

# CHECKLIST

## for storage, handling, and preparation of the Pfizer-BioNTech COVID-19 Vaccine

### THREE VACCINE PRESENTATIONS ARE NOW AVAILABLE

Please see the Dosing and Preparation Guide and the Formulation/Presentation Guide for differences in storage, handling, and preparation requirements.

#### **For individuals 12 years of age and older:**

**DO NOT USE** for ages 5 through 11



**DILUTE BEFORE USE**  
vials with purple caps



**DO NOT DILUTE**  
vials with gray caps

#### **For ages 5 through 11 years:**

**DO NOT USE** for 12 years of age and older



**DILUTE BEFORE USE**  
vials with orange caps  
("Age 5y to <12y" on vial label)

When prepared according to their respective instructions for use, the FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine for ages 12 years and older can be used interchangeably without presenting any safety or effectiveness concerns, but **should not be used** for individuals **5 through 11 years of age**, because of the potential for vaccine administration errors, including dosing errors.

Emergency uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals 5 years of age and older. The emergency uses are 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.

### Selected Safety Information

Do not administer to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of the 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>).

Please see Important Safety Information and Indication & Authorized Use on pages 8 and 9.

Before administration of the vaccine, please **scroll down** and click to review the full Prescribing Information and the respective EUA Fact Sheets.

# MULTIPLE DOSE VIAL FOR AGES 12 AND OLDER - DILUTE BEFORE USE (PURPLE CAP)



## Storage and Handling of the Vaccine and Thermal Shipping Container

**Reminder:** This presentation for **ages 12 and older** comes in a multiple dose vial that contains **6 doses** after dilution.

### Resource materials available on [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com):

- [EUA Fact Sheet for Vaccination Providers \(12 Years & Up\)](#)  
DILUTE BEFORE USE, Purple Cap
- [Full Prescribing Information \(16 years of age and older\)](#)  
DILUTE BEFORE USE, Purple Cap
- [EUA Fact Sheet for Recipients and Caregivers](#)  
(12 Years & Up)
- [Dosing and Preparation Guide](#)
- [Dry Ice Replenishment Sheet](#)
- [Returning Real-Time Temperature Monitor and Thermal Shipping Container Instructions](#)
- [Shipping and Handling Guidelines](#)
- [Formulation/Presentation Guide](#)

### Materials checklist for storage and handling:

- Safety goggles or safety glasses with side shields
- Waterproof insulated gloves
- Box cutter or tool to open box
- Hand truck or dolly to move the thermal shipping container, which can weigh up to ~36 kg (~80 lb)
- Ultra-low-temperature freezer, freezer, or refrigerator; for alternate, temporary storage options available, please visit <https://www.cvdvaccine-us.com>

Vaccines may be received in medium or single-use thermal shipping containers\*

### If using the medium thermal shipping container as temporary storage, you will also need:

- Dry ice supply (ice pellets 10-16 mm, for re-icing)
- Dry ice scoop
- Temperature-monitoring device
- Packing tape or equivalent
- A method for tracking dry ice replenishment dates to ensure protocol is being followed

**\*The single-use thermal shipping container cannot be used as temporary storage.**

### Before receiving the thermal shipping container, you must have:

- A well-ventilated room set up to safely handle the thermal shipping container and dry ice
- An appropriate area for discarding dry ice so it can sublimate from a solid to a gas
- Proper security so only authorized personnel can access the thermal shipping container contents
- Access to an occupational health department that can be consulted to ensure appropriate safeguards

Please see **Important Safety Information and Indication & Authorized Use** on pages 8 and 9.

Before administration of the vaccine, please **scroll down** and click to review the full Prescribing Information and the respective EUA Fact Sheets.

# MULTIPLE DOSE VIAL FOR AGES 12 AND OLDER - DILUTE BEFORE USE (PURPLE CAP)



## Thawing, Dilution, and Preparation

**Reminder:** This presentation for **ages 12 and older** comes in a multiple dose vial that contains **6 doses** after dilution.



