-CVV-USA-0343 (Spanish) submitted to CBER with copy to APLB on 8/4/21

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

Updated as of 5/20/2021

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)	**30 mcg** (0.3 mL)
Intramuscular Injection	**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)azanediyl)bis(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 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]

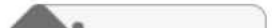
Dose Preparation

- 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

Drives to page 32

- **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

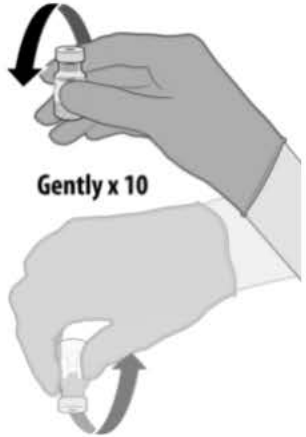


- Thaw vial(s) of the vaccine before use either by:

Thawing Prior to Dilution

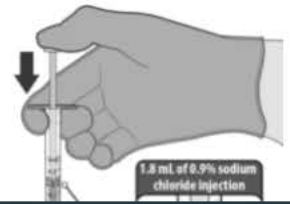


- Thaw vial(s) of the vaccine before use either by:
  - Allowing vial(s) to thaw in the refrigerator [2°C to 8°C (35°F to 46°F)]. A carton of vials may take up to 3 hours to thaw, and thawed vials can be stored in the refrigerator for up to 1 month
  - Allowing vial(s) to sit at room temperature [up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



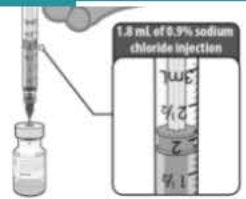
Invert

- 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



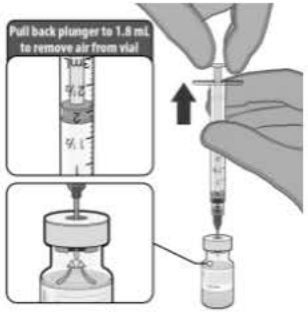
Dilute

- 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)



- 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

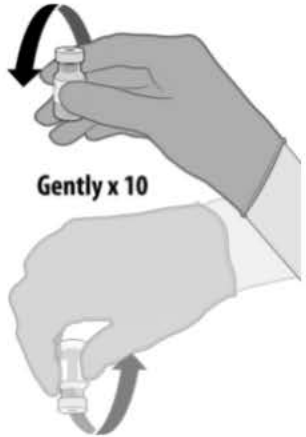
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Equalize

- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL of air into the empty diluent syringe

---



Invert

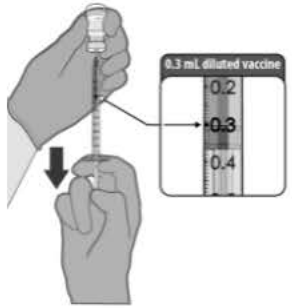
- Gently invert the vial containing the vaccine 10 times to mix
- **Do not shake**
- Inspect the vaccine in the vial
- The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains particulate matter



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
- Administer immediately

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

Drives to https://safetydatasheets.pfizer.com/DirectDocumentDownloader/Document?prd=PF00092~~PDF~~MTR~~PFEM~~EN

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[1]
  - The vaccine is not taken orally and is not available in a capsule or tablet form[1]
- 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 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

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.

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

AUTHORIZED FOR EMERGENCY USE[2]

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*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.

Clinical Efficacy & Safety

Drives to USPI - http://labeling.pfizer.com/ShowLabeling.aspx?id=15623

Drives to http://labeling.pfizer.com/ShowLabeling.aspx?id=15623&format=pdf&#page=15

Drives to http://labeling.pfizer.com/ShowLabeling.aspx?id=15623&format=pdf&#page=6

In individuals 16 years of age and older[1]

Please see the full Prescribing Information to see the clinical trial design and efficacy (Section 14 - pg. 15) and safety (Section 6 - pg. 6).[1]

Drives to https://labeling.pfizer.com/ShowLabeling.aspx?id=14471&format=pdf&#page=21

In individuals 12 through 15 years of age[2]

Please see the EUA Fact Sheet for Vaccination Providers to see the clinical trial design and efficacy (Section 18 - pg. 34) and safety (Section 6 - pg. 21).[2]

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

Drives to http://labeling.pfizer.com/ShowLabeling.aspx?id=14471&format=pdf&#page=34

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.



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Adverse Event Reporting

Report an Adverse Event to VAERS*

Report an Adverse Event to Pfizer

Drives to https://www.pfizersafetyreporting.com/#/en

*This website is neither owned nor controlled by Pfizer. Pfizer does not endorse and is not responsible for the content or services of this site.

Drives to https://vaers.hhs.gov/

Mandatory Requirements for Vaccine Administration Under Emergency Use Authorization[2†]

In order to mitigate the risks of using this unapproved product under EUA and to optimize the potential benefit of the vaccine, the following items are required. Use of unapproved vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. The vaccine is authorized for use in individuals 12 years of age and older.
2. The vaccination provider must communicate to the individual receiving the vaccine or their caregiver, information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" prior to the individual receiving the vaccine.
3. The vaccination provider must include vaccination information in the state/local jurisdiction's Immunization Information System (IIS) or other designated system.
4. The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
    - vaccine administration errors whether or not associated with an adverse event,
    - serious adverse events‡ (irrespective of attribution to vaccination),
    - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
    - cases of COVID-19 that result in hospitalization or death.

Complete and submit reports 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 "the vaccine EUA" in the description section of the report.

5. The vaccination provider is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in adults and children, and cases of COVID-19 that result in hospitalization or death following administration of the vaccine to recipients.

‡Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Other Adverse Event Reporting to VAERS and Pfizer Inc.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information above.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website: www.pfizersafetyreporting.com

Fax number: 1-866-635-8337

Telephone number: 1-800-438-1985

†Vaccination providers administering COMIRNATY® (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.[2]

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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.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

The vaccine may not protect all vaccine recipients.

In clinical studies of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥10%) were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).

In clinical studies of participants 56 years of age and older, the most commonly reported adverse reactions (≥10%) were pain at the injection site (78.2%), fatigue (56.9%), headache (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).

In a clinical study, adverse reactions in adolescents 12 through 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

Before administration of the vaccine, please see full Prescribing Information (16+ years of age) and EUA Fact Sheet for Vaccination Providers (12+ years of age).

Patients should always ask their healthcare providers for medical advice about adverse events. You are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit https://vaers.hhs.gov/reportevent.html or call 1-800-822-7967.

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.



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Questions and Answers About Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA)*

All accordions in section expand

Opens individual question

All

Approval Status

Access to Vaccine Supply

Diluent

Administration

Storage and Stability

Dry Ice

Anchor links to section

Approval Status

Open all

- What is COMIRNATY®? +
- What does FDA approval mean? +
- What is the difference between FDA approval and an EUA? +
- For which age groups has the vaccine received FDA approval? +
- In the clinical trial, what was the efficacy & safety of the vaccine? +

Access to Vaccine Supply

Open all

Thermal Shipping Container

Ensuring Authenticity

Anchor links to section

How can I order the vaccine for my practice, office, or hospital? +

Whom can I call with product questions? +

What is the procedural coverage coding? +

What is the cost of the vaccine? +

Who will provide the syringes and needles? +

Whom do I contact if my ancillary kit is damaged or lost? +

Whom do I contact if supplies in the ancillary kit are missing or damaged when opening the shipment? +

Whom do I contact for additional ancillary kit supplies (eg, vaccination cards, syringes, and/or needles)? +

Diluent

Open all

- What type of diluent should I use with the vaccine? +
- How do I dilute the vaccine for administration? +
- Will the vaccine be supplied and shipped with the diluent? +
- How can I order more diluent? +
- How many full doses does the vial contain? +
- Does the number of doses extracted from the vial change how much diluent is required? +
- Can I use locally sourced diluent? +

Administration

Open all

Administration

Open all

Please see the full Prescribing Information for 16 Years & Up and EUA Fact Sheet for Vaccination Providers for 12 Years & Up for dosage, preparation, and administration.

- What is the dosing schedule for the vaccine? +
- Can immunocompromised patients receive a third dose? +
- Are the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY® interchangeable with other COVID-19 vaccines? +
- What if the second dose cannot be provided at 3 weeks (21 days)? +
- Does the vaccine contain live virus? +
- Do I need to wear gloves when handling individual vials? +
- How many doses are in each diluted vial? +

- What are the ingredients included in the vaccine? +
- Can I give this vaccine at the same time as other vaccines? +
- How do I prepare the dose? +
- What syringes should I use for diluting? +
- What syringes and needles should I use for administration? +

Storage and Stability

Open all

- Can I still use the product if it has become frozen after it is originally thawed?[1] +
- How long can I store the vials in the thermal shipping container? +
- How is the vaccine stored? +

- At what temperature does the vaccine need to be stored? +
- Where can I get an ultra-low-temperature freezer? +
- Is there preservative in the vaccine? +
- How long can I store the vials in the ultra-low-temperature freezer? +
- How long can undiluted vials be stored in a refrigerator? +
- Can I still use the product if it has been exposed to light? +
- How long does it take for frozen vials to thaw? +
- Are components of the vaccine vial made with latex? +

Dry Ice

Open all

- Do I still need to monitor the temperature if I am using dry ice? +
- How often do I need to add dry ice to the thermal shipping container? +
- How do I refill the thermal shipping container? +
- Where and how can I get more dry ice? +
- Is there a limit to how long I can use dry ice to maintain temperature, and how many times can I refill the container with dry ice? +
- What type of protective gear should be worn when handling dry ice? +
- How do I dispose of dry ice when I no longer need it? +
- Can I return the thermal shipping container with dry ice? +

Thermal Shipping Container

Open all

- How do I follow up on the status of my product order? +
- Whom do I contact if I have an issue with my shipment? +
- What type of gloves should I use when transferring vial cartons from the thermal shipping container to the refrigerator? +
- How can I return the thermal shipping container and temperature monitor? +
- How should I handle the dry ice inside the thermal shipping container? +
- The Controlant Real-Time Monitor status light is red. What should I do? +
- Can I use the Controlant Real-Time Monitor to monitor the vaccine temperature while using the thermal shipping container as my storage unit? +

What is the NDC? +

What do the package and vials look like? +

Is the vaccine only available in a multiple dose vial? +

What are the weights and dimensions of the thermal shipping container? +

Where is the vaccine being manufactured? +

Ensuring Authenticity

Open all

How can I verify if the vaccine product I receive is authentic? +

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.

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7. Myths and facts about COVID-19 vaccines. Centers for Disease Control and Prevention. Accessed August 11, 2021. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html
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General Product Inquiries
Call 1-877-829-2619.

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

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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 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 immunization 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.

Questions and Answers About Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA)*

Collapses accordions in section

GLOBAL: collapses individual question

All

Approval Status

Access to Vaccine Supply

Diluent

Administration

Storage and Stability

Dry Ice

Approval Status

Close all

What is COMIRNATY®?

COMIRNATY® is the brand name for an FDA-approved vaccine, indicated in individuals 16 years of age and older, to prevent COVID-19 caused by SARS-CoV-2. When a medical product receives FDA approval, a brand name for the product is also approved by the FDA.[3]

What does FDA approval mean?

When the FDA approves a vaccine, it means they have determined, based on substantial evidence, that it is effective for its intended use, and that its benefits outweigh its risks when used according to the product's approved labeling.[4]

What is the difference between FDA approval and an EUA?

The EUA process is different from the FDA approval process. Under an EUA and in the midst of an emergency, the FDA can make a product available for public use based on the best available evidence, without having all the evidence that would be needed for FDA approval or clearance.[4]

When the FDA approves a vaccine, it means they have determined, based on substantial evidence, that it is

Thermal Shipping Container

Ensuring Authenticity

When the FDA approves a vaccine, it means they have determined, based on substantial evidence, that it is effective for its intended use, and that its benefits outweigh its risks when used according to the product's approved labeling.[4]

For which age groups has the vaccine received FDA approval?

The vaccine is FDA approved in individuals 16 years of age and older.[1]

Individuals 12-15 years of age are eligible to receive the vaccine under an Emergency Use Authorization.[2]

In the clinical trial, what was the efficacy & safety of the vaccine?

In individuals 16 years of age and older[1]

Please see the full Prescribing Information to see the clinical trial design and efficacy (Section 14 - pg. 15) and safety (Section 6 - pg. 6).[1]

In individuals 12 through 15 years of age[2]

Please see the EUA Fact Sheet for Vaccination Providers to see the clinical trial design and efficacy (Section 18 - pg. 34) and safety (Section 6 - pg. 21).[2]

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Drives to http://labeling.pfizer.com/ShowLabeling.aspx?id=14471&format=pdf&#page=34

Access to Vaccine Supply

Close all

How can I order the vaccine for my practice, office, or hospital?

The US Government will oversee the distribution and coordination. State, local, and tribal authorities will be responsible for the allocation of doses to populations in their jurisdictions. The CDC will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products and associated ancillary supplies.[5]

Whom can I call with product questions?

For product questions, please call 1-877-829-2619.

What is the procedural coverage coding?

The CPT code for the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY® is 91300. The administrative code is 0001A for the first dose, and 0002A for the second dose.

According to the Emergency Use Authorization Fact Sheet for Vaccination Providers, a third dose of the Pfizer-BioNTech COVID-19 Vaccine (0.3 mL) or COMIRNATY® administered at least 28 days following the first two doses 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] The CPT code for this dose is 91300, and the administrative code is 0003A.

What is the cost of the vaccine?

The federal government has contracted with McKesson for purposes of vaccine distribution, such that no American will be charged for either the COVID-19 vaccine or its distribution.[6]

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Who will provide the syringes and needles?

Syringes and needles are included in the ancillary kits provided by CDC to its jurisdictions. The US Government is overseeing ancillary kit distribution and coordination through McKesson and will provide syringes and needles to meet state, local, and tribal authority vaccination needs. This includes sourcing and providing as many low dead-volume syringes and needles as possible to facilitate extracting 6 doses from the multiple dose vials. For further information, please reach out to your state, local, or tribal health department, or the CDC.[5]

Whom do I contact if my ancillary kit is damaged or lost?

Please contact McKesson Customer Service: Phone #: 833-272-6634 Email: SNSSupport@McKesson.com.

Whom do I contact if supplies in the ancillary kit are missing or damaged when opening the shipment?

Please contact McKesson Customer Service: Phone #: 833-272-6634 Email: SNSSupport@McKesson.com.

Whom do I contact for additional ancillary kit supplies (eg, vaccination cards, syringes, and/or needles)?

Please contact your Vaccine State Immunization Program Manager.

Diluent

Close all

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What type of diluent should I use with the vaccine?

Dilute with sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic saline.[1]

How do I dilute the vaccine for administration?

Dilute the thawed vaccine by adding 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP, into the vial. **Do not add more than 1.8 mL of diluent.**[1] Please see the full Prescribing Information and refer to the Dosing & Administration section for specific guidelines on preparation of the vaccine.

Drives to page 12

Will the vaccine be supplied and shipped with the diluent?

The diluent will be packaged within the ancillary kits that may arrive 1 to 2 days before the vaccine shipment arrives.[5]

How can I order more diluent?

Diluent will be included in the ancillary kits provided by CDC to its jurisdictions. The US Government will oversee ancillary kit distribution and coordination, and will provide diluent to meet state, local, and tribal authority vaccination needs. If diluent has been damaged or lost, please call 1-800-666-7248 .[5]

How many full doses does the vial contain?

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[1]:

- 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

- 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

Please see the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and refer to the Dosing & Administration section for instructions on preparation and administration.

Drives to page 12

Does the number of doses extracted from the vial change how much diluent is required? —

No. Always use 1.8 mL of sterile 0.9% Sodium Chloride Injection as the diluent irrespective of the number of doses you are ultimately able to extract from the vial.[1]

Can I use locally sourced diluent? —

Yes, it is acceptable to use locally sourced sterile 0.9% Sodium Chloride Injection, USP. Do not use bacteriostatic saline.[1]

Administration

Close all

Please see the full Prescribing Information for 16 Years & Up and EUA Fact Sheet for Vaccination Providers for 12 Years & Up for dosage, preparation, and administration.

Drives to page 12

What is the dosing schedule for the vaccine? —

The vaccine is given as a series of 2 doses 3 weeks apart.[1] Please see the Dosing & Administration section for instructions on preparation, administration, and adverse event reporting requirements, as well as Safety

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Information for the vaccine.

According to the Emergency Use Authorization Fact Sheet for Vaccination Providers, a third dose of the Pfizer-BioNTech COVID-19 Vaccine (0.3 mL) administered at least 28 days following the first two doses 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]

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Can immunocompromised patients receive a third dose?

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 first two doses 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]

Are the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY® interchangeable with other COVID-19 vaccines?

There are no data available on the interchangeability of this vaccine with other COVID-19 vaccines to complete the vaccination series.[1]

What if the second dose cannot be provided at 3 weeks (21 days)?

Per the full Prescribing Information and EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers), the second dose of the vaccine should be given 3 weeks after the first dose.[1,2]

For more information, refer to the CDC Interim Clinical Considerations for authorized mRNA vaccines.

Drives to https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Does the vaccine contain live virus?

No, the vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.[7]

Do I need to wear gloves when handling individual vials?

Yes, when working with individual vials, wear protective gloves in order to properly handle the vials.[8]

How many doses are in each diluted vial?

After dilution, vials of vaccine contain six doses of 0.3 mL of vaccine. Low dead-volume (LDV) 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[1,2]:

- 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
- See LDV Information Sheet

PP-CVV-USA-0302 submitted to CBER with copy to APLB on 6/2/21

What are the ingredients included in 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)azanediyl)bis(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.[1]

Can I give this vaccine at the same time as other vaccines?

According to the Emergency Use Authorization Fact Sheet for Vaccination Providers, there is no information on the co-administration of this vaccine with other vaccines.[2]

Also see the CDC's Summary Document for Interim Clinical Considerations for use of COVID-19 Vaccines Currently Authorized in the United States.

