Pfizer-BioNTech COVID-19 Vaccine

SHIPPING AND HANDLING GUIDELINES

To ensure appropriate controls are in place, review the Dry Ice Safety Data Sheet BEFORE accessing the contents from the thermal shipping container and consult with your Occupational Health Department.

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by FDA, but has been authorized for emergency use by FDA under an Emergency Use Authorization to prevent Coronavirus Disease 2019 (COVID-19) for use in individuals 16 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 FD&C Act unless the declaration is terminated or authorization revoked sooner.

Current as of March 17, 2021. For the most up-to-date brochure, visit [www.cvdvaccine.com](http://www.cvdvaccine.com).

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CONNECT WITH US

For general questions about the Pfizer-BioNTech COVID-19 Vaccine, visit www.cvdvaccine.com or call the telephone number provided below.

www.cvdvaccine.com

1-877-VAX-C019
(1-877-829-2619)

For countries outside of the US, visit www.pfizer.com/products/product-contact-information to see the list of Pfizer’s Global Medical Information Numbers.
GENERAL INFORMATION

This guide details user processes and procedures that must be followed upon receiving the Pfizer-BioNTech COVID-19 Vaccine.

The nature of this vaccine requires it to be kept at extremely low temperatures during shipment and storage after it arrives. To achieve this, multiple dose vials of the frozen vaccine are shipped in insulated thermal shipping containers containing dry ice. This allows the vaccine to remain frozen at this low temperature.

For information about specific temperature requirements and ranges to monitor, as well as dry ice safety, storage, and handling, please go to www.cvdvaccine.com.

FACTS ABOUT DRY ICE

Dry ice is the frozen form of carbon dioxide. When heated, most frozen solids melt to a liquid form, but dry ice transforms directly into a gas (sublimation). Dry ice sublimes at temperatures at or above -109°F (-78°C).

The main hazards of dry ice include asphyxiation and burns. 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. To ensure appropriate controls are in place, review the Dry Ice Safety Data Sheet BEFORE accessing the contents from the thermal shipping container and consult with your Occupational Health Department.
HANDLING

Use caution when lifting the shipping container, as it may be heavy. Depending on the amount of vaccine ordered, the shipping container can weigh approximately 36 kg (80 lb). Do not place anything on top of the thermal shipping container. Contact Pfizer Customer Service at 1-877-VAX-CO19 (1-877-829-2619) immediately to communicate any issues.

Do not open the vial trays or remove vials until you are ready for thawing or use. Visit www.cvdvaccine.com for further information.

You will need to take precautions when preparing to handle dry ice. 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. Make sure you are wearing safety glasses with side shields or safety goggles and waterproof insulated gloves when handling dry ice.

To ensure all appropriate safeguards are in place, review the Dry Ice Safety Data Sheet, and consult with your Occupational Health Department.

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 and dispose of the vial pieces in a medical sharps container using forceps, tongs, or other appropriate tools.
GENERAL SAFETY GUIDANCE FOR DRY ICE  ‘CAUTION’

Do not touch - avoid eye contact
Use waterproof insulated gloves when removing or adding dry ice to prevent cold burns and frostbite. Avoid contact with face and eyes. Wear safety glasses with side shields or safety goggles.

Do not eat
Dry ice is harmful if eaten or swallowed. If ingested, seek immediate medical care.

Do not store in confined spaces
Dry ice changes to a gas very rapidly at room temperature, displacing oxygen. Only use dry ice in open or well-ventilated areas.

Do not place in airtight containers
Airtight containers may explode as dry ice rapidly expands to a gas when exposed to temperatures above -109°F (-78°C).
VENTILATION
At room temperature (including most cold storage temperatures), dry ice becomes carbon dioxide gas, which may cause difficulty breathing or suffocation. If dry ice has been in a closed area, trailer, or container, open doors and allow adequate ventilation before entering. **If you feel short of breath or develop a headache, these may be signs that you have inhaled too much carbon dioxide. Leave the area immediately.** Carbon dioxide is heavier than air and accumulates in low, poorly ventilated spaces.

Operational practices for accessing a closed area where dry ice is present should be reviewed and agreed upon with your Occupational Health and Safety officer.