### **Materials checklist for vaccine preparation:** (Dilute Before Use, 12 years of age and older)

- If removing from ultra-low-temperature storage:** Personal protective equipment (including waterproof insulated gloves that allow manual dexterity)
- Secondary container, such as a small tray, to transport vials removed from original vial carton
- 3-mL or 5-mL syringe (for dilution)
- 21-gauge or narrower needle (for dilution)
- Low dead-volume syringe and/or needle (for administration) appropriate for intramuscular injection
- Vials of sterile 0.9% Sodium Chloride Injection, USP (for one-time use)
- Antiseptic swabs
- Sharps container for disposal

**Please see Important Safety Information and Indication & Authorized Use on pages 8 and 9.**

**Before administration of the vaccine, please click to see**

Fact Sheets and Prescribing Information for individuals 12 years of age and older

[Full Prescribing Information \(16 years of age and older\) DILUTE BEFORE USE, Purple Cap](#)

[Full Prescribing Information \(16 years of age and older\) DO NOT DILUTE, Gray Cap](#)

[EUA Fact Sheet for Vaccination Providers \(12 years of age and older\), DILUTE BEFORE USE, Purple Cap](#)

[EUA Fact Sheet for Vaccination Providers \(12 years of age and older\), DO NOT DILUTE, Gray Cap](#)

[Recipients and Caregivers Fact Sheet \(12 years of age and older\)](#)

Fact Sheets for individuals 5 through 11 years of age

[EUA Fact Sheet for Vaccination Providers \(5 through 11 years of age\), DILUTE BEFORE USE, Orange Cap](#)

[Recipients and Caregivers Fact Sheet \(5 through 11 years of age\)](#)

# MULTIPLE DOSE VIAL FOR AGES 12 AND OLDER - DO NOT DILUTE (GRAY CAP)



## Storage and Handling of the Vaccine and Thermal Shipping Container

**Reminder: DO NOT DILUTE.** This presentation for ages 12 and older comes in a multiple dose vial that contains 6 doses.

**Resource materials available on [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com):**

- |  |  |
|--|--|
| <input type="checkbox"/> EUA Fact Sheet for Vaccination Providers (12 Years & Up)<br>DO NOT DILUTE, Gray Cap | <input type="checkbox"/> Dosing and Preparation Guide  |
| <input type="checkbox"/> Full Prescribing Information (16 years of age and older)<br>DO NOT DILUTE, Gray Cap | <input type="checkbox"/> Dry Ice Replenishment Sheet   |
| <input type="checkbox"/> EUA Fact Sheet for Recipients and Caregivers<br>(12 Years & Up)                     | <input type="checkbox"/> Returning Real-Time Temperature Monitor and Thermal Shipping Container Instructions |
|  | <input type="checkbox"/> Shipping and Handling Guidelines  |
|  | <input type="checkbox"/> Formulation/Presentation Guide  |

### Materials checklist for storage and handling:

- Safety goggles or safety glasses with side shields
- Waterproof insulated gloves
- Box cutter or tool to open box
- Hand truck or dolly to move the thermal shipping container, which can weigh up to ~36 kg (~80 lb)
- Ultra-low-temperature freezer\* or refrigerator; for alternate, temporary storage options available, please visit <https://www.cvdvaccine-us.com>

**\*DO NOT STORE IN STANDARD FREEZER**

Vaccines may be received in medium or single-use thermal shipping containers<sup>†</sup>

**If using the medium thermal shipping container as temporary storage, you will also need:**

- Dry ice supply (ice pellets 10-16 mm, for re-icing)
- Dry ice scoop
- Temperature-monitoring device
- Packing tape or equivalent
- A method for tracking dry ice replenishment dates to ensure protocol is being followed

**† The single-use thermal shipping container cannot be used as temporary storage.**

### Before receiving the thermal shipping container, you must have:

- |  |   |
|--|---|
| <input type="checkbox"/> A well-ventilated room set up to safely handle the thermal shipping container and dry ice | <input type="checkbox"/> Proper security so only authorized personnel can access the thermal shipping container contents    |
| <input type="checkbox"/> An appropriate area for discarding dry ice so it can sublimate from a solid to a gas      | <input type="checkbox"/> Access to an occupational health department that can be consulted to ensure appropriate safeguards |

Please see Important Safety Information and Indication & Authorized Use on pages 8 and 9.

Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.

# MULTIPLE DOSE VIAL FOR AGES 12 AND OLDER - DO NOT DILUTE (GRAY CAP)



## Thawing and Preparation

**Reminder: DO NOT DILUTE.** This presentation for ages 12 and older comes in a multiple dose vial that contains **6 doses**.



### Materials checklist for vaccine preparation:

(Do Not Dilute, 12 years of age and older)

- If removing from ultra-low-temperature storage:** Personal protective equipment (including waterproof insulated gloves that allow manual dexterity)
- Secondary container, such as a small tray, to transport vials removed from original vial carton
- Low dead-volume syringe and/or needle (for administration) appropriate for intramuscular injection
- Antiseptic swabs
- Sharps container for disposal

**Please see Important Safety Information and Indication & Authorized Use on pages 8 and 9.**

**Before administration of the vaccine, please click to see**

Fact Sheets and Prescribing Information for individuals 12 years of age and older

[Full Prescribing Information \(16 years of age and older\) DILUTE BEFORE USE, Purple Cap](#)