Drives to https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf

How do I prepare the dose?

Please see the Dosing & Administration section of this website for instructions on how to prepare the vaccine.

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What syringes should I use for diluting?

A 3 mL syringe should be used for diluent withdrawal and mixing. A 5 mL syringe is also acceptable. Please see the Dosing & Administration section for instructions on vaccine preparation.[8]

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What syringes and needles should I use for administration?

Use a 1 mL syringe. Low dead-volume syringes and/or needles should be used. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. If a low dead-volume syringe is not available, a standard 1 mL syringe may be used.[1,2,8] Please see the Dosing & Administration section for

Drives to page 12

instructions on vaccine administration.

Storage and Stability

Close all

Can I still use the product if it has become frozen after it is originally thawed?[1]

No, you should not use the vaccine if it has become frozen after thawing.[1] The vaccine must then be discarded in a sharps container.[8] If you are a healthcare professional in the US and want additional information, visit https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine or call 1-800-438-1985 to talk to a Pfizer Medical Information representative.

How long can I store the vials in the thermal shipping container?

With proper dry ice replenishment, the thermal shipping container may be used as temporary storage for the 195-pack cartons for up to 30 days from delivery.[8]

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.[8]

How is the vaccine stored?

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.[8]

Vials must be kept protected from light until ready to use.[1]

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*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.

If you have lots that will expire shortly, please click here for more information.

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At what temperature does the vaccine need to be stored?

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.[8]

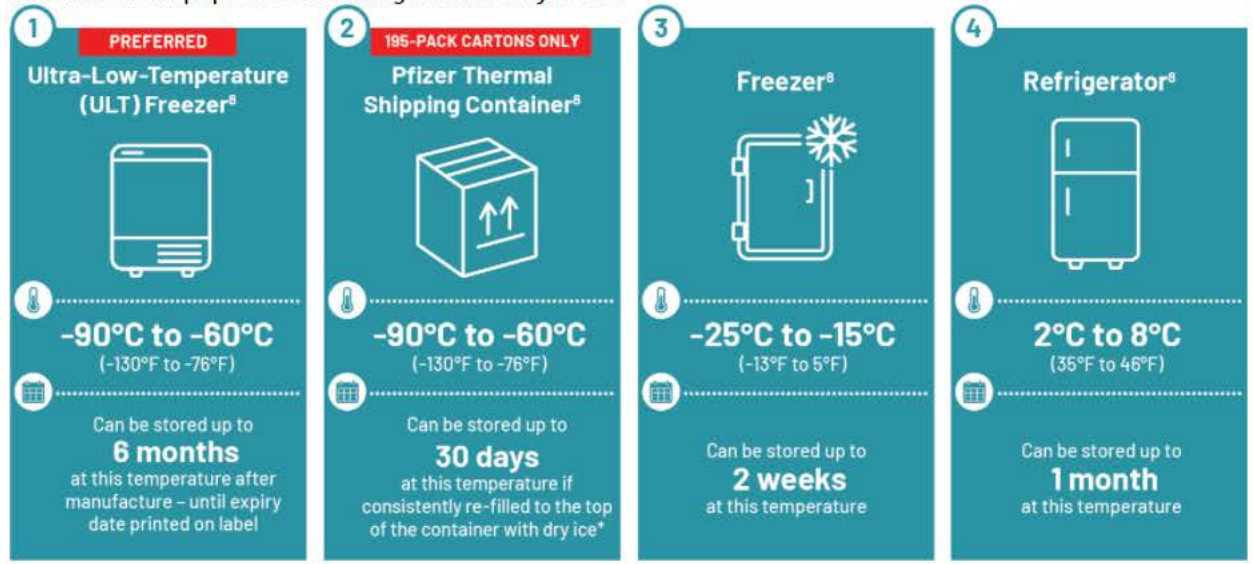
Vials must be kept protected from light until ready to use.[1]

1 PREFERRED 2 195-PACK CARTONS ONLY 3 4

At what temperature does the vaccine need to be stored?

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.[8]

Vials must be kept protected from light until ready to use.[1]



*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.

If you have lots that will expire shortly, please click here for more information.

Drives to page 86

Where can I get an ultra-low-temperature freezer?

Ultra-low-temperature freezer vendors* include but are not limited to Thermo Fisher Scientific, Haier Biomedical, and Stirling Ultracold.

*This information is based on the data provided by the vendors listed. By including them, Pfizer is not endorsing the vendors nor making guarantees about their products. Please contact the vendor directly for availability. If you are a vendor and would like to add, edit, or delete your information, please call 1-877-829-2619.

Is there preservative in the vaccine?

No, the vaccine does not contain preservative.[1]

How long can I store the vials in the ultra-low-temperature freezer?

Undiluted vaccine vials can be stored in an ultra-low-temperature freezer until expiration, which is 6 months from the time of manufacturing.[8] Please check the expiration date on the vials and, if you have lots that will expire shortly, please click here for more information.

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How long can undiluted vials be stored in a refrigerator?

Undiluted vials may be stored in the refrigerator at 2°C to 8°C (35°F to 46°F) for up to 1 month prior to dilution.[1]

Can I still use the product if it has been exposed to light?

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

Can I still use the product if it has been exposed to light?

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.[1] If you are a healthcare professional residing in the US and have questions about using the vaccine, call 1-800-438-1985 to talk to a Medical Information Specialist or go to https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine for more information.

How long does it take for frozen vials to thaw?

In the refrigerator at 2°C to 8°C (35°F to 46°F)[1]:

- 25-pack cartons will take up to 2 hours to thaw
- 195-pack cartons will take up to 3 hours to thaw

Individual vials will take less time. If needed, a frozen vial may be thawed at room temperature (up to 25°C [77°F]) for 30 minutes.[1]

Are components of the vaccine vial made with latex?

The vial stoppers are not made with natural rubber latex.[1]

Dry Ice

Close all

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Do I still need to monitor the temperature if I am using dry ice?

- 25-pack cartons will take up to 2 hours to thaw
- 195-pack cartons will take up to 3 hours to thaw

Individual vials will take less time. If needed, a frozen vial may be thawed at room temperature (up to 25°C [77°F]) for 30 minutes.[1]

Are components of the vaccine vial made with latex? —

The vial stoppers are not made with natural rubber latex.[1]

Dry Ice

Close all

Do I still need to monitor the temperature if I am using dry ice? —

Yes, the temperature of vaccine product must always be monitored in accordance with local requirements.[8] Please refer to the CDC's Vaccine Storage and Handling Toolkit for guidance on storage and handling of vaccines at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

How often do I need to add dry ice to the thermal shipping container? —

If you are using the thermal shipping container as temporary storage for the 195-pack cartons, the container must be opened, inspected, and replenished with dry ice within 24 hours of receipt. **Do not open the vial cartons or remove vials until you are ready for thawing or use.** It is recommended that the thermal shipping container not be opened more than 2 times a day and should not be opened for more than 3 minutes at a time. If these guidelines are followed, the thermal shipping container should be replenished with dry ice every 5 days. If the thermal shipping container is opened more frequently, replenishment will need to occur more often.[8] Please refer to

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the Product Storage & Dry Ice section for instructions for replenishing dry ice.

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.[8]

How do I refill the thermal shipping container?

For Softbox containers: Fill any low areas in the side compartments of the thermal shipping container with dry ice pellets until completely filled, so that it is equal with but does not exceed the top edges of the box that holds the vial cartons. Reinsert the dry ice pod on top of the box that holds the vial cartons. Then fill the dry ice pod to the top with dry ice (do not overfill).[8]

For AeroSafe containers: Fill any low areas in the side compartments of the thermal shipping container with dry ice pellets until completely filled, so that it is equal with but does not exceed the top edges of the side compartments. Reinsert the dry ice pod on top of the box that holds the vial cartons. Then fill the dry ice pod to the top with dry ice (do not overfill).[8]

Where and how can I get more dry ice?

Dry ice vendors* include but are not limited to Airgas, Linde, Continental Carbonic Products Inc, and Matheson.

*This information is based on the data provided by the vendors listed. By including them, Pfizer is not endorsing the vendors nor making guarantees about their products. Please contact the vendor directly for availability. If you are a vendor and would like to add, edit, or delete your information, please call 1-877-829-2619.

Is there a limit to how long I can use dry ice to maintain temperature, and how many times can I refill the container with dry ice?

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The thermal shipping container may be used as temporary storage for the 195-pack cartons for up to 30 days from delivery. It is recommended that the thermal shipping container not be opened more than 2 times a day, and shouldn't be opened for more than 3 minutes at a time. If these guidelines are followed, after dry ice replenishment within 24 hours, the thermal shipping container should then be replenished with dry ice every 5 days. If the thermal shipping container is opened more frequently, replenishment will need to occur more often.[8]

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.[8]

What type of protective gear should be worn when handling dry ice?

Wear safety goggles or safety glasses with side shields and waterproof insulated gloves for handling dry ice.[8] Click here to view the Dry Ice Safety Data Sheet.

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Drives to page 72

How do I dispose of dry ice when I no longer need it?

Dry ice can be hazardous. Take necessary precautions by reviewing the Dry Ice Safety Data Sheet in the Product Storage & Dry Ice section and consulting with your Occupational Health Department. To discard the dry ice, open the thermal shipping container and leave it at room temperature in a well-ventilated area. The dry ice will sublime from a solid to a gas.[8]

Can I return the thermal shipping container with dry ice?

No, safely discard the dry ice when the thermal shipping container is no longer needed.[8] Review the Dry Ice Safety Data Sheet and consult your Occupational Health Department for further guidance.

Thermal Shipping Container

Close all

How do I follow up on the status of my product order?

If you are a healthcare professional trying to locate your order of the vaccine and you reside in the US, you can call 1-800-666-7248.

Whom do I contact if I have an issue with my shipment?

If you are a healthcare professional having an issue with your shipment of the vaccine and you reside in the US, you can call 1-800-666-7248.

What type of gloves should I use when transferring vial cartons from the thermal shipping container to the refrigerator?

Wear waterproof insulated gloves to prevent skin contact while transferring vial cartons from the thermal shipping container to the refrigerator.[8]

How can I return the thermal shipping container and temperature monitor?

To return the thermal shipping container and temperature-monitoring device, use the preprinted return shipping label included inside the container and apply over the existing shipping label. After the thermal shipping container is no longer needed to store the vaccine, you should discard the dry ice. To discard, open the thermal shipping container and leave it at room temperature in a well-ventilated area. The dry ice will sublime from a solid to a gas. Take necessary precautions by reviewing the Dry Ice Safety Data Sheet and consulting with your Occupational Health Department.[8]

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Ensure the Dry Ice UN1845 markings and diamond-shaped Class 9 hazard label on the thermal shipping container are covered by placing a blank label over them in preparation for the return, as the container no longer contains dry ice. Blank sticker labels to place over the UN1845 markings can be found on the back page of the Shipping and Handling Guidelines. You can contact the carrier identified on the return label to arrange the return.[8]

For additional assistance on returns, call 1-701-540-4039 if in the US.

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How should I handle the dry ice inside the thermal shipping container?

Dry ice can be hazardous. Take necessary precautions by reviewing the Dry Ice Safety Data Sheet and consulting 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 working with dry ice.[8] Please visit the Product Storage & Dry Ice section for step-by-step instructions for safely handling the thermal shipping container.

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The Controlant Real-Time Monitor status light is red. What should I do?

When the shipment status light is red, this means that the device is functioning properly but has recorded an out-of-range temperature.[8]

You will automatically receive a shipment delivery email from Controlant, the temperature-monitoring device company. This email will include a Quality Disposition Report, which will confirm the product disposition and actions required if the status light is red.[8]

Can I use the Controlant Real-Time Monitor to monitor the vaccine temperature while using the thermal shipping container as my storage unit?

Yes, you will be able to use the temperature-monitoring device to monitor the vaccine temperature.[8] Contact Controlant customer service at: 1-701-540-4039 or visit https://in.controlant.com/onsitemonitoring to access the

Controlant customer service at: 1-701-540-4039 or visit https://in.controlant.com/onsitemonitoring to access the Controlant Onsite Monitoring Playbook and instructional videos.

What is the NDC?

According to the EUA Fact Sheet for Vaccination Providers, the NDC for Pfizer-BioNTech COVID-19 Vaccine labeled vials is 59267-1000-3 for 25-pack cartons and 59267-1000-2 for 195-pack cartons.[2]

What do the package and vials look like?

For 195-pack cartons[8]:



Softbox

AeroSafe



For 25-pack cartons[8]:



Softbox **AeroSafe**

Is the vaccine only available in a multiple dose vial?

Yes, the vaccine is only available in multiple dose vials.[1]

What are the weights and dimensions of the thermal shipping container?

- External Dimensions of the Aerosafe 47L7: 17.5" x 17.5" x 21.5"[8]
- External Dimensions of Softbox Medium ULT: 15.75" x 15.75" x 22.04"[8]

- Dimension of one 25-pack carton: approximately 3.26" x 3.26" x 1.54"[8]
- Dimension of one 195-pack carton: approximately 9" x 9" x 2"[8]
- Weight range for both thermal shipping containers: approximately 64 lb to 80 lb (29 kg to 36 kg)[8]

Where is the vaccine being manufactured?

Multiple Pfizer manufacturing locations (Puurs, Belgium and Kalamazoo, Michigan).[8]

Ensuring Authenticity

Close all

How can I verify if the vaccine product I receive is authentic?

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[1]
- 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**[8]
- Ensure the safety of the vaccine vials by limiting access to only authorized personnel. The location they are

FDA-CBER-2021-5683-0951179

- 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[5,9]

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.

- Two types of thermal shipping containers are used to transport the vaccine: a Softbox thermal shipping container and an AeroSafe thermal shipping container. Their outer appearance is different, but their components are very similar. Both thermal shipping containers contain a dry ice pod, vial cartons, box that holds the vial cartons, foam lid, and an outer box housing all the components[8]
- The vaccine is contained in 2 mL type 1 glass preservative-free multiple dose vials with 0.45 mL of frozen liquid drug product[8]

For 195-pack cartons[8]:



FDA-CBER-2021-5683-0951180

For 195-pack cartons[8]:



Softbox

AeroSafe



For 25-pack cartons[8]:







Softbox AeroSafe

- External Dimensions of the Aerosafe 47L7: 17.5" x 17.5" x 21.5"[8]
- External Dimensions of Softbox Medium ULT: 15.75" x 15.75" x 22.04"[8]
- Dimension of one 25-pack carton: approximately 3.26" x 3.26" x 1.54"[8]
- Dimension of one 195-pack carton: approximately 9" x 9" x 2"[8]
- Weight range for both thermal shipping containers: approximately 64 lb to 80 lb (29 kg to 36 kg)[8]

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. Proprietary name review for biologic products. US Food & Drug Administration. Accessed August 11, 2021. https://www.fda.gov/vaccines-blood-biologics/labeling-cber-regulated-products/proprietary-name-review-biologic-products
4. Understanding the regulatory terminology of potential preventions and treatments for COVID-19. US Food & Drug Administration. Accessed August 11, 2021. https://www.fda.gov/consumers/consumer-updates/understanding-regulatory-terminology-potential-preventions-and-treatments-covid-19
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6. Biden administration purchases additional doses of COVID-19 vaccines from Pfizer and Moderna. US Department of Health & Human Services. Accessed August 16, 2021. https://www.hhs.gov/about/news/2021/02/11/biden-administration-purchases-additional-doses-covid-19-vaccines-from-pfizer-and-moderna.html
7. Myths and facts about COVID-19 vaccines. Centers for Disease Control and Prevention. Accessed August 11, 2021. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html
8. Data on File. Pfizer Inc. New York, NY.
9. McCurry MC. Secure disposal of vaccine vials and packaging recommendations. US Department of Defense; 2020.

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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 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 immunization 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.

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.

Drives to page 32

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

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

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

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

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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



Updated as of 6/10/2021

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

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

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Dry Ice Replenishment Sheet

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

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

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Updated as of 5/20/2021

Dry Ice Replenishment Sheet



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.

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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.



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Dry Ice Replenishment Sheet

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

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Safety and Storage

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Safe Handling Guidelines for Dry Ice

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

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Dry Ice Safety Data Sheet

Access the Dry Ice Safety Data Sheet.

Click here

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Product Safety Data Sheet

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

Click here

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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.



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.

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Dry Ice Safety Data Sheet

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Product Safety Data Sheet

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Returning Your Thermal Shipping Container

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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

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Storage and Handling[3]

- 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
  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

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.



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

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Sto

- 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
  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

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		
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 **cumulative** time the vials are stored at -25°C to -15°C (-13°F to 5°F) should be tracked and **should not**

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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

Drives to https://safetydatasheets.pfizer.com/DirectDocumentDownloader/Document?prd=PF00096~~PDF~~MTR~~PFE~~EN

Upon clicking, opens all accordions

Open all

Frozen Vials Prior to Use[1] +

Transportation of Frozen Vials[1] +

Frozen Vials Prior to Use[1] +

Transportation of Frozen Vials[1] +

Thawed Vials Before Dilution[1] +

Transportation of Thawed Vials[1] +

Vials After Dilution[1] +

Upon clicking, opens individual accordions

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

Drives to this question on pg 54

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®

Frozen Vials Prior to Use[1]

Collapses individual accordion

- 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
- 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
- Cartons and vials of the vaccine with an expiry date of August 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[2]

Printed Expiry Date[2]	Updated Expiry Date2[2]
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

- 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

Transportation of Frozen Vials[1]

- If local redistribution is needed and full vial cartons containing vials cannot be transported at -90°C to -60°C (-130°F to -76°F), vials may be transported at -25°C to -15°C (-13°F to 5°F)
- Any hours used for storage or transport at -25°C to -15°C (-13°F to 5°F) count against the 2-week limit for storage at -25°C to -15°C (-13°F to 5°F)
- Frozen vials transported at -25°C to -15°C (-13°F to 5°F) may be returned one time to the recommended storage condition of -90°C to -60°C (-130°F to -76°F)

Thawed Vials Before Dilution[1]

Thawed Under Refrigeration

- Thaw and then store undiluted vials in the refrigerator [2°C to 8°C (35°F to 46°F)] for up to 1 month. A carton of 25 vials or 195 vials may take up to 2 or 3 hours, respectively, whereas a fewer number of vials will thaw in less time

Thawed at Room Temperature

- For immediate use, thaw undiluted vials at room temperature [up to 25°C (77°F)] for 30 minutes. Thawed vials can be handled in room light conditions. **Vials must reach room temperature before dilution**
- Undiluted vials may be stored at room temperature for no more than 2 hours

Transportation of Thawed Vials[1]

- Available data support transportation of one or more thawed vials at 2°C to 8°C (35°F to 46°F) for up to 12 hours

Vials After Dilution[1]

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- After dilution, store vials between 2°C to 25°C (35°F to 77°F) and use within 6 hours from the time of dilution
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light
- Any vaccine remaining in vials must be discarded after 6 hours
- Do not refreeze

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 professional[1]
  - The vaccine is not taken orally and is not available in a capsule or tablet form[1]
- 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]

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- 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

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.

