

Subject to change based on emerging data, regulatory guidance,  
manufacturing and technical developments, among other risks.  
Content is current as of February 8, 2021.

## Pfizer-BioNTech COVID-19 Vaccine

---

# SHIPPING AND HANDLING GUIDELINES

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

Health Canada has authorized the use of this vaccine under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*.



# TABLE OF CONTENTS

CONNECT WITH US .....	3
GENERAL INFORMATION .....	4
FACTS ABOUT DRY ICE .....	4
HANDLING .....	5
GENERAL SAFETY GUIDANCE FOR DRY ICE .....	6
VENTILATION .....	7
BURN TREATMENT .....	7
DRY ICE DISPOSAL .....	7
DRY ICE REPLENISHMENT .....	7
CONTENTS AND PACKAGING .....	8-9
UNPACKING .....	10-12
DISCARDING DRY ICE .....	13
RETURNING THE THERMAL SHIPPING CONTAINER .....	14-15

## CONNECT WITH US

For general questions about Pfizer-BioNTech COVID-19 Vaccine, visit **CVDvaccine.ca** or call the telephone number provided below.

**CVDvaccine.ca**



**1-833-VAX-COVI  
(1-833-829-2684)**

Pfizer-BioNTech COVID-19 Vaccine is 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.

The use of Pfizer-BioNTech COVID-19 Vaccine is permitted under an interim authorization delivered in accordance with section 5 of the COVID-19 [Interim order \(IO\)](#).\*

Patients should be advised of the nature of the authorization. The interim authorization is associated with Terms and Conditions that need to be met by the Market Authorization Holder to ascertain the continued quality, safety and efficacy of the product. For further information on authorization under this pathway, please refer to Health Canada's *IO Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*.

\* <https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html#a2.8>

## GENERAL INFORMATION

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

To maintain the integrity of the vaccine, it must be kept at ultra-low temperatures ( $-80^{\circ}\text{C}$  to  $-60^{\circ}\text{C}$  [ $-112^{\circ}\text{F}$  to  $-76^{\circ}\text{F}$ ]). Multiple-dose vials of the frozen vaccine product are shipped in an insulated thermal shipping container with dry ice to keep the vaccine frozen at these ultra-low temperatures. It's critical that the vaccine is maintained under these temperature conditions **during shipment and storage after it arrives.**

---

**For information about specific temperature requirements and ranges to monitor, as well as dry ice safety, storage, and handling, please go to [CVDvaccine.ca](https://www.cvdvaccine.ca).**

---

## 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 sublimates at temperatures at or above  $-78^{\circ}\text{C}$  ( $-109^{\circ}\text{F}$ ).

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 in asphyxiation. Exposed skin should be protected from contact with dry ice. To ensure appropriate controls are in place, **please refer to the Dry Ice Safety Data Sheet BEFORE accessing the contents from the thermal shipping container and consult with your Occupational Health Department.**



## HANDLING

When you receive the thermal shipping container, inspect to confirm you received the number of vial trays you ordered. **Do not open the vial trays or remove vials until you are ready for thawing or use.** Visit [CVDvaccine.ca](https://www.cvdvaccine.ca) for further information. Contact Pfizer Customer Service at **1-833-VAX-COVI (1-833-829-2684)** immediately to communicate any issues.

Use caution when lifting the shipping container, as it may be heavy. Depending on the amount of vaccine ordered, the shipping container can weigh up to approximately 36.5 kg (81 lbs). Consult with your Occupational Health Department for guidelines regarding lifting heavy items.

**When preparing to handle dry ice, you'll need to take precautions.** 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, please refer to the Dry Ice Safety Data Sheet, and consult with your Occupational Health Department.



*Masks were worn due to pandemic; refer to Dry Ice Safety Data Sheet for dry ice protection.*

## 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  $-78^{\circ}\text{C}$  ( $-109^{\circ}\text{F}$ ).

## 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 the storage area. **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. For information on first aid measures, please refer to the Dry Ice Safety Data Sheet.**

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.