[Full Prescribing Information \(16 years of age and older\) DO NOT DILUTE, Gray Cap](#)

[EUA Fact Sheet for Vaccination Providers \(12 years of age and older\), DILUTE BEFORE USE, Purple Cap](#)

[EUA Fact Sheet for Vaccination Providers \(12 years of age and older\), DO NOT DILUTE, Gray Cap](#)

[Recipients and Caregivers Fact Sheet \(12 years of age and older\)](#)

Fact Sheets for individuals 5 through 11 years of age

[EUA Fact Sheet for Vaccination Providers \(5 through 11 years of age\), DILUTE BEFORE USE, Orange Cap](#)

[Recipients and Caregivers Fact Sheet \(5 through 11 years of age\)](#)

# MULTIPLE DOSE VIAL FOR AGES 5 THROUGH 11 - DILUTE BEFORE USE (ORANGE CAP)



## Storage and Handling of the Vaccine and Thermal Shipping Container

**Reminder:** The presentation for **ages 5 through 11** comes in a multiple dose vial that contains **10 doses** after dilution.

### Resource materials available on [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com):

- [EUA Fact Sheet for Vaccination Providers \(5 through 11 Years\) DILUTE BEFORE USE, Orange Cap](#)
- [EUA Fact Sheet for Recipients and Caregivers \(5 through 11 years\)](#)
- [Dosing and Preparation Guide](#)
- [Returning Real-Time Temperature Monitor Instructions](#)
- [Shipping and Handling Guidelines - Single-Use Thermal Shipping Container](#)
- [Formulation/Presentation Guide](#)
- [Dry Ice Safety Data Sheet](#)

### Materials checklist for storage and handling:

- Safety goggles or safety glasses with side shields
- Waterproof insulated gloves
- Box cutter or tool to open box
- Hand truck or dolly to move the thermal shipping container. Use caution when lifting the thermal shipping container, as it may be heavy
- Ultra-low-temperature freezer\* or refrigerator; for alternate, temporary storage options available, please visit <https://www.cvdvaccine-us.com>

**\*DO NOT STORE IN STANDARD FREEZER**

### Before receiving the thermal shipping container, you must have:

- A well-ventilated room set up to safely handle the thermal shipping container and dry ice
- An appropriate area for discarding dry ice so it can sublimate from a solid to a gas
- Proper security so only authorized personnel can access the thermal shipping container contents
- Access to an occupational health department that can be consulted to ensure appropriate safeguards

Please see **Important Safety Information and Indication & Authorized Use** on pages 8 and 9.

Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.

# MULTIPLE DOSE VIAL FOR AGES 5 THROUGH 11 - DILUTE BEFORE USE (ORANGE CAP)



## Thawing, Dilution, and Preparation

**Reminder:** The presentation for **ages 5 through 11** comes in a multiple dose vial that contains **10 doses** after dilution.



### Materials checklist for vaccine preparation:

(Dilute Before Use, 5 through 11 years of age)

- If removing from ultra-low-temperature storage:** Personal protective equipment (including waterproof insulated gloves that allow manual dexterity)
  - Secondary container, such as a small tray, to transport vials removed from original vial carton
- 3-mL or 5-mL syringe (for dilution)
- 21-gauge or narrower needle (for dilution)
- 1 mL low dead-volume syringe and/or needle (for administration) appropriate for intramuscular injection
- Vials of sterile 0.9% Sodium Chloride Injection, USP (for one-time use)
- Antiseptic swabs
- Sharps container for disposal

**Please see Important Safety Information and Indication & Authorized Use on pages 8 and 9.**

**Before administration of the vaccine, please click to see**

Fact Sheets and Prescribing Information for individuals 12 years of age and older

[Full Prescribing Information \(16 years of age and older\) DILUTE BEFORE USE, Purple Cap](#)

[Full Prescribing Information \(16 years of age and older\) DO NOT DILUTE, Gray Cap](#)

[EUA Fact Sheet for Vaccination Providers \(12 years of age and older\), DILUTE BEFORE USE, Purple Cap](#)

[EUA Fact Sheet for Vaccination Providers \(12 years of age and older\), DO NOT DILUTE, Gray Cap](#)

[Recipients and Caregivers Fact Sheet \(12 years of age and older\)](#)

Fact Sheets for individuals 5 through 11 years of age

[EUA Fact Sheet for Vaccination Providers \(5 through 11 years of age\), DILUTE BEFORE USE, Orange Cap](#)

[Recipients and Caregivers Fact Sheet \(5 through 11 years of age\)](#)

## Important Safety Information and Indication & Authorized Use

### Important Safety Information

Do not administer to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of the 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 vaccines, in particular in adolescents. 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.