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55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by
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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.

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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 immunization 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.

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

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.

Anchor link to Letter of Authorization (LOA) on page 137. If the LOA is updated, this document will be updated to display the most recent LOA

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

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Checklist for Storage, Handling, and Preparation

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

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

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.

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- 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
  - HCP Lot Letter
  - Additional Lot Details

Drives to https://www.pfi.sr/hcp-lot-letter

Drives to https://www.pfi.sr/lot-numbers



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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



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Updated as of 5/20/2021

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Updated as of 5/20/2021

Pocket Guide for Preparation and Administration

PP-CVV-USA-0307 (English) submitted to CBER with copy to APLB on 7/13/21

PP-CVV-USA-0343 (Spanish) submitted to CBER with copy to APLB on 8/4/21

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



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How to Prepare and Administer the Vaccine Poster

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



Updated as of 5/20/2021

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



Updated as of 5/20/2021

Pocket Guide for Preparation and Administration

FDA-CBER-2021-5683-0951208

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



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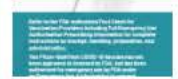
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Drive to https://vaers.hhs.gov/

Adverse Event Reporting

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Drives to https://www.pfizersafetyreporting.com/#/en

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Helpful links

Drives to https://www.cdc.gov/coronavirus/2019-ncov/index.html

Information About COVID-19 From the CDC*

Medical Information

Drives to https://www.pfizermedicalinformation.com/en-us/pfizer-biontech-covid-19-vaccine

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Medical Information

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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[1]
- 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 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

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.



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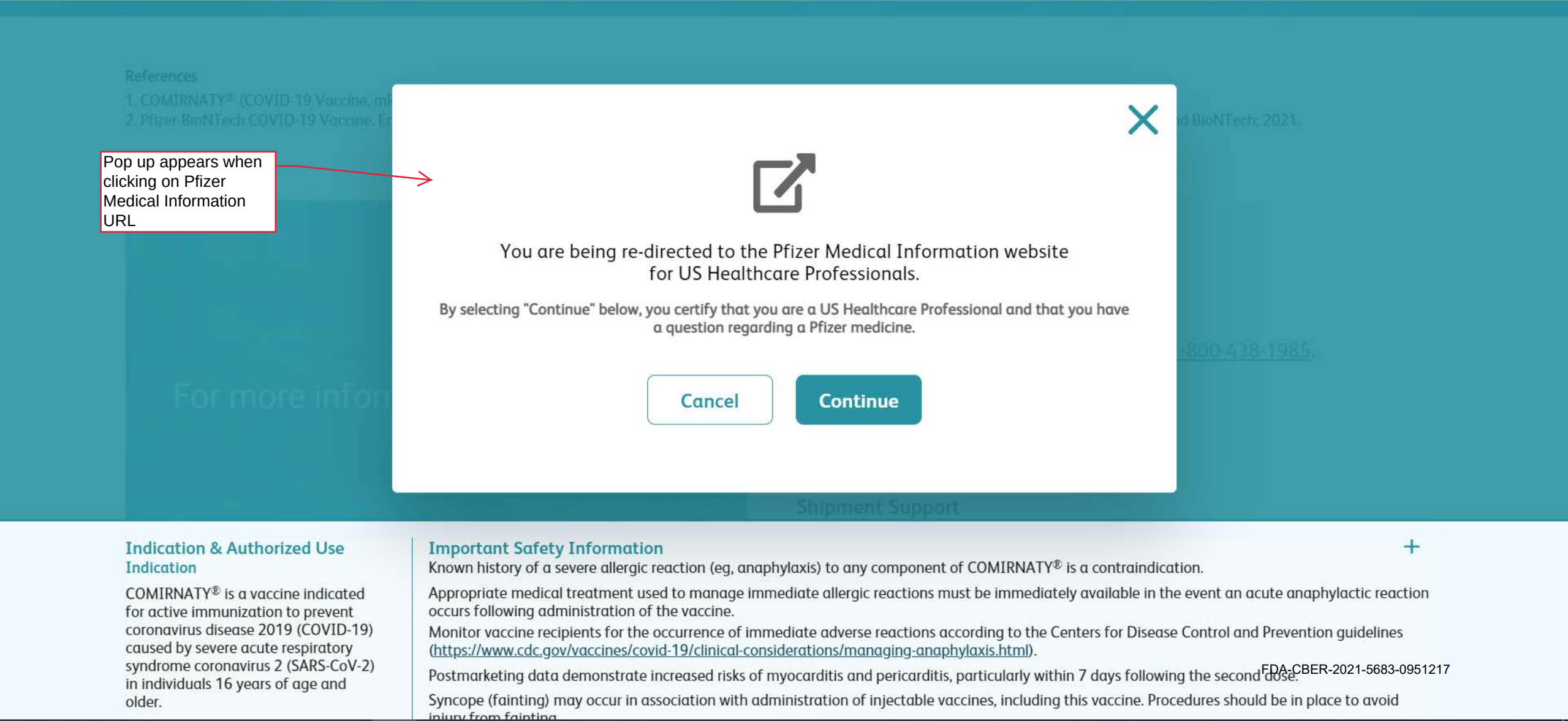
Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

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.

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Pop up appears when clicking on Pfizer Medical Information URL



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.

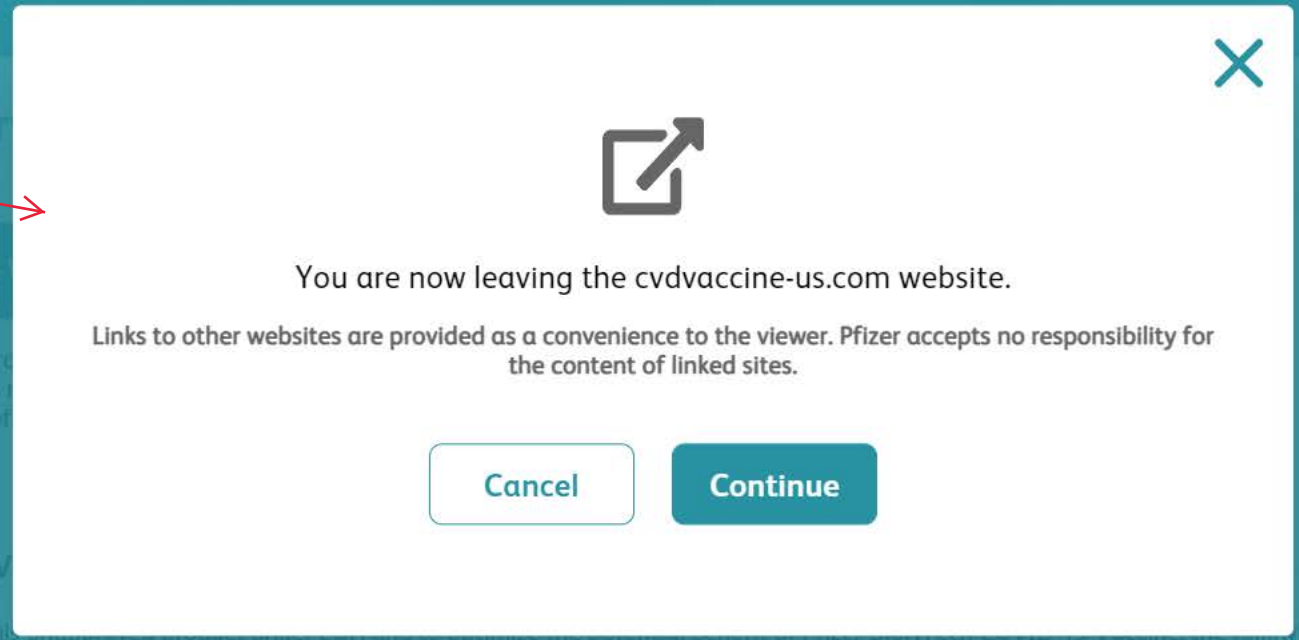
Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine.

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.

Pop up appears when clicking on a URL that leaves the site



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

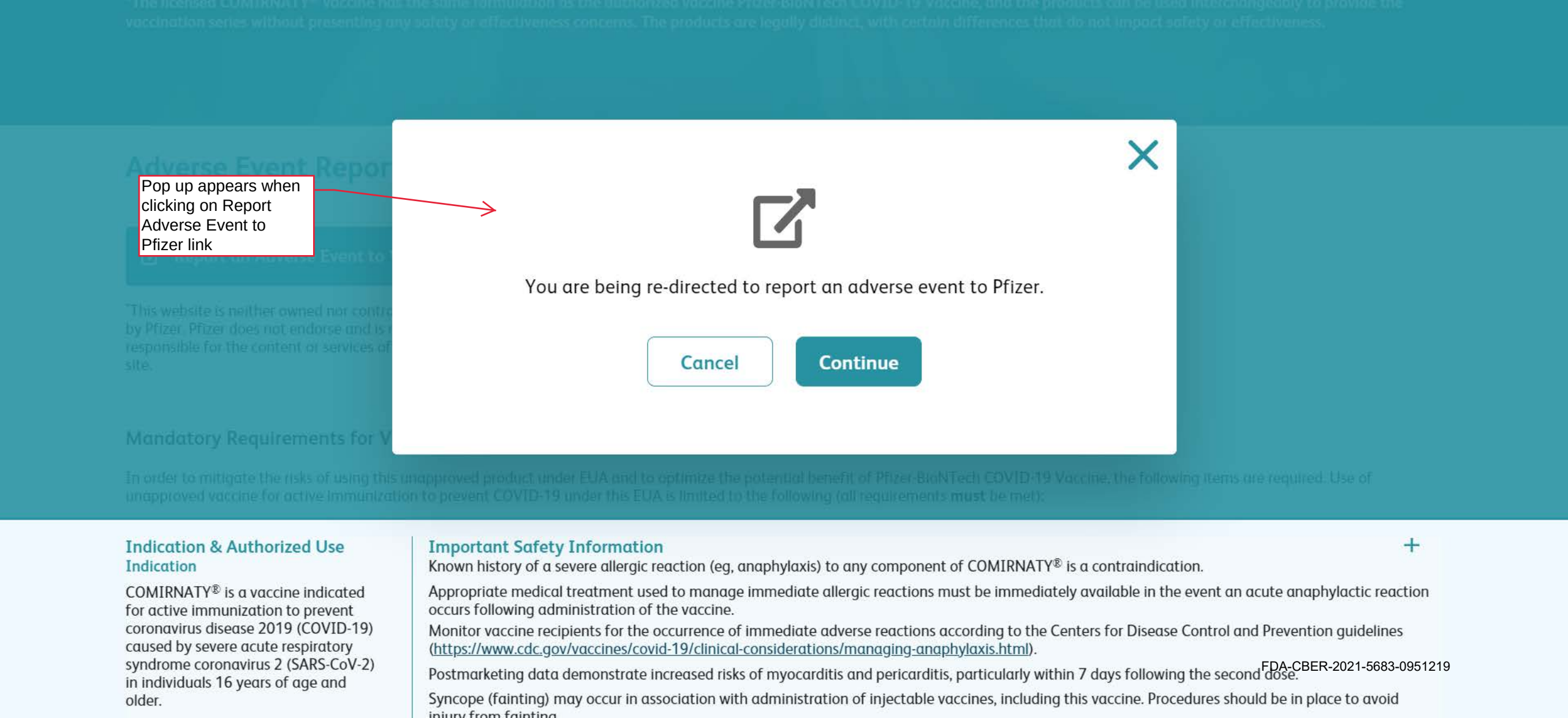
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Syncope (fainting) may occur in association with administration of injectable vaccines, including this vaccine. Procedures should be in place to avoid injury from fainting.

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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.

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.

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"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.

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Important Safety Information +

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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.

This site is intended for U.S. Healthcare Professionals.

Indication & Authorized Use

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.

Authorized Use

COMIRNATY® (COVID-19 Vaccine, mRNA) is also authorized for emergency use in individuals 12 through 15 years and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 12

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

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in individuals 16 years of age and older.

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The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 12 years of age and older, and provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

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.

Important Safety Information +

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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

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Indication & Authorized Use

Safety Info

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

EUA Letter & Fact Sheets (12 Years & Up)

FDA EUA Letter (12 Years & Up)

EUA Fact Sheet for Vaccination Providers - English (12 Years & Up)

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

YEARS OF AGE[1]

In individuals 16 years of age and older, the Pfizer-BioNTech COVID-19 Vaccine, also

Important Safety Information

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Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following

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Indication & Authorized Use

Safety Info

Full Prescribing Information (FDA Approved

Important Safety Information

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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.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine.

The vaccine may not protect all vaccine recipients.

In clinical studies of participants 16 through 55 years of age, the most commonly reported adverse reactions (≥10%) were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (45.5%), chills (41.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).

In clinical studies of participants 56 years of age and older, the most commonly reported adverse reactions (≥10%) were pain at the injection site (78.2%), fatigue (56.9%), headache (45.9%), muscle pain (32.5%), chills (24.8%), joint pain (21.5%), injection site swelling (11.8%), fever (11.5%), and injection site redness (10.4%).

In a clinical study, adverse reactions in adolescents 12 through 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

Before administration of the vaccine, please see full Prescribing Information (16+ years of age) and EUA Fact Sheet for Vaccination Providers (12+ years of age).

Patients should always ask their healthcare providers for medical advice about adverse events. You are encouraged to report negative side effects of vaccines to the US Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit https://vaers.hhs.gov/reportevent.html or call 1-800-822-7967.

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.

Authorized Use

COMIRNATY® (COVID-19 Vaccine, mRNA) is also authorized for emergency use in individuals 12 through 15 years and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 12 years of age and older, and provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

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Indication & Authorized Use

Safety Info

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

EUA Letter & Fact Sheets (12 Years & Up)

BIONTECH Pfizer

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 immunization 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.

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

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BIONTECH Pfizer

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An der Goldgrube 12
55131 Mainz, Germany
Marketing Authorization Holder

Manufactured by Pfizer Inc.
New York, NY
10017

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Dedicated to Authorized Use

Select Site

Full Prescribing Information (FDA Approved 18 Years & Up)

Full Prescribing Information (FDA Approved 12 Years & Up)

BIONTECH Pfizer

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),[1] has been authorized to prevent COVID-19 caused by SARS-CoV-2.[1]

AUTHORIZED FOR EMERGENCY USE[1]

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 the 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 FDC Act, 21 U.S.C. 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.[1]

The licensed COMIRNATY® vaccine has the same formulation as the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine, but the licensed vaccine may be administered to individuals without amending any authorization in effect for the EUA-authorized vaccine. Otherwise, any distinctions in how the vaccine is administered do not impact safety or effectiveness.

Download and print the resources below. View the Full Prescribing Information for 16 Years & Up or the Full Prescribing Information for 12 Years & Up.

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

Current Full Prescribing Information

EUA Fact Sheet for Vaccination Providers (12 Years & Up)

Current Fact Sheet

How to Prepare and Administer the Vaccine Poster

English

Español

Sheet

Updated as of 5/20/2021

Dosing and Administration[1]

Vaccine is administered as a series of 2 doses three weeks apart[1]

Day 0

30 mcg (0.3 mL)

Intramuscular Injection

Day 21

30 mcg (0.3 mL)

Intramuscular Injection

According to the Emergency Use Authorization Fact Sheet for Vaccination Providers, **a third dose may be administered to individuals at least 28 days following the second dose of the vaccine to achieve a sufficient level of antibodies in individuals who are moderately to severely immunocompromised, as a series is considered to have an equivalent level of immunocompromise.**

Multiple Dose Vial – Six Doses

After dilution, each vial of the vaccine contains six doses of 0.3 mL. Discard any unused portion six hours after the vial is punctured or if vaccine is not used within the storage time limit. Do not refreeze. Do not combine vials, even if they may not be sufficient volume to withdraw a dose. Do not pool doses. Do not use syringes of the type of syringe and needle:

- Each dose must contain 0.3 mL of vaccine
- If the vaccine is diluted, ensure that the total volume per dose is at least 0.3 mL, discard the dose if it is less than 0.3 mL
- Do not use vaccine sources from multiple vials

Description

The vaccine is a sterile suspension for injection for intramuscular use. The vaccine is a white to off-white suspension in multiple-dose vials; each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP before use. After dilution, each vial contains 6 doses of 0.3 mL each. Each dose is designed to deliver 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2.

Each 0.3 mL dose of the vaccine also includes the following ingredients:

ALC-0315 (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate) (part of SM-102), 0.43 mg; cholesterol, 0.09 mg; 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 0.09 mg; potassium chloride, 0.2 mg; monobasic potassium phosphate, 0.2 mg; sodium chloride, 1.17 mg; dibasic sodium phosphate dihydrate, and sucrose, 68 mg. The diluent is sterile 0.9% Sodium Chloride Injection, USP; constituents of the diluent may be found in the Description section.

The vaccine does not contain preservatives.

The stopper does not contain latex and natural rubber latex.