BURN TREATMENT
Dry ice may cause cold burns to the skin. Use waterproof insulated gloves when handling dry ice. Seek medical care as directed by the [Dry Ice Safety Data Sheet](#).

DISPOSAL
Once dry ice is no longer needed, open the container and leave it at room temperature in a well-ventilated area. It will readily sublime from a solid to a gas. DO NOT leave dry ice in an unsecured area. DO NOT place in drain or flush in toilet. DO NOT dispose in trash. DO NOT place in a closed area such as an airtight container or walk-in cooler.

DRY ICE REPLENISHMENT
The thermal shipping container can be used as a temporary storage device. For dry ice replenishment requirements, dry ice pellet size, and pack-out instructions for replenishing the thermal shipping container with dry ice, see the [Thermal Shipping Container Dry Ice Replenishment Instructions](#).
CONTENTS AND PACKAGING

There are two types of thermal shipping containers: a Softbox thermal shipping container and an AeroSafe thermal shipping container. Their outer appearance is different, but their components are very similar. **Do not discard the original thermal shipping container or any of its components.**

**Softbox**

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A DRY ICE POD</td>
<td>Holds the top layer of dry ice</td>
</tr>
<tr>
<td>B VIAL TRAYS</td>
<td>Vial trays look like small pizza boxes. Each vial tray contains multiple dose vials</td>
</tr>
<tr>
<td>C BOX THAT HOLDS THE VIAL TRAYS</td>
<td>Box within the thermal shipping container that includes the vial trays. This box should not be removed</td>
</tr>
<tr>
<td>D FOAM LID</td>
<td>Top foam lid that includes an embedded temperature-monitoring device and remains connected to the box</td>
</tr>
<tr>
<td>E THERMAL SHIPPING CONTAINER</td>
<td>Outer box of the thermal shipping container</td>
</tr>
</tbody>
</table>
The thermal shipping container you received is approximately 36 kg (80 lb) and should be opened on the floor, as it may be heavy.

### AeroSafe

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>A DRY ICE POD</td>
<td>Holds the top layer of dry ice</td>
</tr>
<tr>
<td>B VIAL TRAYS</td>
<td>Vial trays look like small pizza boxes. Each vial tray contains multiple dose vials</td>
</tr>
<tr>
<td>C ALUMINUM INNER LINING</td>
<td>Structure that holds the vial trays in place, is integrated into the thermal shipping container</td>
</tr>
<tr>
<td>D FOAM LID</td>
<td>Top foam lid that includes an embedded temperature-monitoring device and remains connected to the box</td>
</tr>
<tr>
<td>E THERMAL SHIPPING CONTAINER</td>
<td>Outer box of the thermal shipping container</td>
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</table>
## UNPACKING THERMAL SHIPPING CONTAINERS

### Step Instructions

1. For both types of thermal shipping containers, you must first break the seal to open.

2. When you open the thermal shipping container, **you will see a temperature-monitoring device embedded in the foam lid**.

   Take caution when opening the thermal shipping containers. On the Softbox lid, you’ll notice one flap of the thermal shipping container is permanently affixed to the lid. Do not pull this flap. When opening the lid, use the three finger holes in the foam lid, which will then allow the lid to swing open.

   Gently open the AeroSafe lid using the cutout in the foam lid.

   The lids of both the Softbox and AeroSafe thermal shipping containers will remain attached to the outer box of the thermal shipping container.
The temperature-monitoring device continuously tracks the temperature during shipment to ensure the frozen vaccine product has been maintained at the required temperature during transport to vaccination centers. Upon receipt, press and hold the stop button for 5 seconds. Sites are responsible for continuing to monitor the product storage temperature.

Information about temperature monitoring can be found at [www.cvdvaccine.com](http://www.cvdvaccine.com).

Make sure that you are now wearing waterproof insulated gloves and safety glasses with side shields or safety goggles as you prepare to handle layers of the container that have dry ice.

Beneath the foam lid is the dry ice pod, which holds a layer of dry ice to help maintain the temperature of the multiple dose vials.

There will also be dry ice in compartments in the container that surround the box that holds the vial trays.

If using the thermal shipping container as temporary storage, both of those areas will need to be filled when replenishing the dry ice.