#### Primary Series Adverse Events:

In clinical studies (30 mcg modRNA) of participants 16 through 55 years of age, the most commonly reported adverse reactions ( $\geq 10\%$ ) 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 (30 mcg modRNA) of participants 56 years of age and older, the most commonly reported adverse reactions ( $\geq 10\%$ ) 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 (30 mcg modRNA) of adolescents 12 through 15 years of age, adverse reactions following the administration of the primary series 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%).

In a clinical study (10 mcg modRNA) in children 5 through 11 years of age, adverse reactions following administration of any primary series dose included pain at the injection site (84.3%), fatigue (51.7%), headache (38.2%), injection site redness (26.4%), injection site swelling (20.4%), muscle pain (17.5%), chills (12.4%), fever (8.3%), joint pain (7.6%), lymphadenopathy (0.9%), nausea (0.4%), rash (0.3%), malaise (0.1%), and decreased appetite (0.1%).

#### Booster Dose Adverse Events:

In a clinical study (30 mcg modRNA) of participants 18 through 55 years of age, adverse reactions following administration of a booster dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), joint pain (25.3%), lymphadenopathy (5.2%), nausea (0.7%), decreased appetite (0.3%), rash (0.3%), and pain in extremity (0.3%).

### Indication & Authorized Use

The FDA-approved COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine for individuals 12 years of age and older, when prepared according to their respective instructions for use, can be used interchangeably.

COMIRNATY® (COVID-19 Vaccine, mRNA) and the Pfizer-BioNTech COVID-19 Vaccine intended for individuals 12 years of age and older should not be used for individuals 5 through 11 years of age because of the potential for vaccine administration errors, including dosing errors.

#### 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, Indication & Authorized Use continued on next page.*

**Before administration of the vaccine, please scroll down and click to review the full Prescribing Information and the respective EUA Fact Sheets.**



## Important Safety Information and Indication & Authorized Use (cont'd)

### Authorized Use

The Pfizer-BioNTech COVID-19 Vaccine has received Emergency Use Authorization (EUA) from FDA to prevent COVID-19 in individuals 5 years of age and older to provide:

- a 10 mcg modRNA 2-dose primary series to individuals 5 through 11 years of age
- a 30 mcg modRNA 2-dose primary series to individuals 12 years of age and older
- a 10 mcg modRNA third primary series dose to individuals 5 through 11 years of age who have been determined to have certain kinds of immunocompromise
- a 30 mcg modRNA third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a 30 mcg modRNA single booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY<sup>®</sup> (COVID-19 Vaccine, mRNA)
- a 30 mcg modRNA single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination

COMIRNATY<sup>®</sup> (COVID-19 Vaccine, mRNA) is authorized for emergency use to provide:

- a 30 mcg modRNA 2-dose primary series to individuals 12 through 15 years of age
- a 30 mcg modRNA third primary series dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a 30 mcg modRNA single booster dose to individuals 12 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 Vaccine or COMIRNATY<sup>®</sup> (COVID-19 Vaccine, mRNA)
- a 30 mcg modRNA single booster dose to individuals 18 years of age and older who have completed primary vaccination with a different authorized COVID-19 vaccine. The dosing interval for the heterologous booster dose is the same as that authorized for a booster dose of the vaccine used for primary vaccination

Emergency uses of the vaccine have not been approved or licensed by FDA, but have been authorized by FDA, under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) in individuals 5 years of age and older. The emergency uses are 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.

**Please see Important Safety Information and Indication & Authorized Use on pages 8 and 9.**

**Before administration of the vaccine, please click to see**

Fact Sheets and Prescribing Information for individuals 12 years of age and older

[Full Prescribing Information \(16 years of age and older\) DILUTE BEFORE USE, Purple Cap](#)

[Full Prescribing Information \(16 years of age and older\) DO NOT DILUTE, Gray Cap](#)

[EUA Fact Sheet for Vaccination Providers \(12 years of age and older\), DILUTE BEFORE USE, Purple Cap](#)

[EUA Fact Sheet for Vaccination Providers \(12 years of age and older\), DO NOT DILUTE, Gray Cap](#)

[Recipients and Caregivers Fact Sheet \(12 years of age and older\)](#)

Fact Sheets for individuals 5 through 11 years of age

[EUA Fact Sheet for Vaccination Providers \(5 through 11 years of age\), DILUTE BEFORE USE, Orange Cap](#)

[Recipients and Caregivers Fact Sheet \(5 through 11 years of age\)](#)

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**Current as of January 3, 2022. For the most up-to-date version,  
visit [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com).**

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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.

PP-CVV-USA-0467  
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