Dosing and Schedule

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

The EUA-authorized COMIRNATY® (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine that has been authorized for emergency use and is interchangeable to provide the COVID-19 vaccination series.[1]

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 one dose of the Pfizer-BioNTech COVID-19 Vaccine should receive the vaccine to complete the vaccination series.

According to the Emergency Use Authorization Fact Sheet for Vaccination Providers, a third dose may be administered to individuals at least 28 days following the second dose of the vaccine to achieve a sufficient level of antibodies in individuals 12 years of age who have undergone solid organ transplantation or are diagnosed with conditions that are considered to be of equivalent level of immunocompromise.[2]

Dose Preparation

- The Multiple Dose Vial contains a volume of 2.63 mL to ensure that six doses can be withdrawn. **Dose out contents preservative**. Each vial must be diluted with 1.8 mL of sterile 0.9% Sodium Chloride Injection, USP before use.
- Filling must be checked in the refrigerated (2°C to 8°C / 35°F to 46°F) or at room temperature (up to 25°C / 77°F).
- Before dilution, the vial may be transported in the cartridge within its off-white opaque shipping container.
- 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 each.
- 0.9% Sodium Chloride Injection, USP is not packaged with the vaccine and must be sourced separately. **Do not substitute diluents. Do not use bacteriostatic 0.9% Sodium Chloride Injection, USP, Bacteriostatic Water for Injection, USP, or any other diluent. Do not add more than 1.8 mL of diluent to the vial.** See Description section for additional information on the preparation.
- **After dilution**, the vaccine will be an off-white suspension. **Do not use if particulates other than white to off-white amorphous particles are observed.**

Strict adherence to aseptic technique must be followed

Thawing Prior to Dilution

- Thaw vial(s) of the vaccine before use either:
  - Allowing vial(s) to thaw in the refrigerator (2°C to 8°C / 35°F to 46°F). Allow 2 hours and 30 min for vial to thaw. Once thawed, the vial can be stored for up to 5 days in the refrigerator (2°C to 8°C / 35°F to 46°F).
  - Allowing vial(s) to sit at room temperature (up to 25°C / 77°F) for 30 minutes.
- Using either thawing method, each must reach room temperature prior to dilution and must be diluted within 2 hours.

Gently Mix

- Before dilution, gently mix the vial by inverting the vial 10 times.
- **Do not shake.**
- Visually inspect vaccine in the vial.
- The vaccine will be an off-white suspension. Do not use if vaccine is discolored or contains extraneous particles.

Dilute

- Dilute vial with 1.8 mL Sodium Chloride Injection, USP 0.9% solution.
- Using sterile technique, withdraw 1.8 mL of 0.9% sodium chloride diluent syringe (21 gauge or narrower needle).
- Cleanse the vaccine vial stopper with a single-use alcohol prep pad.
- Add 1.8 mL of Sodium Chloride Injection, USP into the vaccine vial.

Equalize

- Equalize vial pressure before removing the needle from the vial by withdrawing 1.8 mL of air into the empty diluent syringe.

Gently Mix

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

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 alcohol prep pad. Withdraw **0.3 mL** of the vaccine, ensuring that the withdrawn volume syringe and needle.
- Each dose must contain 0.3 mL of vaccine.
- If the vaccine is diluted, ensure that the total volume per dose is at least 0.3 mL, discard the dose if it is less than 0.3 mL
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any vaccine volume.
- Do not pool doses from multiple vials

Review the Product Safety Data Sheet for the vaccine before handling. Avoid contact with skin and mucous membranes. Ensure that appropriate personal protective equipment is worn when handling vaccine. Remove broken glass with forceps and dispose of as biohazardous waste. Use an alcohol pad on the stopper of the vial and allow it to dry before puncture.

Administration

Visually inspect each dose in the dosing syringe for particulate matter and discoloration prior to administration. Discard dose if such matter is observed.

- verify the final dosing volume of 0.3 mL
- confirm there are no particulates in the vial and the dilution is observed
- if particulate matter or discoloration is observed or contains particulate matter

Administer the vaccine intramuscularly.

After dilution, each vial of the vaccine contains six doses of 0.3 mL of vaccine. Use dedicated syringes and needles for each dose withdrawn from the vial. Do not pool doses. Do not combine vials, even if they may not be sufficient volume to withdraw a dose. Do not administer without a sixth dose from a single vial. Prospective studies have not been conducted.

- 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 vaccine volume.
- Do not pool doses from multiple vials

Review the Product Safety Data Sheet for the vaccine before handling. Avoid contact with skin and mucous membranes. Ensure that appropriate personal protective equipment is worn when handling vaccine. Remove broken glass with forceps and dispose of as biohazardous waste. Use an alcohol pad on the stopper of the vial and allow it to dry before puncture.

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

- Pfizer-BioNTech COVID-19 Vaccine, mRNA and ensuring that people have accurate information about the vaccine, including that it is authorized or approved and how it is administered. We are working closely with the Foundation office of illegitimate vaccines to prevent counterfeit vaccines from entering the supply chain and to protect patients.
- Pfizer-BioNTech COVID-19 Vaccine, mRNA is supplied in vials and is available in a carton of 10 vials.
- Authorized healthcare providers administering Pfizer-BioNTech COVID-19 Vaccine, mRNA should verify that the vial has dispersed in a vial with a **gray plastic cap** and a **gray label** with **a gray-scored crossbar** and **the wording "12+ years old purple border"**.
- Vials with a purple cap or the vaccine vial by looking at the vaccine vial label. Vials with purple caps or purple borders should not be used.
- Vials with purple caps or purple borders should receive vials or vaccines that contain different formulations and may not be authorized or approved for use in your country.
- Vials with purple caps or purple borders should not be used.
- Vials with purple caps or purple borders should receive vials or vaccines that contain different formulations and may not be authorized or approved for use in your country.
- Vials with purple caps or purple borders should not be used.

If you suspect the vaccine you have received may be counterfeit, contact us at 1.800.438.1985 or productsecurity@pfizer.com for additional information.

Learn more about counterfeit medicines at www.fda.gov/drugs/drug-safety-and-availability/fdas-efforts-regarding-falsified-and-counterfeit-drugs.

References

1. COMIRNATY® (COVID-19 Vaccine, mRNA) Emergency Use Authorization. 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. COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. Version 3. September 16, 2020 Proposed. U.S. Centers for Disease Control and Prevention. 2020.
4. Pfizer-BioNTech COVID-19 Vaccine, mRNA Emergency Use Instructions. US Department of Defense. 2021.

For more information

Pfizer Customer Service
Call: 1.800.879.3477

Medical Information
Email: medicalinformation@pfizer.com
or call: 1.800.438.1985

General Product Inquiries
Call: 1.877.829.2619

Shipment Support
US Trade Customer Service
Call: 1.800.955.7268

BIONTECH Pfizer

Manufactured by BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

Manufactured by Pfizer Inc.
New York, NY
10017

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Indication & Authorized Use

Safety Info

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

EUA Letter & Fact Sheets (12 Years & Up)

BIONTECH Pfizer

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 immunization 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.**

Clinical Efficacy & Safety

In individuals 16 years of age and older[1]

Please see the full Prescribing Information to see the clinical trial design and efficacy (Section 14 - pg. 15) and safety (Section 6 - pg. 6).[1]

In individuals 12 through 15 years of age[2]

Please see the EUA Fact Sheet for Vaccination Providers to see the clinical trial design and efficacy (Section 18 - pg. 34) and safety (Section 6 - pg. 21).[2]

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.

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.

BIONTECH Pfizer

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.

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Business Authorized Use

Safety Info

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

EUA Letter & Fact Sheets (12 Years & Up)

BIONTECH Pfizer

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 immunization 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 the U.S. Food and Drug Administration (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 FDCA, 21 U.S.C. 360bbb-3(b)(1), 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 may 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.**

Adverse Event Reporting

Report an Adverse Event to VAERS

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Report an Adverse Event to Pfizer

Mandatory Requirements for Vaccine Administration Under Emergency Use Authorization[2,3]

In order to mitigate the risks of using this unapproved vaccine under EUA and to optimize the potential benefit of the vaccine, the following conditions are required by the Commissioner (or designee) to assure elements to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. The vaccine is authorized for use in individuals 12 years of age and older.
2. The vaccination provider must communicate to the individual receiving the vaccine and their caregiver, information consistent with the "Vaccine Information Fact Sheet for Recipients and Caregivers" prior to the individual receiving the vaccine.
3. The vaccination provider must include vaccination information in the data/local jurisdiction immunization information system (IIS) or other designated system.
4. The vaccination sponsor must report the mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS):
   - vaccine administration errors whether or not associated with an adverse event,
   - serious adverse events[4] (irrespective of attribution to vaccination),
   - cases of Multisystem Inflammatory Syndrome (MIS) in adults and children, and
   - cases of COVID-19 that result in hospitalization or death.

   Complete and submit reports 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 "this vaccine EUA" in the description section of the report.
5. The vaccination sponsor is responsible for responding to FDA requests for information about vaccine administration errors, adverse events, cases of MIS in children and adults, and cases of COVID-19 that result in hospitalization or death following administration of the vaccine to recipients.

*Serious adverse events are defined as:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- An important medical event that based on appropriate medical judgment may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Other Adverse Event Reporting to VAERS and Pfizer Inc.

Vaccination providers may report to VAERS other adverse events that are not required to be reported using the contact information below.

To the extent feasible, report adverse events to Pfizer Inc. using the contact information below or by providing a copy of the VAERS form to Pfizer Inc.

Website: www.pfizersafetyreporting.com

Fax number: 1-866-635-8337

Telephone number: 1-800-438-1985

[2]Vaccination providers administering COMIRNATY® (COVID-19 Vaccine, mRNA) must adhere to the same reporting requirements.[2]

Important Safety Information

Known history of a severe allergic reaction (eg, anaphylaxis) to any component of COMIRNATY® to a coronavirus 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 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 vaccine, including this vaccine. Procedures should be in place to avoid injury from fainting.

Immunocompromised persons, including individuals receiving immunosuppressive therapy, may have a diminished immune response to the vaccine.

The vaccine may not protect all vaccine recipients.

In clinical studies of participants 16 through 55 years of age, the most commonly reported local adverse events (≥10%) were pain at the injection site (88.6%), fatigue (70.1%), headache (64.9%), muscle pain (61.5%), chills (45.5%), joint pain (27.5%), fever (17.8%), and injection site swelling (10.6%).

In clinical studies of participants 56 years of age and older, the most commonly reported local adverse reactions (≥10%) were pain at the injection site (78.9%), fatigue (59.4%), headache (50.9%), muscle pain (32.5%), chills (34.8%), joint pain (29.5%), injection site swelling (11.8%), fever (13.5%), and injection site redness (10.4%).

In a clinical study, adverse reactions in adolescents 12 through 15 years of age included pain at the injection site (90.5%), fatigue (77.1%), headache (74.2%), chills (43.2%), muscle pain (42.2%), fever (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%).

Before administration of the vaccine, please see full Prescribing Information (16+ years of age) and EUA Fact Sheet for Vaccination Providers (12+ years of age).

Patients should always ask their healthcare providers for medical advice about adverse events. You are encouraged to report negative side effects of vaccines to the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Visit https://vaers.hhs.gov/reportevent.html or call 1-800-822-7967.

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.

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.

BIONTECH Pfizer

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's proprietary mRNA technology, was developed by both BioNTech and Pfizer.

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Select Audience | Select Language

Full Prescribing Information (FDA Approved 16 Years & Up, US)

EUA Letter & Fact Sheets (12 Years & Up)

BIONTECH | Pfizer

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

In individuals 16 years of age and older, the COMIRNATY® COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA),[1] has been approved to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2.

AUTHORIZED FOR EMERGENCY USE[2]

The emergency use of this 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 individuals 12 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 Act, 21 U.S.C. 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.[2]

Questions and Answers About Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA)

Select a category

- All
- Approved Status
- Access to Vaccine Supply
- Diluent
- Administration
- Storage and Stability
- Dry Ice
- Thermal Shipping Container
- Ensuring Authenticity

Approved Status

Open all

- What is COMIRNATY®?
- What does FDA approval mean?
- What is the difference between FDA approval and an EUA?
- For which age groups has the vaccine received FDA approval?
- In the clinical trial, what were the efficacy & safety of the vaccine?
- How can I order the vaccine for my practice, office, or hospital?
- Whom can I call with product questions?
- What is the procedural coverage/coding?
- What is the cost of the vaccine?
- Who will provide the syringes and needles?
- Where do I contact if my ancillary kit is damaged or lost?
- Where do I contact if supplies in the ancillary kit are missing or damaged when opening the shipping container?
- Where do I contact for additional ancillary kit supplies (eg, vaccination cards, syringe, sterile needles)?

Access to Vaccine Supply

Open all

- How can I order the vaccine for my practice, office, or hospital?
- Whom can I call with product questions?
- What is the procedural coverage/coding?
- What is the cost of the vaccine?
- Who will provide the syringes and needles?

Diluent

Open all

- What type of diluent should I use with the vaccine?
- How do I dilute the vaccine for administration?
- Will the vaccine be supplied and shipped with the diluent?
- How can I order more diluent?
- How many half doses does the vial contain?
- Does the number of doses extracted from the vial change how much diluent is required?
- Can I use locally sourced diluent?

Administration

Open all

Please see the full Prescribing Information for 16 Years & Up and EUA Fact Sheet for Vaccination Providers for 12 Years & Up for dosage, preparation, and administration.

- What is the dosing schedule for the vaccine?
- Can immunocompromised patients receive a third dose?
- Are the Pfizer-BioNTech COVID-19 Vaccine and COMIRNATY® interchangeable with other COVID-19 vaccines?
- What if the second dose cannot be provided at 3 weeks (21 days)?
- Do I need to wear gloves when handling individual vials?
- What are the ingredients included in the vaccine?
- Can I give this vaccine at the same time as other vaccines?
- How do I prepare the dose?
- What syringes should I use for dosing?
- What syringes and needles should I use for administration?

Storage and Stability

Open all

- Can I still use the product if it has been exposed to light or temperatures outside the limits?
- How long can I store the vial in the thermal shipping container?
- What is the vaccine stored?
- At what temperature does the vaccine need to be stored?
- Is there preservative in the vaccine?
- How long can I store the vials in the office low temperature freezer?
- How long can unrefrozen vials be stored in a refrigerator?
- How often do I need to add dry ice to the thermal shipping container?
- How long does it take for frozen vials to thaw?
- How do I refreeze the thermal shipping container?
- Where and how can I get more dry ice?
- Is there a limit to how long I can use the thermal shipping container or how many times I can refill the container with dry ice?
- What type of protective gear should be worn when handling dry ice?
- How do I dispose of dry ice when I no longer need it?
- What is the NDC?
- What do the package and vials look like?
- Is the vaccine only available in a multiple dose vial?
- What are the weights and dimensions of the thermal shipping container?
- Where is the vaccine being manufactured?

Ensuring Authenticity

Open all

- How can I verify if the vaccine product I receive is authentic?

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
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PDA-2000-2021-0000-0012

1. COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech's website.
2. Emergency Use Authorization for Vaccines to Prevent Coronavirus Disease 2019 (COVID-19). Guidance for Industry. U.S. Food and Drug Administration's website.
3. Proprietary name review for biologic products. U.S. Food and Drug Administration's website.
4. Interchangeability and biosimilarity. Centers for Disease Control and Prevention's website.
5. Understanding the regulatory terminology of COVID-19 vaccines. Immunization Action Coalition's website.
6. Vaccine Information Statement (VIS). Centers for Disease Control and Prevention's website.
7. Pfizer-BioNTech COVID-19 Vaccine Emergency Use Instructions (EUI). Pfizer's website.
8. Vaccine Administration Management System (VAMS). Centers for Disease Control and Prevention's website.
9. Vaccine Safety Net. Centers for Disease Control and Prevention's website.
10. Vaccine Adverse Event Reporting System (VAERS). Centers for Disease Control and Prevention's website.
11. Vaccine Injury Compensation Program. U.S. Department of Health & Human Services website.
12. Pfizer-BioNTech COVID-19 Vaccine administration package instructions. Pfizer's website.
13. Pfizer-BioNTech COVID-19 Vaccine Fact Sheets and Frequently Asked Questions. Centers for Disease Control and Prevention's website.

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Indications & Authorized Use

Safety Info

Full Prescribing Information (Pfizer-BioNTech COVID-19 Vaccine)

Full Letter of Fact Sheets (U.S. Vaccine)

BIONTECH Pfizer

FDA APPROVED FOR INDIVIDUALS >16 YEARS OF AGE

In individuals 12 years of age and older, the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA)[1] has been approved for active immunization 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 16 years of age and older, subject to the terms of the EUA. 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 EUA-authorized Pfizer-BioNTech COVID-19 Vaccine and is interchangeable to provide the same immunization benefit. The COMIRNATY® vaccine and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine are not legally distinct, with certain differences that do not impact safety or effectiveness."

Questions and Answers About Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA)

Select a category

Approved Status

What is COMIRNATY®?

What does FDA approval mean?

What is the difference between FDA-approved and an EUA?

For which age groups has the vaccine received FDA approval?

Is the clinical trial, what was the efficacy & safety of the vaccine?

Access to Vaccine Supply

How can I order the vaccine for my practice, office, or hospital?

When can I still with product questions?

What is the procedural coverage coding?

What is the cost of the vaccine?

Who will provide the syringes and needles?

Whom do I contact if my ancillary kit is damaged upon arrival?

Whom do I contact if supplies in the ancillary kit are missing or damaged when opening the shipment?

Whom do I contact for additional ancillary kit supplies (eg, vaccination cards, syringes, sterile needles)?

Diluent

What type of diluent should I use with the vaccine?

How do I dilute the vaccine for administration?

Will the vaccine be supplied and shipped with the diluent?

How can I order more diluent?

How many full doses did the vial contain?

Does the number of doses extracted from the vial change how much diluent is required?

Can I use locally sourced diluent?

