

# THERMAL SHIPPING CONTAINER DRY ICE REPLENISHMENT INSTRUCTIONS

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

\*The licensed COMIRNATY® vaccine has the same formulation as the authorized vaccine Pfizer-BioNTech COVID-19 Vaccine, and they can be used interchangeably without presenting any safety or effectiveness concerns. Although they may be manufactured in different facilities, the products offer the same safety and effectiveness.

The 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) for use in individuals 12 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

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>).

Global: Drives to <http://labeling.pfizer.com/ShowLabeling.aspx?id=15623>

Please see Important Safety Information and Indication & Authorized Use on pages 5 and 6.

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



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

Global: Drives to <http://labeling.pfizer.com/ShowLabeling.aspx?id=14472&format=pdf>

# THERMAL SHIPPING CONTAINER DRY ICE REPLENISHMENT INSTRUCTIONS

Current as of October 5, 2021. For the most up-to-date brochure, visit [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com).

## CAUTION:

Use of dry ice in confined spaces (small rooms or walk-in coolers) and/or poorly ventilated areas can result in depletion of oxygen, causing asphyxiation. Exposed skin should be protected from contact with dry ice. Wear safety goggles or safety glasses with side shields.<sup>1</sup> To ensure appropriate controls are in place, review the Dry Ice Safety Data Sheet BEFORE accessing the contents of the thermal shipping container and consult with your Occupational Health Department.

Follow the instructions and requirements outlined in this booklet when using the thermal shipping container for temporary storage of the vaccine.

Only the thermal shipping container for 195-pack cartons may be used as temporary storage for up to 30 days.<sup>1</sup>

The thermal shipping containers including less than 195-pack cartons should not be used as temporary storage.

## THERMAL SHIPPING CONTAINER TEMPORARY STORAGE DRY ICE REPLENISHMENT INSTRUCTIONS

**Note:** Please read the following ancillary documents included with the thermal shipping container before unpacking and/or replenishing dry ice in the thermal shipping container:

1. [Dry Ice Safety Data Sheet](#)

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

2. [Shipping and Handling Guidelines](#)

Drives to: <https://www.cvdvaccine-us.com/images/pdf/195-Pack%20Shipping%20and%20Handling%20Guidelines.pdf>

Also available by visiting [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com).

## IMPORTANT INFORMATION<sup>1</sup>

- **24 Hours:** The thermal shipping container is qualified with a minimum of 20 kg of dry ice pellets (10 mm–16 mm pellets). If you are using the thermal shipping container as temporary storage, **the container must be opened, inspected, and replenished with dry ice within 24 hours of receipt**
- For the thermal shipping container to maintain the ultra-low temperatures required, it is recommended that the thermal shipping container itself be stored at 15°C to 25°C (59°F to 77°F)
- **To help maintain the level of dry ice and the temperature of the vaccine product:**
  - 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:** Replenish dry ice in the thermal shipping container **every 5 days**
- If more frequent openings are necessary, more frequent dry ice replenishment will be required. Be sure to replenish dry ice in the thermal shipping container at the end of business on days when the vaccination site will be closed the following day, such as weekends or holidays
- For information on handling the vial cartons and vials, please visit [www.cvdvaccine-us.com](http://www.cvdvaccine-us.com)
- **After use, the thermal shipping container and the temperature-monitoring device must be returned to the supplier to help Pfizer fulfill its commitment to reusable resources**

Please see Important Safety Information and Indication & Authorized Use on pages 5 and 6.

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

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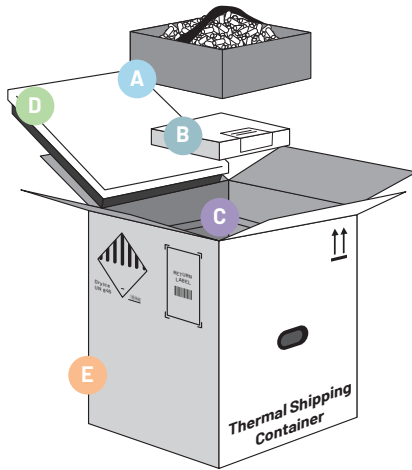
# THERMAL SHIPPING CONTAINER DRY ICE REPLENISHMENT INSTRUCTIONS

**CAUTION:** Use of dry ice in confined spaces (small rooms or walk-in coolers) and/or poorly ventilated areas can result in depletion of oxygen, causing asphyxiation. Exposed skin should be protected from contact with dry ice. Wear safety goggles or safety glasses with side shields.<sup>1</sup> To ensure appropriate controls are in place, review the Dry Ice Safety Data Sheet BEFORE accessing the contents of the thermal shipping container and consult with your Occupational Health Department.

## UNPACKING THE THERMAL SHIPPING CONTAINER<sup>1</sup>

**1** Before opening the thermal shipping container, make sure the area in which you are working has proper ventilation. Use of dry ice in confined spaces, such as small rooms, walk-in coolers, and/or poorly ventilated areas, can result in depletion of oxygen, causing asphyxiation.