## DRY ICE 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 drain or flush in toilet.
- DO NOT dispose in the trash.
- DO NOT place in a closed area such as an airtight container or walk-in cooler.

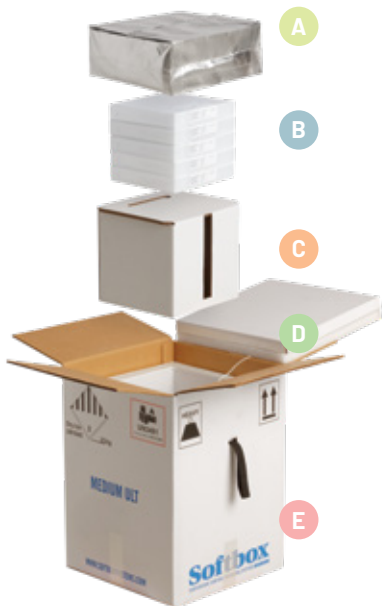
## DRY ICE REPLENISHMENT

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 re-icing the thermal shipping container, visit **[CVDvaccine.ca](https://www.cvdvaccine.ca)**. Follow the Guidelines for Safe Storage and Handling of Dry Ice.

## 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



Item	Description
A DRY ICE POD	<i>Holds the top layer of dry ice.</i>
B VIAL TRAYS	<i>Vial trays look like small pizza boxes and contain multiple-dose vials. Each thermal shipping container will have up to 5 vial trays inside.</i>
C BOX THAT HOLDS THE VIAL TRAYS	<i>Box within the thermal shipping container that includes the vial trays. This box has handles and can be fully removed from the thermal shipping container.</i>
D FOAM LID	<i>Top foam lid that includes an embedded temperature-monitoring device and remains connected to the box.</i>
E THERMAL SHIPPING CONTAINER	<i>Outer box of the thermal shipping container.</i>



## CONTENTS AND PACKAGING

The thermal shipping container you received can weigh up to approximately 36.5 kg (81 lbs) and should be opened on the floor, as it may be heavy. Consult with your Occupational Health Department for guidelines regarding lifting heavy items.

### AeroSafe



Item	Description
A DRY ICE POD	Holds the top layer of dry ice.
B VIAL TRAYS	Vial trays look like small pizza boxes and contain multiple-dose vials. Each thermal shipping container will have up to 5 vial trays inside.
C BOX THAT HOLDS THE VIAL TRAYS	Box within the thermal shipping container that includes the vial trays. This box can be fully removed from the thermal shipping container.
D FOAM LID	Top foam lid that can be removed from the AeroSafe thermal shipping container. The temperature-monitoring device can be found embedded in the foam lid.
E THERMAL SHIPPING CONTAINER	Outer box of the thermal shipping container.

# UNPACKING THERMAL SHIPPING CONTAINERS

## Step Instructions

### Softbox

### AeroSafe

- 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.** In the Softbox thermal shipping container, this lid will be attached to the thermal shipping container.

Take caution when opening the Softbox lid, as 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.

When opening the AeroSafe foam lid, gently remove the entire lid (with the temperature-monitoring device still attached) and place to the side. Do not remove the temperature-monitoring device from the inner lid or container, because it must be returned with the thermal shipping container after use.



*The Softbox thermal shipping container has an attached foam lid, which is permanently affixed to the lid.*



*The AeroSafe thermal shipping container has a foam lid that comes completely off.*

3

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 centres.

**Upon receipt, press and hold the stop button for 5 seconds. Sites are responsible for continuing to monitor the product storage temperature using their own monitoring device.**



*The temperature-monitoring device you receive will be either a Controlant Real-Time Monitor (pictured above to the left) or a Sensitech® Temperature Monitor (pictured above to the right).*

---

**Information about temperature monitoring, including devices, can be found at [CVDvaccine.ca](http://CVDvaccine.ca).**

---

4

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 re-icing.**

Using your waterproof insulated gloves, remove the dry ice pod.