Administration

Where on the Advisory Committee on Immunization Practices (ACIP) Guidelines for 1 Dose & for the FDA Fact Sheet for Healthcare Providers for 1 Dose & for the dosage, preparation, and administration.

What is the dosing schedule for the vaccine?

Can immunocompromised patients receive a third dose?

Are the Pfizer-BioNTech COVID-19 Vaccine and Moderna COVID-19 Vaccine interchangeable with other COVID-19 vaccines?

What if the second dose cannot be provided at 3 weeks (21 days)?

Does the vaccine contain live virus?

Do I need to wear gloves when handling defrosted vials?

How many doses are in each diluted vial?

What are the ingredients included in the vaccine?

Can I give the vaccine at the same time as other vaccines?

How do I prepare the dose?

What syringes should I use for dosing?

What syringes and needles should I use for administration?

Storage and Stability

Can I still use the product if it has been thawed more than 6 is originally frozen?

How long can I store the vials in the thermal shipping container?

How is the vaccine stored?

At what temperatures does the vaccine need to be stored?

Is there preservative in the vaccine?

How long can I store the vials in the ultra-low temperature freezer?

How long can undiluted vials be stored in a refrigerator?

Can I still use the product if it has been exposed to light?

How long does it take for frozen vials to thaw?

Dry Ice

Do I still need to monitor the temperature if I am using dry ice?

How often do I need to add dry ice to the thermal shipping container?

What type of protective gear should be worn when handling dry ice?

How do I dispose of dry ice when I no longer need it?

How long can I store the vials in the thermal shipping container with dry ice?

Can I return the thermal shipping container with dry ice?

Thermal Shipping Container

How do I follow up on the status of my product order?

What do I do if I have an issue with my shipment?

What type of gloves should I use when transferring vial carriers from the thermal shipping container to the refrigerator?

How can I return the thermal shipping container at temperature monitor?

What is the NDC?

What do the package and vials look like?

Is the vaccine only available in a multiple-dose vial?

What are the weight and dimensions of the thermal shipping container?

Where is the vaccine being manufactured?

Ensuring Authenticity

How can I verify if the vaccine product I receive is authentic?

References:
1. COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. New York, NY: Pfizer Inc.; 2021.
2. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers). Pfizer Inc. Revised August 2021.

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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
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Indications & Administration Use

Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) EUA 27234 Rev 1

Fact Sheet for Recipients and Caregivers EUA 27234 Rev 1

BIONTECH Pfizer

FDA APPROVED FOR INDIVIDUALS 16 YEARS OF AGE AND OLDER, and FDA AUTHORIZED for ages 12 through 15 Years Old

The Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA), has been approved for the prevention of COVID-19 caused by SARS-CoV-2.[1]

AUTHORIZED FOR EMERGENCY USE

The emergency use of the product listed in this fact sheet is authorized 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 16 years of age and older, respectively, who are not currently authorized for the alternative EUA product under Section 564A(c) of the Act, 21 U.S.C. 360bbb-3(c), in declaration is terminated or otherwise revoked (after which the product may no longer be used under this EUA).

"The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine. Vaccination providers may administer the licensed COMIRNATY® vaccine to individuals 16 years of age and older in accordance with the vaccine's approved labeling. Vaccination providers may administer the authorized vaccine to individuals 12 through 15 years of age in accordance with the conditions of this EUA. The authorized vaccine and the licensed vaccine are not interchangeable."

To view the vaccine's prescribing information, please click here: Full EUA Prescribing Information: Emergency Use Authorization for Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19) for Individuals 12 Years of Age and Older

Vaccination Storage & Dry Ice Safety Handling

Pfizer-BioNTech COVID-19 Vaccine is provided as ultra-low temperature (-112°C) freeze between -90°C and -60°C (-130°F and -76°F) vaccine that must be stored frozen until ready to thaw and use. Vaccine vials must be thawed before use. Once thawed, the vaccine can be stored for up to 10 weeks between 2°C to 8°C (36°F to 46°F). Once thawed, the vaccine cannot be refrozen. Thawed vaccine can be handled in room light conditions. Each vial has a label with an orange border that turns gray after the vial has been thawed.

Pfizer-BioNTech COVID-19 Vaccine is supplied in trays containing 195 vials. Each tray contains 3 packages of 25 vials and 1 package of 20 vials. Each vial contains 5 doses of 0.3 mL vaccine after dilution. Each tray contains 975 doses after dilution

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Indications & Authorized Use

Select a Topic

Full Prescribing Information (FDA Approved)

Select a Topic

BIONTECH | Pfizer

FDA APPROVED FOR PEOPLE AGES 5 YEARS OF AGE[1]

The vaccine is approved at age and older, the Pfizer-BioNTech COVID-19 Vaccine, previously 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 AGES 6 MONTHS THROUGH 4 YEARS OF AGE[2]

The emergency use of the product formerly known as COMIRNATY® is authorized by FDA, but has been authorized by FDA under an Emergency Use Authorization (EUA) to prevent coronavirus disease 2019 (COVID-19) in individuals 6 months through 4 years of age, and older, and the vaccine 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]

Vaccination Storage & Handling

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

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Updated as of 8/16/2021

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

English

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Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Guidelines

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Updated as of 5/23/2021

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

Download

Updated as of 5/23/2021

Dry Ice Replacement Sheet

Information on dry ice replacement, including how to request dry ice as well as a replacement of thermal packaging.

Download

Updated as of 3/16/2021

Safe Handling Guidelines for Dry Ice Shipments

Facts about dry ice, general safety guidelines, and thermal protection.

Click here

Dry Ice Safety Data Sheet

Access the Dry Ice Safety Data Sheet.

Click here

Product Safety Data Sheet

Access and print the resources below. View the Full Prescribing Information for "A Years & Up and Pfizer-BioNTech COVID-19 Vaccine Product Safety Data Sheet.

Click here

Updated as of 6/16/2021

Instructions for Returning Dual Chamber Thermal Shipping Container to Customer Support

Instructions for returning dual chamber thermal shipping container to customer support.

Download

Storage and Handling[3]

- Store frozen at –90°C to –60°C (–130°F to –76°F) between the original carton and the vaccine vials. Vaccine has a 9 month shelf life when stored at –90°C to –60°C (–130°F to –76°F).
- Upon delivery:
  - Transfer the thermal shipping container to ultra-cold freezers set to store between –90°C to –60°C (–130°F to –76°F) for storage.
  - Do not open the thermal shipping container.
  - Visually inspect the thermal shipping container for signs of damage.
  - Verify that the thermal shipping container is within the validated shipping duration and its internal temperature indicator is in the correct position.
- Upon delivery:
  - Transfer the thermal shipping container to ultra-cold freezers set to store between –90°C to –60°C (–130°F to –76°F) for storage.
  - Do not open the thermal shipping container.
  - Visually inspect the thermal shipping container for signs of damage.
  - Verify that the thermal shipping container is within the validated shipping duration and its internal temperature indicator is in the correct position.

Do Not Refreeze Thawed Vaccine

Maximum Time at Refrigerator Temperature (2°C to 25°C or 36°F to 77°F) Before Vaccine Is Punctured or Diluted

Unpunctured Vial	Punctured or Diluted Vial
Up to 10 weeks	Up to 12 hours

From ULT Storage (–90°C to –60°C / –130°F to –76°F)

Thawed Unpunctured Vials	Punctured or Diluted Vials
Up to 5 days	Up to 6 hours

From Thermal Shipping Container (–90°C to –60°C / –130°F to –76°F)

Thawed Unpunctured Vials	Punctured or Diluted Vials
Up to 5 days	Up to 6 hours

The thermal shipping container should not be opened more than 2 times per day for a total of 5 minutes per opening.

Store all

Frozen Vials Prior to Use[3]

Transportation of Frozen Vials[3]

Thawed Vials Before Dilution[3]

Transportation of Thawed Vials[3]

Vials After Dilution[3]

For a visual guide to storage options for the vaccine, refer to "How is the vaccine stored?" on the website.

Safety Dispose?[3]

- Do not refreeze.
- Store Sem-fully discharged and end to room temperature prior to use.
- Do not mix with other vaccines.
- Discard vaccine vials in a sharps container in accordance with local, state, and federal laws and regulations. Vaccine contains no preservative and any vaccine remaining in vials must be discarded.

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

- Pfizer is committed to patient safety and ensuring the authenticity of our medicines and vaccines. We are aware of counterfeit products in the marketplace and have a dedicated team for fraudulent offers of illegitimate vaccines and counterfeit versions of our medicines. We investigate suspicious activity reports, work with licensed healthcare professionals, or other stakeholders, and take appropriate action to help ensure the integrity of our supply chain.
- If you suspect the vaccine you have purchased is counterfeit, please contact Pfizer at 1-800-438-1985 or visit https://www.pfizer.com/products/safety/reportproduct-problem.

Reference

1. Pfizer-BioNTech. [COVID-19 Vaccine, mRNA]. Prescribing Information. Pfizer and BioNTech; n.d. [Accessed 8/16/2021].
2. Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Fact Sheet for Vaccine Recipients. Pfizer and BioNTech; n.d. [Accessed 8/16/2021].
3. Data on File. Pfizer Inc. New York, NY.

Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Guidelines. Updated 5/23/2021. Pfizer and BioNTech; n.d. [Accessed 8/16/2021].

Checklist for Storage, Handling, and Preparation of the Pfizer-BioNTech COVID-19 Vaccine. Updated 5/23/2021. Pfizer and BioNTech; n.d. [Accessed 8/16/2021].

For more information

Pfizer Customer Service
call 1-800-879-3477

Medical Information
Visit Pfizer.MedicalInformation.com
call 1-800-438-1985

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

Shipment Support
US Trade Customer Service
Call 1-800-666-2748

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FDA APPROVED FOR PEOPLE AGES 5 +16 YEARS OF AGE[1]

The first vaccine 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 AGES 6 MONTHS THROUGH 15 YEARS OF AGE[2]

The emergency use of the product formerly known as Comirnaty® is authorized by FDA, but has been authorized by FDA under an Emergency Use Authorization (EUA) to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 months through 15 years of age and older, and the emergency use of the product formerly known as Spikevax® is authorized by FDA under an EUA to prevent COVID-19 caused by SARS-CoV-2.[2]

Vaccination Storage & Preparation for Dry Ice Safety Handling

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

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Updated as of 8/16/2021

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

Shipping and Handling Guidelines for Dry Ice Safety

Dry Ice Safety Video

Access the Dry Ice Safety Video Here

Click here

Product Safety Data Sheet

Access the Product Safety Data Sheet Here

Click here

Instructions for Returning Dry Shipper Containers to Your Assigned Shipping Customer

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Instructions for Returning Dry Shipper Containers to Your Assigned Sh

FDA APPROVED FOR PEOPLE AGES 12 YEARS & OLDER[1]

For the prevention of COVID-19 in persons 12 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 against COVID-19 caused by SARS-CoV-2.[1]

AUTHORIZED FOR USE IN PEOPLE AGES 5 THROUGH 11 YEARS OF AGE[2]

The emergency use of the product known as the Pfizer-BioNTech COVID-19 Vaccine, authorized by FDA, but has been authorized by CDC, under an Emergency Use Authorization (EUA), to prevent COVID-19 in persons 5 through 11 years of age, including those who have received a previous dose of any COVID-19 vaccine, and is not approved or licensed for those who should not receive it.[2]

The product is authorized to be used when 3 weeks or more have passed since the first dose.[2]

The EUA for the product is in effect for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the medical product, unless the declaration is terminated or the EUA is otherwise revoked.[2]

The EUA authorizes the use of the product to prevent COVID-19 in individuals 5 through 11 years of age.[2]

The Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers for the Pfizer-BioNTech COVID-19 Vaccine are available at www.cvdvaccine.com.[2]

The product is not FDA approved or licensed for this use.[2]

Vaccination Storage & Handling Resources

Be sure to review the following resources to ensure proper storage of the vaccine:

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

Download

Updated as of 8/19/2021

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 3/16/2021

Dry Ice Replacement Sheet

Information on dry ice replacement. Please see the Pfizer-BioNTech COVID-19 Vaccine Fact Sheets for dry ice replacement in thermal packaging.

Download

Updated as of 3/16/2021

Safe Handling Guidelines for Dry Ice Shipments

Facts about dry ice, general safety guidelines, and thermal protection.

Click here

Dry Ice Safety Data Sheet

Access the Dry Ice Safety Data Sheet.

Click here

Product Safety Data Sheet

Please contact the Vaccine Advisor Line for the Product Safety Data Sheet.

Click here

Returning Your Thermal Shipping Container

Be sure to review the resources below. View the Full Prescribing Information for "A Note to Us and Instructions for Returning Used Thermal Shipping Containers" in Section 16.

Instructions for Returning Used Thermal Shipping Containers

Download

Updated as of 6/16/2021

Instructions for Returning Used Thermal Shipping Containers

Download

Storage and Handling[1]

Refer to the table below for storage and handling between ultra-cold temperatures (-90°C to -60°C) and refrigerated (2°C to 8°C) temperatures.

- Store Pfizer-BioNTech COVID-19 Vaccine between ultra-cold temperatures (-90°C to -60°C) until the first dose is withdrawn from storage.
- Upon withdrawal from ultra-cold storage, the vaccine must be transferred to refrigerated temperatures (2°C to 8°C).
- Upon delivery:
  - Store the unopened thermal shipping container in ultra-cold and refrigerated conditions as needed.
  - Do not open the thermal shipping container until you are ready to remove vials for storage or dose preparation.
- Vials cannot be used for dose preparation until they remain in the freezer, keep the vial cartons in the thermal shipping container until ready to use.
- Do not use dry ice if the thermal shipping container is damaged, due to the transfer times associated with damaged containers.
- Once a refrigerated vial is removed from a vial carton at room temperature, it should not be returned to the refrigerator or frozen again.

Do not refreeze thawed vaccine.

For Undiluted Vials	Maximum Time at Refrigerated Temperature (2°C to 25°C or 36°F to 77°F) Prior to First Use	
	Unpunctured Vial	Opened Vial
From ULT Freezer (-90°C to -60°C / -130°F to -76°F)	Up to 5 days	Up to 5 minutes
From Thermal Shipping Container (-90°C to -60°C / -130°F to -76°F)	Up to 5 days	Up to 5 minutes
From Refrigerator (2°C to 8°C / 36°F to 46°F)	Up to 1 day	Up to 5 minutes

The thermal shipping container should not be opened more than 2 times per day.

Refer to the Full Prescribing Information for "A Note to Us and Instructions for Returning Used Thermal Shipping Containers" in Section 16.

Show all

Frozen Vials Prior to Use[1]

Transportation of Frozen Vials[1]

Thawed Vials Before Dilution[1]

Transportation of Thawed Vials[1]

Vials After Dilution[1]

For a visual guide to storage options for the vaccine, refer to "How is the vaccine stored?" in the Fact Sheet.

Safety Dispose-It™

- Have sharps disposal container available.
- Store Safety Dispose-It™ in a safe location.
- Do not overfill sharps container.

Discard vaccine vials in a sharps container in accordance with applicable local, state, and federal regulations or guidelines unless state or federal law requires they cannot be recycled.

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

- Pfizer is committed to patient safety and ensuring the authenticity of our medicines and vaccines. Counterfeit, illegal, and substandard medicines and vaccines are a serious threat to public health and can be fraudulent offers of illegitimate vaccines.
- Pfizer-BioNTech COVID-19 Vaccine is the authentic vaccine manufactured by Pfizer and BioNTech.
- Pfizer-BioNTech COVID-19 Vaccine is distributed in the United States by Pfizer.
- Pfizer-BioNTech COVID-19 Vaccine is also known as COMIRNATY®.
- Pfizer-BioNTech COVID-19 Vaccine is not distributed to retail pharmacies, independent pharmacies, chain pharmacies, wholesalers, distributors, or other third parties. Pfizer-BioNTech COVID-19 Vaccine is not distributed to licensed healthcare professionals, or other authorized entities, through online auction sites.
- Pfizer-BioNTech COVID-19 Vaccine is not sold directly to consumers.

If you suspect the vaccine you have purchased is counterfeit, please contact 1-800-438-1985 or visit https://www.pfizer.com/products/counterfeit-medicines-vaccines.

References:

1. COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech; 2021.
2. Pfizer-BioNTech COVID-19 Vaccine Letter of Authorization and Fact Sheets for Healthcare Providers Administering Vaccine (Vaccination Providers) and Recipients and Caregivers. Dec 11, 2020.
3. Data on File. Pfizer Inc. New York, NY.
4. Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines. September 29, 2021. Accessed October 1, 2021. https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
5. Data on File. Pfizer Inc. New York, NY. Updated December, 2020.

For more information

Pfizer Customer Service
call 1-800-879-3477

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

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

Shipment Support
US Trade Customer Service
Call 1-800-666-2748

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FDA APPROVED FOR PEOPLE AGED 16 YEARS & OLDER[1]

For the prevention of COVID-19 in this age group, the Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA), has been approved for active immunization against COVID-19 caused by SARS-CoV-2.[1]

AUTHORIZED FOR USE IN PEOPLE AGED 12 YEARS & OLDER[2]

The emergency use of the product formerly known as Comirnaty by FDA, but has been authorized by FDA, under an Emergency Use Authorization (EUA), to prevent coronavirus disease 2019 (COVID-19) in individuals 12 years of age and older, and for the administration of a third dose to those who are moderately or severely immunocompromised.[2]

The licensed COMIRNATY® vaccine has the same formulation as the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine, and the vaccines may be used interchangeably to provide the COVID-19 vaccine dose series.[2]

There is no change to the way the vaccine is administered.[2]

Use of the vaccine should be in accordance with official recommendations.[2]

Please see the EUA section of the FDA website for the most current information.[2]

Vaccination Storage & Dry Ice Safety Handling

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

Download

Updated as of 8/16/2021

Pfizer-BioNTech COVID-19 Vaccine Shipping and Handling Guidelines

Download

Updated as of 5/21/2021

Dry Ice Safety Training Video

Access the Dry Ice Safety Video Now!