Using your waterproof insulated gloves, remove the dry ice pod.
Each vial tray looks like a small pizza box, and contains multiple dose vials.

If you received a Softbox thermal shipping container, you will now see a lid for the box that holds the vial trays. Open this lid to access the vial trays. There will be up to 5 vial trays inside.

Carefully remove the vial trays. Leave the box containing the vial trays inside the thermal shipping container when accessing or removing the vial trays.

If you received the AeroSafe thermal shipping container, there will be no box that holds the vial trays. Instead, the vial trays are immediately visible and housed within the aluminum inner lining of the thermal shipping container. Carefully remove the vial trays from the aluminum inner lining.

Remember, do not open the vial trays or remove vials until you are ready for thawing or use. Visit www.cvdvaccine.com for further information.

Review the Pfizer-BioNTech COVID-19 Vaccine Safety Data Sheet (available by visiting https://safetydatasheets.pfizer.com/).

You must immediately store the vaccine product, preferably in an ultra-low-temperature (ULT) freezer.

If a ULT freezer is not available, the thermal shipping container may be used as temporary storage. If using the thermal shipping container as temporary storage, it must be opened, inspected, and replenished within 24 hours of receipt. However, there are alternate, temporary storage options available; visit www.cvdvaccine.com.
DISCARDING DRY ICE

After the thermal shipping container is no longer needed to store the vaccine, you can discard the dry ice. Take necessary precautions by reviewing the Dry Ice Safety Data Sheet, and consult with your Occupational Health Department.

To discard, open the thermal shipping container and leave it at room temperature in a well-ventilated area. It will sublime from a solid to a gas. DO NOT leave dry ice in an unsecured area. DO NOT place in drain or flush in toilet. DO NOT dispose in trash. DO NOT place in a closed area such as an airtight container or walk-in cooler.

In the US, issues with the shipment should be immediately communicated to Pfizer Customer Service at 1-800-666-7248. For countries outside of the US, visit www.pfizer.com/products/product-contact-information to see the list of Pfizer’s Global Medical Information Numbers.
RETURNING TEMPERATURE-MONITORING DEVICE AND THERMAL SHIPPING CONTAINER

The thermal shipping container may be used as temporary storage for up to 30 days from delivery.

After use, the thermal shipping container, including the temperature-monitoring device, must be returned to the supplier to help Pfizer fulfill its commitment to reusable resources.

When the thermal shipping container is ready to be returned, and all the components are inside, seal it with tape. A preprinted return shipping label will be included inside the thermal shipping container or already adhered to the flap of the thermal shipping container. **Contact the carrier identified on the return label to arrange the return.**

When coordinating the return of the Softbox thermal shipping container, apply the preprinted return shipping label over the existing shipping label.

The AeroSafe thermal shipping container has a peel-away tape backing under the flaps to seal the container closed. When coordinating the return of the AeroSafe thermal shipping container, follow instructions on the flap of the thermal shipping container to ensure the return label is facing outside.

**Ensure Authenticity—Help Prevent Counterfeiting:** 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 trays as medical waste or deface or safely crush all materials so they cannot be reused. Remember, Pfizer-BioNTech COVID-19 Vaccines are only available through government-authorized vaccination centers - such as hospitals, outpatient clinics, pharmacies, and community vaccination locations. The Pfizer-BioNTech COVID-19 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.

**Elements Required for Return**

- Thermal shipping container and inner components
- Temperature-monitoring device
- Dry ice pod
Note: 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.

For Softbox, blank sticker labels to place over the UN1845 markings can be found on the back page of the Shipping and Handling Guidelines.

For AeroSafe, a label can be found on the inside flap of the thermal shipping container. This label is to cover both the UN1845 markings and the original shipping label.

For assistance on returns, you can contact:
US number: +1 701-540-4039
EU/UK number: +44 161-519-6199
pfizer.logistics@controlant.com

Additional contacts for AeroSafe returns:
US number: +1 855-551-4919
returns@aerosafeglobal.com

Place the thermal shipping container at a designated pickup location.
Use peel-off stickers to cover UN1845 markings.

Ensure the Dry Ice UN1845 markings and diamond-shaped Class 9 hazard label on the thermal shipping container are covered by placing blank labels over them, in preparation for the return, as the container no longer contains dry ice.