*The Softbox thermal shipping container has compartments that allow dry ice to be distributed on all sides of the box. They are only accessible after removing the dry ice pod.*



*The AeroSafe thermal shipping container has dry ice compartments on the sides that can be accessed with the dry ice pod still in the container.*

---

**Each vial tray looks like a small pizza box, and contains multiple-dose vials. When diluted, each multiple-dose vial contains 6 doses.**

**Low dead-volume syringes and/or needles (e.g., low dead-volume luer lock syringes) can be used to extract 6 doses from a single vial. In order to ensure consistent withdrawal of 6 doses of 0.3 mL, it is important to adhere to minimizing volume loss during dose extraction. If standard syringes and needles are used, there may not be sufficient volume to extract a 6<sup>th</sup> dose from a single vial.**

Vial labels and cartons may state that after dilution, a vial contains 5 doses of 0.3 mL. The information on this document and in the Product Monograph regarding the number of doses per vial after dilution supersedes the number of doses stated on the vial labels and cartons.

---

5

You will now see the box that holds the vial trays.

Open the box and you will see the vial trays. There will be up to 5 vial trays inside.

Remove the box that holds the vial trays from the thermal shipping container in order to access and remove the vial trays.



**Remember, do not open the vial trays or remove vials until you are ready for thawing or use.** Visit [CVDvaccine.ca](http://CVDvaccine.ca) for further information.

---

6

**After removing the vial trays from the thermal shipping container, you must immediately store the vaccine product in the ultra-low-temperature freezer.**

If an ultra-low-temperature 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 with dry ice within 24 hours of receipt.**

After replenishing the thermal shipping container, inspected vial trays should be returned inside and the box taped closed. You should ensure to monitor the temperature inside the thermal shipper using your own monitoring device.



*Masks were worn due to pandemic.*

---

**For information about specific temperature requirements and ranges to monitor, temporary storage information, and re-icing the thermal shipping container, please go to [CVDvaccine.ca](https://www.cvdvaccine.ca).**

---

## DISCARDING DRY ICE

**After the thermal shipping container is no longer needed, you can discard the dry ice.**

Take necessary precautions by reviewing the Dry Ice Safety Data Sheet, and consulting 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 drain or flush in toilet.**
- **DO NOT dispose in the trash.**
- **DO NOT place in a closed area such as an airtight container or walk-in cooler.**



*Masks were worn due to pandemic; refer to Dry Ice Safety Data Sheet for dry ice protection.*

---

**Issues with the shipment should be immediately communicated to Pfizer Customer Service at 1-833-VAX-COVI (1-833-829-2684).**

---

## RETURNING REAL-TIME TEMPERATURE MONITOR 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 using 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 affixed to the inner flap of the thermal shipping container. When coordinating the return of the Softbox thermal shipping container, apply the preprinted return shipping label over the existing shipping label. When coordinating the return of the AeroSafe thermal shipping container, follow instructions on the inner flap of the thermal shipping container to ensure the return label is facing outside.

**You can contact the carrier identified on the return label to arrange the return.**

Discard empty vial trays as medical waste so they cannot be reused.

### **Elements Required for Return**

#### **Softbox:**

- Temperature-monitoring device
- Foam lid (remains attached to box)
- Dry ice pod
- Box that holds the vial trays

#### **AeroSafe:**

- Temperature-monitoring device
- Foam lid (can be fully removed from box)
- Dry ice pod
- Box that holds the vial trays

**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.**

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

**For assistance on returns, you can contact Pfizer Customer Service at 1-833-VAX-COVI (1-833-829-2684).**

Place the thermal shipping container at the front desk, or 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 these blank labels over them, in preparation for the return, as the container no longer contains dry ice.

Please consult the Product Monograph at [www.pfizer.ca/pm/en/COVID-19Vaccine.pdf](http://www.pfizer.ca/pm/en/COVID-19Vaccine.pdf) for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The Product Monograph is also available upon request by calling **1-833-VAX-COVI** (1-833-829-2684).



© 2021 Pfizer Canada ULC, Kirkland, Quebec H9J 2M5

Distributed for BioNTech Manufacturing GmbH An der Goldgrube 12, 55131 Mainz, Germany

PP-CVV-CAN-0026-EN