Click here

Dry Ice Safety Quick Sheet

Access the Dry Ice Safety Quick Sheet Now!

Click here

Safety and Storage

Safety and Storage Information Now Available Below: View the Full Prescribing Information for 16 Years & Up and Full Prescribing Information for 12 Years & Up.

English

Español

Click here

Updated as of 8/16/2021

Safe Handling Guidelines for Dry Ice Packaging

Facts about dry ice, general safety guidelines, and thermal protection.

Download

Product Safety Data Sheet

Access and print the resources below. View the Full Prescribing Information for 16 Years & Up and Full Prescribing Information for 12 Years & Up.

Click here

Returning Your Thermal Shipping Container

Access and print the resources below. View the Full Prescribing Information for 16 Years & Up and Full Prescribing Information for 12 Years & Up.

Storage and Handling[2]

Pre-Dilution Storage Conditions	Maximum Time at Refrigerated Temperature (2°C to 8°C or 36°F to 46°F) Before Dilution	Optional Two Additional Months
	Optional Four Additional Hours	Optional Two Additional Hours
From ULT Storage (-90°C to -60°C / -130°F to -76°F)	Up to 5 days	Up to 2 weeks
From Thermal Shipping Container (-90°C to -60°C / -130°F to -76°F)	Up to 5 days	Up to 2 weeks
From Refrigerated Storage (2°C to 8°C / 36°F to 46°F)	Up to 5 days	Up to 1 month

The thermal shipping container should not be opened more than 2 times per day for a total of 5 minutes per opening.[2]

Vials in the thermal shipping container for COVID-19 Vaccine must remain in the thermal shipping container and not be opened more than 2 times per day.[2]

Refer to the Pfizer-BioNTech COVID-19 Vaccine Shipping and Handling Guidelines for more information.

Show All

Frozen Vials Prior to Use[2]

Transportation of Frozen Vials[2]

Thawed Vials Before Dilution[2]

Transportation of Thawed Vials[2]

Vials After Dilution[2]

For a visual guide to storage options for the vaccine, refer to "How is the vaccine stored?" on the FAQs page.

Safety Dispose-T

- Do not recap needles
- Store Sure-Lok Backcap and tool in Sharps Disposal Container
- Remove needle from syringe

Discard vaccine vials in a sharps container in accordance with applicable local requirements. Vaccine vials should not be recycled or reused as waste or be commingled with other waste streams.

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

- Pfizer is committed to patient safety and ensuring the authenticity of our medicines and vaccines. Counterfeit, illegal, and substandard medicines and vaccines are a serious threat to public health and can be fraudulent offers of illegitimate vaccines to unsuspecting patients. Pfizer has a dedicated team of investigators, analysts, forensic chemists, and former law enforcement officers who work to protect patients from counterfeit, illegal, and substandard medicines and vaccines.
- If you suspect the vaccine you have purchased is counterfeit, please contact Pfizer at 1-800-438-1985 and https://www.pfizer.com/contact/safety/reporting-product-issues.

References

1. Comirnaty. Package insert. U.S. Food and Drug Administration. Pfizer-BioNTech; 2021.
2. Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers). Pfizer-BioNTech; 2021.
3. Data on File. Pfizer Inc. New York, NY.
4. Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID-19 Vaccines. September 29, 2021. Accessed October 1, 2021. https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

For more information

Pfizer Customer Service
call 1-800-879-3477

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

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

Shipment Support
US Trade Customer Service
Call 1-800-666-2748

The Pfizer-BioNTech COVID-19 Vaccine, BNT162b2 is authorized for use under an Emergency Use Authorization (EUA) to prevent COVID-19 in individuals 12 years of age and older, and for the administration of a third dose to those who are moderately or severely immunocompromised.

The licensed vaccine has the same formulation as the EUA-authorized vaccine, and the vaccines may be used interchangeably to provide the COVID-19 vaccine dose series.

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FDA APPROVED FOR PEOPLE AGES 5 YEARS OF AGE[1]

The only vaccine for persons of age and older, the Pfizer-BioNTech COMIRNATY (COVID-19 Vaccine, mRNA), 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 PEOPLE AGES 6 MONTHS THROUGH 4 YEARS OF AGE[2]

The emergency use of the product known as the Pfizer-BioNTech COVID-19 Vaccine, authorized by FDA, but has been authorized by CDC, under an Emergency Use Authorization (EUA) to prevent COVID-19 caused by SARS-CoV-2.[2]

The Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 12 years of age and older, and the Pfizer-BioNTech COVID-19 Vaccine is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product, unless terminated or revoked by FDA.

The Pfizer-BioNTech COVID-19 Vaccine is authorized for use in individuals 6 months of age through 11 years of age.

The Pfizer-BioNTech COVID-19 Vaccine is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product, unless terminated or revoked by FDA.

"The licensed COMIRNATY® vaccine has the same formulation as the Pfizer-BioNTech COVID-19 Vaccine authorized under EUA. The vaccine is manufactured under the same conditions and using the same processes to ensure the quality, safety, and effectiveness of the vaccine. The product is the same, and the vaccine can be used interchangeably to meet recommended vaccination needs."[3]

Vaccination Storage & Preparation

The vaccine should be promptly stored at -90°C to -60°C (-130°F to -76°F) and the expiry date adjusted accordingly when stored in this temperature range. Alternatively, the vaccine can be stored at 2°C to 8°C (35°F to 46°F) for up to 2 weeks until the end of the original unopened container's expiry date. Vials should not exceed 2 weeks.

The vaccine should be stored in either 2 packs or 10 packs cartons. The thawed shipping container should be labeled with the new storage conditions and the new expiry date. Do not refreeze the vaccine once it has been thawed. Avoid exposure to strong and temperature conditions available outside the vaccine packaging. Do not shake the vial.

For more information, see the FDA section of the Prescribing Information for 5 to 11 years and the Prescribing Information for Vaccination Providers for 12 Years & Older.

CAUTION
Updated as of 4/18/2022

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

Download

Updated as of 9/16/2021

Pfizer-BioNTech COVID-19 Vaccine Shipping and Handling Guidelines

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Updated as of 5/23/2021

Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Guidelines

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CAUTION
Updated as of 3/16/2021

Dry Ice Replacement Sheet

Information on dry ice replacement. Please refer to the Prescribing Information for dry ice replacement in Section 16 How Supplied/Storage and Handling.

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Updated as of 3/16/2021

Dry Ice Safety Data Sheet

Access the Dry Ice Safety Data Sheet.

Click here

Updated as of 3/16/2021

Safe Handling Guidelines for Dry Ice

Facts about dry ice, general safety guidelines, and thermal protection.

Click here

Product Safety Data Sheet

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

Click here

Safety and Storage

Safety and storage information below. View the Full Prescribing Information for 5 to 11 Years & Older and the Prescribing Information for Vaccination Providers for 12 Years & Older.

Returning Your Thermal Shipping Container

Instructions for the vaccine below. View the Prescribing Information for Returning Thermal Shipping Containers.

English
Español

Shipping Container Return Instructions

- Use only the thermal shipping container to confirm receipt and return vaccine to be destroyed.
- Do not return the thermal shipping container to the thermal shipping container.
- Wait until the thermal shipping container is empty before you return it.
- Do not remove and tool transferring between storage and shipping boxes.
- Do not remove the thermal shipping container from the box. Keep the cut corner in the box.
- Do not remove the thermal shipping container from the box. Keep the cut corner in the box.
- Do not remove the thermal shipping container from the box. Keep the cut corner in the box.

Show all

Re-freezing Instructions	Maximum Time at Refrigerated Temperature (2°C to 25°C or 36°F to 77°F) Before Vaccine Must Be Used	Thawed Vial Storage	Thawed Vial Storage
From ULT Freezer (-90°C to -60°C / -130°F to -76°F)	10 hours	Up to 5 months	Up to 5 months
From Thermal Shipping Container	10 hours	Up to 5 months	Up to 5 months
From Refrigerator (2°C to 8°C / 36°F to 46°F)	10 hours	Up to 5 months	Up to 5 months

The thermal shipping container should not be returned to the thermal shipping container if the temperature is outside the range of -90°C to -60°C (-130°F to -76°F) or 2°C to 8°C (35°F to 46°F). Temperature excursions outside the range of -90°C to -60°C (-130°F to -76°F) or 2°C to 8°C (35°F to 46°F) may result in reduced vaccine potency. Do not refreeze the vaccine once it has been thawed. To help maintain the level of dry ice and the temperature, do not open the container.

Do not return the thermal shipping container to the thermal shipping container if the temperature is outside the range of -90°C to -60°C (-130°F to -76°F) or 2°C to 8°C (35°F to 46°F). Temperature excursions outside the range of -90°C to -60°C (-130°F to -76°F) or 2°C to 8°C (35°F to 46°F) may result in reduced vaccine potency. Do not refreeze the vaccine once it has been thawed. To help maintain the level of dry ice and the temperature, do not open the container.

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Show all

Frozen Vials Prior to Use?

Transportation of Frozen Vials?

Thawed Vials Before Dilution?

Transportation of Thawed Vials?

Vials After Dilution?

For a visual guide to storage options for the vaccine, refer to "How is the vaccine stored?" in the Quick Reference Guide.

Safety Dispose?

- Store unopened vials in the refrigerator.
- Store open fully discharged and seal to avoid contamination.
- Store in the refrigerator for 10 hours.

Discard vaccine vials in a sharps container in accordance with local, state, and federal regulations. Vaccine vials and needles as medical waste as 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 the authenticity of its medicines and vaccines. Pfizer has established a global program to help prevent counterfeit medicines and vaccines for fraudulent offers of illegitimate vaccines. Counterfeit medicines may contain the wrong ingredients, the correct ingredients in the wrong amounts, or fraudulent packaging.
- Pfizer has established a global program to help prevent counterfeit medicines and vaccines. The vaccine is not taken orally and is not distributed in retail pharmacies. The vaccine is not taken orally and is not distributed in retail pharmacies.
- Pfizer has established a global program to help prevent counterfeit medicines and vaccines. The vaccine is not taken orally and is not distributed in retail pharmacies. The vaccine is not taken orally and is not distributed in retail pharmacies.
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If you suspect the vaccine you have purchased or received is counterfeit, please call 1-866-248-3187 and visit https://www.pfizer.com/products/safety/fraudulent-medicines.

References

1. Food and Drug Administration. FDA approves first COVID-19 vaccine. FDA News Release. August 23, 2021. https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine. Accessed September 29, 2021.
2. Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers). Revised August 12, 2021. Accessed September 3, 2021.
3. Data on file. Pfizer Inc. New York, NY.
4. Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Fact Sheet for Recipients and Caregivers. September 29, 2021. Accessed September 29, 2021.
5. Pfizer-BioNTech COVID-19 Vaccine Emergency Use Authorization Fact Sheet for Recipients and Caregivers. September 29, 2021. Accessed September 29, 2021.

For more information

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

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

Shipment Support
US Trade Customer Service
Call 1-800-666-2748

This site is intended only for U.S. healthcare professionals. Information provided on this site is not intended for patients or consumers. Please see the Prescribing Information for Vaccination Providers for 12 Years & Older and the Prescribing Information for 5 to 11 Years & Older.

FDA-CBER-2021-5683-0001138

FDA APPROVED FOR INDIVIDUALS ≥ 18 YEARS OF AGE[1,2]

The emergency use of the product with the EUA remains in effect for use in children 6 months through 17 years of age, and the EUA is not terminated. The 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.

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AUTHORIZED FOR EMERGENCY USE[2]

The emergency use of the product with the EUA remains in effect for use in children 6 months through 17 years of age, and the EUA is not terminated. The 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.

Moderna COVID-19 Vaccine is the first mRNA vaccine authorized in the U.S. to help protect individuals ≥ 18 years of age from COVID-19 caused by SARS-CoV-2.

Vaccination Storage & Dry Ice Safety Handling

The vaccine should be promptly stored in the refrigerator at 2°C to 8°C (36°F to 46°F) upon receipt. Do not freeze. Do not use if the vaccine has been frozen. Do not shake. Do not dilute. Do not use if the product is temperature excursion or temperature is unknown. Do not use if the vial is damaged. Do not use if the product is beyond the expiration date. Vaccine vials must be stored in the original carton to protect from light. Once thawed, the vaccine can be stored for up to 30 days between 2°C to 8°C (36°F to 46°F). Record the date and time the vaccine is removed from the freezer and placed in the refrigerator. Once thawed, do not refreeze. Discard unused vaccine after 30 days.

Updated as of 07/30/2021

Checklist for Storage, Handling, and Administration of the Moderna COVID-19 Vaccine

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Updated as of 07/30/2021

FDA-Issued Moderna COVID-19 Vaccine Fact Sheet for Healthcare Providers

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Updated as of 07/30/2021

100-Location Moderna COVID-19 Vaccine Shipping and Handling Guidelines

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Updated as of 08/30/2021

Dry Ice Safety Handling

Dry Ice Safety Data Sheet

Click here

Updated as of 08/30/2021

Product Safety Data Sheet

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

Click here

Updated as of 08/30/2021

Instructions for Retaining Data from Temperature Monitoring Devices

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Storage and Handling[1]

- Storage Upon Receipt
- Storage Conditions
- Temperature Excursions
- Vaccine Preparation
- Do not open vial unless and vaccine is to be used immediately. Do not use if vial is damaged.
- Suspend the thawed shipping container for 10 minutes before opening to allow residual dry ice vapor to dissipate.
- Vial Inspection and Vaccine Preparation
- Vaccine Administration

Temperature Conditions	Time Limit	Source
From EXT Storage to Thawed	Up to 30 days	Moderna
From Thawed to Refrigerated	Up to 30 days	Moderna
From Refrigerated to Room Temperature	Up to 12 hours	Moderna

The thermal shipping container should not be opened if more than 3 months since thawed.

Once the thermal shipping container is opened, the vaccine must be stored between 2°C to 8°C (36°F to 46°F) and the expiry date of the vaccine must be updated to reflect the new storage conditions.

The thermal shipping container should not be opened if more than 3 months since thawed.

Once the thermal shipping container is opened, the vaccine must be stored between 2°C to 8°C (36°F to 46°F) and the expiry date of the vaccine must be updated to reflect the new storage conditions.

Cartons and vials of the vaccine will be marked with a new expiry date. The vaccine can be stored for a total of 30 days from the date it was removed in new box. 3 months beyond the original thawing date, whichever is sooner. Do not refreeze the vaccine once it has been thawed. Record the date and time the vaccine is removed from the freezer and placed in the refrigerator. Once thawed, the vaccine can be stored for up to 30 days between 2°C to 8°C (36°F to 46°F). Discard unused vaccine after 30 days.

Cartons and vials of the vaccine will be marked with a new expiry date. The vaccine can be stored for a total of 30 days from the date it was removed in new box. 3 months beyond the original thawing date, whichever is sooner. Do not refreeze the vaccine once it has been thawed. Record the date and time the vaccine is removed from the freezer and placed in the refrigerator. Once thawed, the vaccine can be stored for up to 30 days between 2°C to 8°C (36°F to 46°F). Discard unused vaccine after 30 days.

Show all

Freeze Once Note to Self

- Vials must be frozen and stored at -50°C to -15°C (-58°F to 5°F) upon receipt. Do not freeze.
- Do not store at the Multi-Dose Vial under the original carton to protect from light. Once thawed, remove the vial carton. Temperature excursions between 8°C to 25°C (46°F to 77°F) for a cumulative period of 24 hours. Do not refreeze. Do not use if the vial is damaged. Do not use if the product is beyond the expiration date. Do not use if the vial is damaged. Do not use if the product is beyond the expiration date.

Temperature Conditions	Time Limit	Source
From EXT Storage to Thawed	Up to 30 days	Moderna
From Thawed to Refrigerated	Up to 30 days	Moderna
From Refrigerated to Room Temperature	Up to 12 hours	Moderna

The thermal shipping container should not be opened if more than 3 months since thawed.

Once the thermal shipping container is opened, the vaccine must be stored between 2°C to 8°C (36°F to 46°F) and the expiry date of the vaccine must be updated to reflect the new storage conditions.

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Show all

Thawed Vials Before Dilution*

- Prior dilution, vials must be between 2°C to 8°C (36°F to 46°F) and may be stored for up to 30 days.
- Vials may be stored at room temperature up to 25°C (77°F) for up to 12 hours cumulative before dilution.
- Vials must be discarded if not used within the allotted time.

*Vials must be between 2°C to 8°C (36°F to 46°F) and may be stored for up to 30 days. Vials may be stored at room temperature up to 25°C (77°F) for up to 12 hours cumulative before dilution. Vials must be discarded if not used within the allotted time.

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- Prior dilution, vials must be between 2°C to 8°C (36°F to 46°F) and may be stored for up to 30 days.
- Vials may be stored at room temperature up to 25°C (77°F) for up to 12 hours cumulative before dilution.
- Vials must be discarded if not used within the allotted time.

*Vials must be between 2°C to 8°C (36°F to 46°F) and may be stored for up to 30 days. Vials may be stored at room temperature up to 25°C (77°F) for up to 12 hours cumulative before dilution. Vials must be discarded if not used within the allotted time.

Transportation of Frozen Vials*

- If it is not feasible to maintain the cold chain during transportation, vials may be transported at temperatures between 2°C to 25°C (36°F to 77°F), vials may be transported at -25°C to -15°C (-13°F to 5°F).
- Vials may be transported at temperatures between 2°C to 25°C (36°F to 77°F) vials may be transported at -25°C to -15°C (-13°F to 5°F).

*Vials must be between 2°C to 8°C (36°F to 46°F) and may be stored for up to 30 days. Vials may be stored at room temperature up to 25°C (77°F) for up to 12 hours cumulative before dilution. Vials must be discarded if not used within the allotted time.

For a list of products to arrange options for the transportation of frozen vials, please contact your Pfizer representative.