**2** Below is an overview of the components within the thermal shipping container for dry ice replenishment.



There are multiple types of thermal shipping containers and vial pack sizes, all with similar components. The examples shown below are for illustrative purposes only and may not exactly replicate the type of thermal shipping container you receive.

*Vial carton will be inside either a plastic corrugated box OR a bag, which is located inside the vial carton compartment.*

Item and Description				
<b>A</b> DRY ICE POD	<b>B</b> VIAL CARTONS	<b>C</b> VIAL CARTON COMPARTMENT	<b>D</b> FOAM LID	<b>E</b> THERMAL SHIPPING CONTAINER
<i>Holds the top layer of dry ice</i>	<i>Each carton contains 195, 25, or 10 multiple dose vials, depending on your order</i>	<i>Fixed compartment within the thermal shipping container that holds the vial cartons</i>	<i>Top foam lid that includes an embedded temperature-monitoring device and remains connected to the box</i>	<i>Outer box of the thermal shipping container</i>

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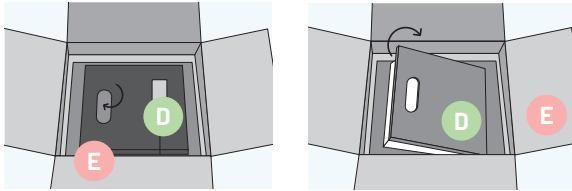
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# THERMAL SHIPPING CONTAINER DRY ICE REPLENISHMENT INSTRUCTIONS

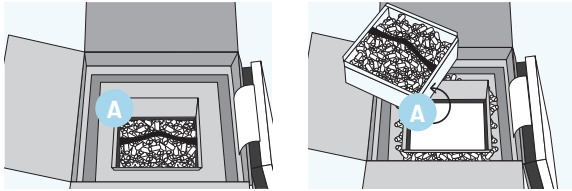
**CAUTION:** Use of dry ice in confined spaces (small rooms or walk-in coolers) and/or poorly ventilated areas can result in depletion of oxygen, causing asphyxiation. Exposed skin should be protected from contact with dry ice. Wear safety goggles or safety glasses with side shields.<sup>1</sup> To ensure appropriate controls are in place, review the Dry Ice Safety Data Sheet BEFORE accessing the contents of the thermal shipping container and consult with your Occupational Health Department.

## UNPACKING THE THERMAL SHIPPING CONTAINER<sup>1</sup>

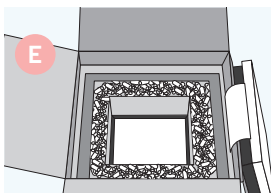
- 3** In a well-ventilated area, open the thermal shipping container (**E**) by cutting the tape on the outside. Gently open the lid using the cutout in the foam lid (**D**).



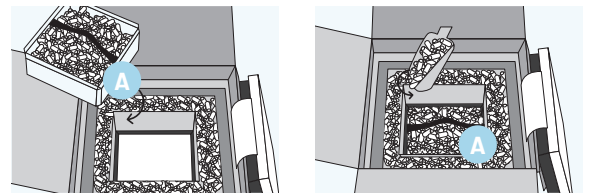
- 4** The dry ice pod (**A**) is visible. While wearing waterproof insulated gloves, lift out the dry ice pod (**A**).



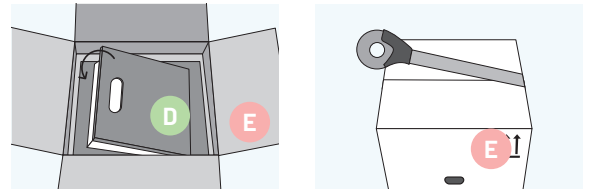
- 5** Fill any low areas in the side compartments of the thermal shipping container (**E**) with dry ice pellets until completely filled, so that it is equal with but does not exceed the top edges of the side compartments.



- 6** Reinsert the dry ice pod (**A**) into the aluminum lining cavity, which holds the vial cartons. The dry ice pod has a ledge that rests on the aluminum lining. Then fill the dry ice pod (**A**) to the top with dry ice (do not overfill).



- 7** Close the foam lid (**D**) and the thermal shipping container (**E**) and reseal with tape. To maintain required temperatures, it is critical that the container lid is flush and properly taped shut.



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## Important Safety Information and Indication & Authorized Use

### 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 ( $\geq 10\%$ ) 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 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 evaluating administration of a booster dose in participants 18 through 55 years of age, the most commonly reported adverse reactions ( $\geq 10\%$ ) following the dose were pain at the injection site (83.0%), fatigue (63.7%), headache (48.4%), muscle pain (39.1%), chills (29.1%), and joint pain (25.3%).

In a clinical study of adolescents 12 through 15 years of age, the most commonly reported adverse reactions 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%).

### Indication & Authorized Use

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.

#### 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 to provide:

- a two-dose primary series in individuals 12 through 15 years
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose in individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
  - 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19

*Authorized Use information continued on next page.*

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

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

### Authorized Use (cont'd)

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 to provide:

- a two-dose primary series in individuals 12 years of age and older
- a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise
- a single booster dose in individuals:
  - 65 years of age and older
  - 18 through 64 years of age at high risk of severe COVID-19
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**Please see Important Safety Information on page 5.**

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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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