*Vials must be between 2°C to 8°C (36°F to 46°F) and may be stored for up to 30 days. Vials may be stored at room temperature up to 25°C (77°F) for up to 12 hours cumulative before dilution. Vials must be discarded if not used within the allotted time.

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- Vials must be between 2°C to 8°C (36°F to 46°F) and may be stored for up to 30 days.
- Vials may be stored at room temperature up to 25°C (77°F) for up to 12 hours cumulative before dilution.
- Vials must be discarded if not used within the allotted time.

*Vials must be between 2°C to 8°C (36°F to 46°F) and may be stored for up to 30 days. Vials may be stored at room temperature up to 25°C (77°F) for up to 12 hours cumulative before dilution. Vials must be discarded if not used within the allotted time.

Vials After Dilution*

- After dilution, store vials between 2°C to 25°C (36°F to 77°F) and use within 6 hours.
- Do not freeze diluted vials. Do not shake. Discard vials if not used within 6 hours.

*Vials must be between 2°C to 8°C (36°F to 46°F) and may be stored for up to 30 days. Vials may be stored at room temperature up to 25°C (77°F) for up to 12 hours cumulative before dilution. Vials must be discarded if not used within the allotted time.

Safety Stopper™

- Vials have a rubber stopper.
- Vials have fully discharged and used to withdraw and inject doses.
- Vials have been designed to reseal after use.

Discard any vaccine vials in a sharps container as soon as possible after use. Do not recap needles or separate a needle from a syringe.

Ensuring the Authenticity of Your COVID-19 Vaccine and Preventing Potential Counterfeit, Fraudulent, or Stolen Vaccine Entering the U.S.

- Pfizer is committed to patient safety and working with our partners to help prevent counterfeit, fraudulent, or stolen vaccine from entering the U.S. supply chain. Pfizer has implemented a number of measures to help ensure the authenticity of our vaccine, including:
- Pfizer has implemented a number of measures to help ensure the authenticity of our vaccine, including:
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This site is intended for U.S. Healthcare Professionals.

Indication & Authorized Use

Safety Info

Full Prescribing Information (FDA Approved 16 Years & Up)

EUA Letter & Fact Sheets (12 Years & Up)

BIONTECH | Pfizer

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 immunization 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]

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

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

Downloads

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

Important Lst Information

- HCP Lst Letter

Additional Lst Details

Updated as of 6/28/2021

How to Prepare and Administer the Vaccine Poster

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Updated as of 6/10/2021

Checklist for Storage, Handling, and Preparation

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Updated as of 5/19/2021

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

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Updated as of 5/21/2021

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

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

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Updated as of 5/20/2021

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To inspect the vaccine you have purchased please read the counterfeit, contact us at 1.800.438.1985 or visit https://www.pfizer.com/products/product-detail/comirnaty#faq

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

Adverse Event Reporting

Report an Adverse Event to VAERS*

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Helpful links

Information About COVID-19 From the CDC*

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Medical Information

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 Pfizer-BioNTech vaccines to protect patients from products that might be counterfeit, stolen, or otherwise not in the chain of legitimate distribution.
  - 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[4]
- Authentic vaccines, manufactured by Pfizer Inc., will include the Pfizer and BioNTech names on the label and not dispensed in a vial with a purple cap. **Two versions of the vial label are in current circulation - with or without a purple border.**
- Ensure the safety of the vaccine with its limited access to only authorized personnel. The location they are stored in must be secure and locked when not in use. To prevent counterfeits, do not accept vaccine vials in sharps containers and empty vial cartons as medical waste or deface or safely crush vial materials so they cannot be reused. Remember, the vaccines are only available through authorized government vaccination centers – such as doctor's offices, pharmacies, hospitals, and healthcare clinics, community vaccination locations, and hospitals. The vaccine can only be administered by licensed healthcare professionals, or other individuals that are supervised 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-detail/comirnaty#faq

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. Pfizer. Pfizer-BioNTech COVID-19 Vaccine
4. COVID-19 Vaccination Program Interim *Playbook for Jurisdiction Operations – September 14, 2020 Version 1.0*. Centers for Disease Control and Prevention; 2020.
5. McCarty MC. Secure disposal of vaccine vials and packaging recommendations. US Department of Defense; 2020.

For more information

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or call 1.800-438-1985

General Product Inquiries
Call 1.877.829.2619

Shipment Support
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Call 1.800.666.7268

BIONTECH | Pfizer

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

Manufactured by Pfizer Inc. New York, NY 10017

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BIONTECH | Pfizer

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*The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine Pfizer-BioNTech COVID-19 Vaccine and is expected to be used interchangeably to provide the authorized series without presenting any risk of a dose-related concerns. The products are not legally distinguishable. Unauthorized lots do not support safety or effectiveness.

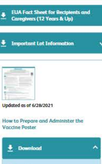
Pfizer-BioNTech COVID-19 Vaccine, also known as COMIRNATY® (COVID-19 Vaccine, mRNA), Resources*

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Important Fact Information



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

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  - 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 be dispensed in a vial with a purple cap. **Two versions of the vial label are in current circulation - with or without a purple border.**
- To ensure the safety of the vaccine with its limited access to only authorized personnel. The location they are stored in must be secure and locked when not in use. To prevent counterfeits, diluted vaccine vials in shipping containers and empty vial cartons as medical waste or deface or safely crush vial materials so they cannot be reused. Remember, the vaccines are only available through authorized pharmacies and vaccination centers – such as doctor's offices, hospitals, pharmacies, community clinics, community vaccination locations, and hospitals. The vaccine can only be administered by licensed healthcare professionals, or other individuals that are supervised 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-information/report-concern

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. Pfizer-BioNTech COVID-19 Vaccine. Fact Sheet.
4. COVID-19 Vaccination Program Interim *Playbook for Jurisdiction Operations – September 14, 2020 Version 1.0.* Centers for Disease Control and Prevention; 2020.
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BIONTECH | Pfizer

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COA-CHEN-2021-0663-080124

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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 immunization 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 product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.[2]

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

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

Downloads

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

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Helpful links

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Medical Information

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 doses or vaccines to protect patients from products that might be counterfeit, contaminated, or otherwise harmful.
  - 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[4]
- 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.**
- Ensure the safety of the vaccine with its limited access to only authorized personnel. The location they are stored in must be secure and locked when not in use. To prevent counterfeits, diluted vaccine vials in sharps containers and empty vial cartons as medical waste or deface or safely crush vial materials so they cannot be reused. Remember, the vaccines are only available through authorized pharmaceutical vaccination centers - such as doctor's offices, hospitals, pharmacies, federal pharmacy, community vaccination locations, and hospitals. The vaccine can only be administered by licensed healthcare professionals, or other individuals that are supervised 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-information/report-concern

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FDA-CBER-2021-5683-0061242

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. Kaiser Permanente. *Vaccine Update: Pfizer-BioNTech COVID-19 Vaccine Program Letters, Playbook for Jurisdiction Operations – September 14, 2020 Version 1.0.* Centers for Disease Control and Prevention; 2020.
4. McCarty MC. Secure disposal of vaccine vials and packaging recommendations. US Department of Defense; 2020.

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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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*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 risk of a dose administration concerns. The products are slightly distinguished in appearance that do not impact safety or effectiveness.

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

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

Downloads

- FDA Emergency Use Authorization Letter
- EUA Fact Sheet for Vaccination Providers (12 Years & Up)
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- 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 doses/vaccines to protect patients from products that might be counterfeit, contain the wrong ingredients, or the wrong dose.
  - 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[4]
- Authentic vaccines, manufactured by Pfizer Inc., will include the Pfizer and BioNTech names on the label and no discernment to red with a purple cap. **Two versions of the vial label are in current circulation - with or without a purple border.**
- Ensure the safety of the vaccine with its limited access to only authorized personnel. The location they are stored in must be secure and locked when not in use. To prevent counterfeits, do not accept vaccine vials in sharps containers and empty vial cartons as medical waste or deface or safely crush vial materials so they cannot be reused. Remember, the vaccines are only available through authorized government vaccination centers – such as doctor's offices, pharmacies, hospitals, healthcare clinics, community vaccination locations, and hospitals. The vaccine can only be administered by licensed healthcare professionals, or other individuals that are supervised vaccinators, at government-authorized vaccination sites. Individual doses are not for sale[4,5]

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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. Pfizer-BioNTech COVID-19 Vaccine. 2021.
4. COVID-19 Vaccination Program Interim *Playbook for Jurisdiction Operations – September 14, 2020 Version 1.0*. Centers for Disease Control and Prevention; 2020.
5. McCarty MC. Secure disposal of vaccine vials and packaging recommendations. US Department of Defense; 2020.

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EUA Letter & Fact Sheets (12 Years & Up)

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

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*The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine Pfizer-BioNTech COVID-19 Vaccine and is expected to be used interchangeably to provide the authorized series without presenting any risk of a dose-related concerns. The products are not legally distinguishable. Information that do not impact safety or effectiveness.

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

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

Downloads

- FDA Emergency Use Authorization Letter
- EUA Fact Sheet for Vaccination Providers (12 Years & Up)
- Full Prescribing Information/FDA Approved - 16 Years & Up)
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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 doses or vaccines to protect patients from products that might be counterfeit, contain no 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[4]
- Authentic vaccines, manufactured by Pfizer Inc., will include the Pfizer and BioNTech names on the label and/or box dispensed to you with a purple cap. **Two versions of the vial label are in current circulation - with or without a purple border.**
- To ensure the safety of the vaccine with its limited access to only authorized personnel. The location they are stored in must be secure and locked when not in use. To prevent counterfeits, clinical vaccine sites work in sharps containers and empty vial cartons as medical waste or deface or safely crush vial materials so they cannot be reused. Remember, the vaccines are only available through authorized government vaccination centers – such as doctor's offices, pharmacies, hospitals, clinics, workplace or community vaccination locations, and hospitals. The vaccine can only be administered by licensed healthcare professionals, or other individuals that are supervised vaccinators, at government-authorized vaccination sites. Individual doses are not for sale[4,5]

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

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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. Pfizer-BioNTech COVID-19 Vaccine. 2021.
4. COVID-19 Vaccination Program Interim *Playbook for Jurisdiction Operations – September 14, 2020 Version 1.0*. Centers for Disease Control and Prevention; 2020.
5. McCarty MC. Secure disposal of vaccine vials and packaging recommendations. US Department of Defense; 2020.

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EUA Letter & Fact Sheets (12 Years & Up)

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

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AUTHORIZED FOR EMERGENCY USE[2]

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*The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine Pfizer-BioNTech COVID-19 Vaccine and is interchangeable to provide the authorized series without presenting any risk of a dose administration error. The products can be easily distinguished by the vaccination sites that do not impact safety or effectiveness.

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

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

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)

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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 doses or vaccines to protect patients from products that might be counterfeit, expired, or unsafe and life-threatening.[3,4]
  - 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[1]
- 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.**
- To ensure the safety of the vaccine with its limited access to only authorized personnel. The location they are stored in must be secure and locked when not in use. To prevent counterfeits, diluted vaccine vials in sharps containers and empty vial cartons as medical waste or deface or safely crush vial materials so they cannot be reused. Remember, the vaccines are only available through authorized pharmacy and vaccination centers – such as doctor's offices, pharmacies, hospitals/health systems, community vaccination locations, and hospitals. The vaccine can only be administered by licensed healthcare professionals, or other individuals that are supervised vaccinators, at government-authorized vaccination sites. Individual doses are not for sale[4,5]

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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. Pfizer. Fact Sheet. Pfizer Inc.; 2020.
4. COVID-19 Vaccination Program Interim *Playbook for Jurisdiction Operations – September 14, 2020 Version 1.0*. Centers for Disease Control and Prevention; 2020.
5. McCarty MC. Secure disposal of vaccine vials and packaging recommendations. US Department of Defense; 2020.

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EUA Letter & Fact Sheets (12 Years & Up)

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Downloads

- FDA Emergency Use Authorization Letter
- EUA Fact Sheet for Vaccination Providers (12 Years & Up)
- Full Prescribing Information/EUA Approved - 16 Years & Up)
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2. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers). Pfizer and BioNTech; 2021.
3. Pfizer. Pfizer Inc. 2021. Accessed May 4, 2021.
4. *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations – September 14, 2020 Version 1.0.* Centers for Disease Control and Prevention; 2020.
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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

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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items are required. Use of unapproved vaccine for active immunization to prevent COVID-19 under this EUA is limited to the following (all requirements **must** be met):

1. The vaccine is authorized for use in

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

August 23, 2021

Pfizer Inc.
Attention: Ms. Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Harkins:

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act or the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes Coronavirus Disease 2019 (COVID-19).[1] On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.[2]

On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act. FDA reissued the letter of authorization on: December 23, 2020,[3] February 25, 2021,[4] May

[1] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. February 4, 2020.

[2] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 18250 (April 1, 2020).

[3] In the December 23, 2020 revision, FDA removed reference to the number of doses per vial after dilution from the letter of authorization, clarified the instructions for vaccination providers reporting to VAERS, and made other technical corrections. FDA also revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to clarify the number of doses of vaccine per vial after dilution and the instructions for reporting to VAERS. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and the Fact Sheet for Recipients and Caregivers were revised to include additional information on safety monitoring and to clarify information about the availability of other COVID-19 vaccines.

[4] In the February 25, 2021 revision, FDA allowed flexibility on the date of submission of monthly periodic safety reports and revised the requirements for reporting of vaccine administration errors by Pfizer Inc. The Fact Sheet for Health Care Providers Administering Vaccine (Vaccination Providers) was revised to provide an update to the storage and transportation temperature for frozen vials, direct the provider to the correct CDC website for information on monitoring vaccine recipients for the occurrence of immediate adverse reactions, to include data from a developmental toxicity study, and add adverse reactions that have been identified during post authorization use. The Fact Sheet for Recipients and Caregivers was revised to add adverse reactions that have been identified during post authorization use.

10, 2021,[5] June 25, 2021,[6] and August 12, 2021.[7]

On August 23, 2021, FDA approved the biologics license application (BLA) submitted by BioNTech Manufacturing GmbH for COMIRNATY (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.

On August 23, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the August 12, 2021 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved BLA. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide updates on expiration dating of the authorized Pfizer-BioNTech COVID-19 Vaccine and to update language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for Recipients and Caregivers, which comprises the Fact Sheet for the authorized Pfizer-BioNTech COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

Pfizer-BioNTech COVID-19 Vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series.[8]

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[5] In the May 10, 2021 revision, FDA authorized Pfizer-BioNTech Vaccine for the prevention of COVID-19 in individuals 12 through 15 years of age, as well as for individuals 16 years of age and older. In addition, FDA revised the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) to include the following Warning: "Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting." In addition, the Fact Sheet for Recipients and Caregivers was revised to instruct vaccine recipients or their caregivers to tell the vaccination provider about fainting in association with a previous injection.

[6] In the June 25, 2021 revision, FDA clarified terms and conditions that relate to export of Pfizer-BioNTech COVID-19 Vaccine from the United States. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to include a Warning about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine. The Fact Sheet for Recipients and Caregivers was updated to include information about myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine.

[7] In the August 12, 2021 revision, FDA authorized a third dose of the Pfizer-BioNTech COVID-19 Vaccine administered at least 28 days following the two dose regimen of this vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

[8] The licensed vaccine has the same formulation as the EUA-authorized 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.

For the December 11, 2020 authorization for individuals 16 years of age and older, FDA reviewed safety and efficacy data from an ongoing phase 1/2/3 trial in approximately 44,000 participants randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. The trial has enrolled participants 12 years of age and older. FDA's review at that time considered the safety and effectiveness data as they relate to the request for emergency use authorization in individuals 16 years of age and older. FDA's review of the available safety data from 37,586 of the participants 16 years of age and older, who were followed for a median of two months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of the available efficacy data from 36,523 participants 12 years of age and older without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirmed the vaccine was 95% effective (95% credible interval 90.3, 97.6) in preventing COVID-19 occurring at least 7 days after the second dose (with 8 COVID-19 cases in the vaccine group compared to 162 COVID-19 cases in the placebo group). Based on these data, and review of manufacturing information regarding product quality and consistency, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 16 years of age and older. Finally, on December 10, 2020, the Vaccines and Related Biological Products Advisory Committee voted in agreement with this conclusion.

For the May 10, 2021 authorization for individuals 12 through 15 years of age, FDA reviewed safety and effectiveness data from the above-referenced, ongoing Phase 1/2/3 trial that has enrolled approximately 46,000 participants, including 2,260 participants 12 through 15 years of age. Trial participants were randomized 1:1 to receive Pfizer-BioNTech COVID-19 Vaccine or saline control. FDA's review of the available safety data from 2,260 participants 12 through 15 years of age, who were followed for a median of 2 months after receiving the second dose, did not identify specific safety concerns that would preclude issuance of an EUA. FDA's analysis of SARS-CoV-2 50% neutralizing antibody titers 1 month after the second dose of Pfizer-BioNTech COVID-19 Vaccine in a subset of participants who had no serological or virological evidence of past SARS-CoV-2 infection confirm the geometric mean antibody titer in participants 12 through 15 years of age was non-inferior to the geometric mean antibody titer in participants 16 through 25 years of age. FDA's analysis of available descriptive efficacy data from 1,983 participants 12 through 15 years of age without evidence of SARS-CoV-2 infection prior to 7 days after dose 2 confirm that the vaccine was 100% effective (95% confidence interval 75.3, 100.0) in preventing COVID-19 occurring at least 7 days after the second dose (with no COVID-19 cases in the vaccine group compared to 16 COVID-19 cases in the placebo group). Based on these data, FDA concluded that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in individuals 12 through 15 years of age. Additionally, FDA determined it is reasonable to conclude, based on the totality of the scientific evidence available, that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine, for the prevention of COVID-19 in individuals 12 through 15 years of age.

For the August 12, 2021 authorization of a third dose of the Pfizer-BioNTech COVID-19 Vaccine in individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise, FDA reviewed safety and effectiveness data reported in two manuscripts on solid organ transplant recipients. The first study was a single arm study conducted in 101 individuals who had undergone various solid organ transplant procedures (heart, kidney, liver, lung, pancreas) a median of 97±8 months earlier. A third dose of the Pfizer-BioNTech COVID-19 Vaccine was administered to 99 of these individuals approximately 2 months after they had received a second dose. Levels of total SARS-CoV-2 binding antibodies meeting the pre-specified criteria for success occurred four weeks after the third dose in 26/59 (44.0%) of those who were initially considered to be seronegative and received a third dose of the Pfizer-BioNTech COVID-19 Vaccine; 67/99 (68%) of the entire group receiving a third vaccination were subsequently considered to have levels of antibodies indicative of a significant response. In those who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 events were reported. A supportive secondary study describes a double-blind, randomized-controlled study conducted in 120 individuals who had undergone various solid organ transplant procedures (heart, kidney, kidney-pancreas, liver, lung, pancreas) a median of 3.57 years earlier (range 1.99-6.75 years). A third dose of a similar mRNA vaccine (the Moderna COVID-19 vaccine) was administered to 60 individuals approximately 2 months after they had received a second dose (i.e., doses at 0, 1 and 3 months); saline placebo was given to 60 individuals or comparison. The primary outcome was anti-RBD antibody at 4 months greater than 100 U/mL. This titer was selected based on NHP challenge studies as well as a large clinical cohort study to indicate this antibody titer was protective. Secondary outcomes were based on a virus neutralization assay and polyfunctional T cell responses. Baseline characteristics were comparable between the two study arms as were pre-intervention anti-RBD titer and neutralizing antibodies. Levels of total SARS-CoV-2 binding antibodies indicative of a significant response occurred four weeks after the third dose in 33/60 (55.0%) of the Moderna COVID-19 vaccinated group and 10/57 (17.5%) of the placebo individuals. In the 60 individuals who received a third vaccine dose, the adverse event profile was similar to that after the second dose and no grade 3 or grade 4 adverse events were reported. Despite the moderate enhancement in antibody titers, the totality of data (i.e., supportive paper by Hall et al. demonstrated efficacy of the product in the elderly and persons with co-morbidities) supports the conclusion that a third dose of the Pfizer-Moderna COVID-19 vaccine may be effective in this population, and that the known and potential benefits of a third dose of Pfizer-BioNTech COVID-19 Vaccine outweigh the known and potential risks of the vaccine for immunocompromised individuals at least 12 years of age who have received two doses of the Pfizer-BioNTech COVID-19 Vaccine and who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization. Additionally, as specified in subsection III.BB, I am authorizing use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA when used to provide a two-dose regimen for individuals aged 12 through 15 years, or

to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of Pfizer-BioNTech COVID-19 Vaccine for the prevention of COVID-19 when administered as described in the Scope of Authorization (Section II) meets the criteria for issuance of an authorization under Section 564(c) of the Act, because:

A. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

B. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine when used to prevent COVID-19 outweigh its known and potential risks; and

C. There is no adequate, approved, and available[9] alternative to the emergency use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19.[10]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Pfizer Inc. will supply Pfizer-BioNTech COVID-19 Vaccine either directly or through authorized distributor(s),[11] to emergency response stakeholders[12] as directed by the U.S.

[9] Although COMIRNATY (COVID-19 Vaccine, mRNA) is approved to prevent COVID-19 in individuals 16 years of age and older, there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA. Additionally, there are no products that are approved to prevent COVID-19 in individuals age 12 through 15, or that are approved to provide an additional dose to the immunocompromised population described in this EUA.

[10] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[11] "Authorized Distributor(s)" are identified by Pfizer Inc. or, if applicable, by a U.S. government entity, such as the Centers for Disease Control and Prevention (CDC) and/or other designee, as an entity or entities allowed to distribute authorized Pfizer-BioNTech COVID-19 Vaccine.

[12] For purposes of this letter, "emergency response stakeholder" refers to a public health agency and its delegates that have legal responsibility and authority for responding to an incident, based on political or geographical boundary lines (e.g., city, county, tribal, territorial, State, or Federal), or functional (e.g., law enforcement or public health range) or sphere of authority to administer, deliver, or distribute vaccine in an emergency situation. In some cases (e.g., depending on a state or local jurisdiction's COVID-19 vaccination response organization and plans), there might be overlapping roles and responsibilities among "emergency response stakeholders" and "vaccination providers" (e.g., if a local health department is administering COVID-19 vaccines; if a pharmacy is acting in an

government, including the Centers for Disease Control and Prevention (CDC) and/or other designee, for use consistent with the terms and conditions of this EUA;
- The Pfizer-BioNTech COVID-19 Vaccine covered by this authorization will be administered by vaccination providers[13] and used only to prevent COVID-19 in individuals ages 12 and older; and
- Pfizer-BioNTech COVID-19 Vaccine may be administered by a vaccination provider without an individual prescription for each vaccine recipient.

This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide a two-dose regimen for individuals aged 12 through 15 years, or to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Product Description

The Pfizer-BioNTech COVID-19 Vaccine 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. The Pfizer-BioNTech COVID-19 Vaccine does not contain a preservative.

Each 0.3 mL dose of the Pfizer-BioNTech COVID-19 Vaccine contains 30 mcg of a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2. Each dose of the Pfizer-BioNTech COVID-19 Vaccine also includes the following ingredients: lipids (0.43 mg (4-hydroxybutyl)azanediyl)bis(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) contributes an additional 2.16 mg sodium chloride per dose.

official capacity under the authority of the state health department to administer COVID-19 vaccines). In such cases, it is expected that the conditions of authorization that apply to emergency response stakeholders and vaccination providers will all be met.

[13] For purposes of this letter, "vaccination provider" refers to the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g., non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program. If the vaccine is exported from the United States, a "vaccination provider" is a provider that is authorized to administer this vaccine in accordance with the laws of the country in which it is administered. For purposes of this letter, "healthcare provider" also refers to a person authorized by the U.S. Department of Health and Human Services (e.g., under the PREP Act Declaration for Medical Countermeasures against COVID-19) to administer FDA-authorized COVID-19 vaccine (e.g., qualified pharmacy technicians and State-authorized pharmacy interns acting under the supervision of a qualified pharmacist). See, e.g., HHS. *Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 and Republication of the Declaration*. 85 FR 79190 (December 9, 2020).

The dosing regimen is two doses of 0.3 mL each, 3 weeks apart. A third dose may be administered at least 28 days following the second dose of the two dose regimen of this vaccine to individuals 12 years of age or older who have undergone solid organ transplantation, or individuals 12 years of age or older who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

The manufacture of the authorized Pfizer-BioNTech COVID-19 Vaccine is limited to those facilities identified and agreed upon in Pfizer's request for authorization.

The Pfizer-BioNTech COVID-19 Vaccine vial label and carton labels are clearly marked for "Emergency Use Authorization." The Pfizer-BioNTech COVID-19 Vaccine is authorized to be distributed, stored, further redistributed, and administered by emergency response stakeholders when packaged in the authorized manufacturer packaging (i.e., vials and cartons), despite the fact that the vial and carton labels may not contain information that otherwise would be required under the FD&C Act.

Pfizer-BioNTech COVID-19 Vaccine is authorized for emergency use with the following product-specific information required to be made available to vaccination providers and recipients, respectively (referred to as "authorized labeling"):

- Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers): Emergency Use Authorization (EUA) of Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19)

- Vaccine Information Fact Sheet for Recipients and Caregivers About COMIRNATY (COVID-19 Vaccine, mRNA) and Pfizer-BioNTech COVID-19 Vaccine to Prevent Coronavirus Disease (COVID-19).

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of Pfizer-BioNTech COVID-19 Vaccine, when used to prevent COVID-19 and used in accordance with this Scope of Authorization (Section II), outweigh its known and potential risks.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine may be effective in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, I have concluded that Pfizer-BioNTech COVID-19 Vaccine (as described in this Scope of Authorization (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of Pfizer-BioNTech COVID-19 Vaccine under this EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms of this EUA and

under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), Pfizer-BioNTech COVID-19 Vaccine is authorized to prevent COVID-19 in individuals 12 years of age and older as described in the Scope of Authorization (Section II) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

III. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

Pfizer Inc. and Authorized Distributor(s)

A. Pfizer Inc. and authorized distributor(s) will ensure that the authorized Pfizer-BioNTech COVID-19 Vaccine is distributed, as directed by the U.S. government, including CDC and/or other designee, and the authorized labeling (i.e., Fact Sheets) will be made available to vaccination providers, recipients, and caregivers consistent with the terms of this letter.

B. Pfizer Inc. and authorized distributor(s) will ensure that appropriate storage and cold chain is maintained until delivered to emergency response stakeholders' receipt sites.

C. Pfizer Inc. will ensure that the terms of this EUA are made available to all relevant stakeholders (e.g., emergency response stakeholders, authorized distributors, and vaccination providers) involved in distributing or receiving authorized Pfizer-BioNTech COVID-19 Vaccine. Pfizer Inc. will provide to all relevant stakeholders a copy of this letter of authorization and communicate any subsequent amendments that might be made to this letter of authorization and its authorized labeling.

D. Pfizer Inc. may develop and disseminate instructional and educational materials (e.g., video regarding vaccine handling, storage/cold-chain management, preparation, disposal) that are consistent with the authorized emergency use of the vaccine as described in the letter of authorization and authorized labeling, without FDA's review and concurrence, when necessary to meet public health needs during an emergency. Any instructional and educational materials that are inconsistent with the authorized labeling are prohibited.

E. Pfizer Inc. may request changes to this authorization, including to the authorized Fact Sheets for the vaccine. Any request for changes to this EUA must be submitted to Office of Vaccines Research and Review (OVRR)/Center for Biologics Evaluation and Research (CBER). Such changes require appropriate authorization prior to implementation.[14]

[14] The following types of revisions may be authorized without reissuing this letter: (1) changes to the authorized labeling; (2) non-substantive editorial corrections to this letter; (3) new types of authorized labeling, including new fact sheets; (4) new carton/container labels; (5) expiration dating extensions; (6) changes to manufacturing

F. Pfizer Inc. will report to Vaccine Adverse Event Reporting System (VAERS):
   - Serious adverse events (irrespective of attribution to vaccination);
   - Cases of Multisystem Inflammatory Syndrome in children and adults; and
   - Cases of COVID-19 that result in hospitalization or death, that are reported to Pfizer Inc.

   These reports should be submitted to VAERS as soon as possible but no later than 15 calendar days from initial receipt of the information by Pfizer Inc.

G. Pfizer Inc. must submit to Investigational New Drug application (IND) number 19736 periodic safety reports at monthly intervals in accordance with a due date agreed upon with the Office of Biostatistics and Epidemiology (OBE)/CBER beginning after the first full calendar month after authorization. Each periodic safety report is required to contain descriptive information which includes:
   - A narrative summary and analysis of adverse events submitted during the reporting interval, including interval and cumulative counts by age groups, special populations (e.g., pregnant women), and adverse events of special interest;
   - A narrative summary and analysis of vaccine administration errors, whether or not associated with an adverse event, that were identified since the last reporting interval;
   - Newly identified safety concerns in the interval; and
   - Actions taken since the last report because of adverse experiences (for example, changes made to Healthcare Providers Administering Vaccine (Vaccination Providers) Fact Sheet, changes made to studies or studies initiated).

H. No changes will be implemented to the description of the product, manufacturing process, facilities, or equipment without notification to and concurrence by FDA.

I. All manufacturing facilities will comply with Current Good Manufacturing Practice requirements.

J. Pfizer Inc. will submit to the EUA file Certificates of Analysis (CoA) for each drug product lot at least 48 hours prior to vaccine distribution. The CoA will include the established specifications and specific results for each quality control test performed on the final drug product lot.

K. Pfizer Inc. will submit to the EUA file quarterly manufacturing reports, starting in July 2021, that include a listing of all Drug Substance and Drug Product lots produced after issuance of this authorization. This report must include lot number, manufacturing site, date of manufacture, and lot disposition, including those lots that

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processes, including tests or other authorized components of manufacturing; (7) new conditions of authorization to require data collection or study. For changes to the authorization, including the authorized labeling, of the type listed in (3), (6), or (7), review and concurrence is required from the Preparedness and Response Team (PREP)/Office of the Center Director (OD)/CBER and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS).

were quarantined for investigation or those lots that were rejected. Information on the reasons for lot quarantine or rejection must be included in the report.

L. Pfizer Inc. and authorized distributor(s) will maintain records regarding release of Pfizer-BioNTech COVID-19 Vaccine for distribution (i.e., lot numbers, quantity, release date).

M. Pfizer Inc. and authorized distributor(s) will make available to FDA upon request any records maintained in connection with this EUA.

N. Pfizer Inc. will conduct post-authorization observational studies to evaluate the association between Pfizer-BioNTech COVID-19 Vaccine and a pre-specified list of adverse events of special interest, along with deaths and hospitalizations, and severe COVID-19. The study population should include individuals administered the authorized Pfizer-BioNTech COVID-19 Vaccine under this EUA in the general U.S. population (12 years of age and older), populations of interest such as healthcare workers, pregnant women, immunocompromised individuals, subpopulations with specific comorbidities. The studies should be conducted in large scale databases with an active comparator. Pfizer Inc. will provide protocols and status update reports to the IND 19736 with agreed-upon study designs and milestone dates.

Emergency Response Stakeholders

O. Emergency response stakeholders will identify vaccination sites to receive authorized Pfizer-BioNTech COVID-19 Vaccine and ensure its distribution and administration, consistent with the terms of this letter and CDC's COVID-19 Vaccination Program.

P. Emergency response stakeholders will ensure that vaccination providers within their jurisdictions are aware of this letter of authorization, and the terms herein and any subsequent amendments that might be made to the letter of authorization, instruct them about the means through which they are to obtain and administer the vaccine under the EUA, and ensure that the authorized labeling [i.e., Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Vaccine Information Fact Sheet for Recipients and Caregivers] is made available to vaccination providers through appropriate means (e.g., e-mail, website).

Q. Emergency response stakeholders receiving authorized Pfizer-BioNTech COVID-19 Vaccine will ensure that appropriate storage and cold chain is maintained.

Vaccination Providers

R. Vaccination providers will administer the vaccine in accordance with the authorization and will participate and comply with the terms and training required by CDC's COVID-19 Vaccination Program.

S. Vaccination providers will provide the Vaccine Information Fact Sheet for Recipients and Caregivers to each individual receiving vaccination and provide the necessary information for receiving their second dose and/or third dose.

T. Vaccination providers administering the vaccine must report the following information associated with the administration of the vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):
   - Vaccine administration errors whether or not associated with an adverse event
   - Serious adverse events (irrespective of attribution to vaccination)
   - Cases of Multisystem Inflammatory Syndrome in children and adults
   - Cases of COVID-19 that result in hospitalization or death

   Complete and submit reports to VAERS online at https://vaers.hhs.gov/reportevent.html. The VAERS reports should include the words "Pfizer-BioNTech COVID-19 Vaccine EUA" in the description section of the report. More information is available at vaers.hhs.gov or by calling 1-800-822-7967. To the extent feasible, report to Pfizer Inc. by contacting 1-800-438-1985 or by providing a copy of the VAERS form to Pfizer Inc.; Fax: 1-866-635-8337.

U. Vaccination providers will conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.

V. Vaccination providers will monitor and comply with CDC and/or emergency response stakeholder vaccine management requirements (e.g., requirements concerning obtaining, tracking, and handling vaccine) and with requirements concerning reporting of vaccine administration data to CDC.

W. Vaccination providers will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to CDC, and FDA for inspection upon request.

Conditions Related to Printed Matter, Advertising, and Promotion

X. All descriptive printed matter, advertising, and promotional material, relating to the use of the Pfizer-BioNTech COVID-19 Vaccine shall be consistent with the authorized labeling, as well as the terms set forth in this EUA, and meet the requirements set forth in section 502(a) and (n) of the FD&C Act and FDA implementing regulations.

Y. All descriptive printed matter, advertising, and promotional material relating to the use of the Pfizer-BioNTech COVID-19 Vaccine clearly and conspicuously shall state that:

- This product has not been approved or licensed by FDA, but has been authorized for emergency use by FDA, under an 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.

Condition Related to Export

Z. If the Pfizer-BioNTech COVID-19 Vaccine is exported from the United States, conditions C, D, and O through Y do not apply, but export is permitted only if 1) the regulatory authorities of the country in which the vaccine will be used are fully informed that this vaccine is subject to an EUA and is not approved or licensed by FDA and 2) the intended use of the vaccine will comply in all respects with the laws of the country in which the product will be used. The requirement in this letter that the authorized labeling (i.e., Fact Sheets) be made available to vaccination providers, recipients, and caregivers in condition A will not apply if the authorized labeling (i.e., Fact Sheets) are made available to the regulatory authorities of the country in which the vaccine will be used.

Conditions With Respect to Use of Licensed Product

AA. COMIRNATY (COVID-19 Vaccine, mRNA) is now licensed for individuals 16 years of age and older. There remains, however, a significant amount of Pfizer-BioNTech COVID-19 vaccine that was manufactured and labeled in accordance with this emergency use authorization. This authorization thus remains in place with respect to that product for the previously-authorized indication and uses (i.e., for use to prevent COVID-19 in individuals 12 years of age and older with a two-dose regimen, and to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise).

BB. This authorization also covers the use of the licensed COMIRNATY (COVID-19 Vaccine, mRNA) product when used to provide a two-dose regimen for individuals aged 12 through 15 years, or to provide a third dose to individuals 12 years of age or older who have undergone solid organ transplantation or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise. Conditions A through W in this letter apply when COMIRNATY (COVID-19 Vaccine, mRNA) is provided for the uses described in this subsection III.BB, except that product manufactured and labeled in accordance with the approved BLA is deemed to satisfy the manufacturing, labeling, and distribution requirements of this authorization.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

Denise M. Hinton -S

Digitally signed by Denise M. Hinton -S
Date: 2021.08.23 08:36:37 -04'00'

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures