

For US Healthcare Providers

COVID-19 vaccines from BioNTech and Pfizer ultra-low temperature (ULT) shipping & handling information and FAQs

For questions regarding shipments from wholesalers, please contact the wholesaler directly.

Please see [Storage and Handling Guidelines – Single-Use Thermal Shipping Container](#) and [Storage and Handling Guidelines – Medium Thermal Shipping Container](#) Brochures for additional information. Brochures will be included in each ULT shipment as well as on the cvdvaccine-us.com website.

Please see the [COMIRNATY® \(COVID-19 Vaccine, mRNA\) Full Prescribing Information](#) and [EUA Fact Sheets for Vaccination Providers and Recipients and Caregivers](#) or visit cvdvaccine-us.com.

Single-Use and Medium Thermal Shipping Containers

The vaccine is provided in a **Single-Use** or **Medium Thermal Shipping Container**.

Single-Use Thermal Shipping Container

Ensure the label on the container states **Single-Use ULT**.

This container may NOT be used as temporary storage.

You must immediately store the vaccine product, in a ULT freezer -90 °C to -60 °C (-130 °F to -76 °F) or at 2 °C to 8 °C (35 °F to 46 °F).

Please review the [Shipping and Handling Guidelines for Single-Use Shipping Containers](#).

Do not return any unused vaccine product with your shipping container.

The **temperature-monitoring device must be returned to the supplier** to help Pfizer fulfill its commitment to reusable resources. Remove the temperature-monitoring device and the temperature-monitoring return kit from the Single-Use Thermal Shipping Container.

For complete instructions on how to return the temperature-monitoring device using the included temperature-monitoring return kit, please refer to the **Return Instructions** downloadable resource available at [cvdvaccine-us.com](https://www.cvdvaccine-us.com).

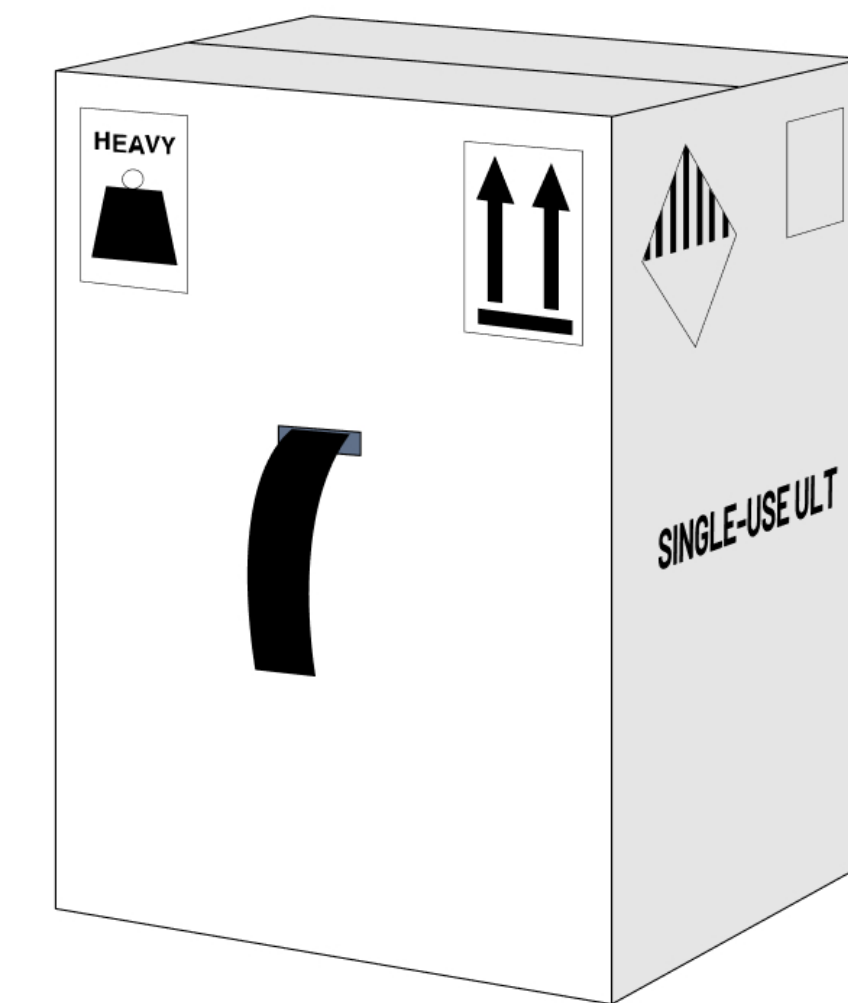
Do not use the product until you have received the quality disposition report from Controlant advising on further use.

For assistance on Controlant customer support, you can contact:

US number: 1-701-540-4039

pfizer.logistics@controlant.com

After removal of the temperature-monitoring device and temperature-monitoring return kit, the Single-Use Thermal Shipping Container should be disposed of at your facility.



[Click here](#) to learn more about returning the temperature-monitoring device.

ULT=ultra-low temperature.

Please see the [COMIRNATY® \(COVID-19 Vaccine, mRNA\) Full Prescribing Information and EUA Fact Sheets for Vaccination Providers and Recipients and Caregivers](#) or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com).

Medium Thermal Shipping Container

Ensure the label on the container states **Medium ULT**.

You must immediately store the vaccine product, in a ULT freezer -90 °C to -60 °C (-130 °F to -76 °F) or at 2 °C to 8 °C (35 °F to 46 °F).

Please review the [Shipping and Handling Guidelines for Medium Thermal Shipping Containers](#).

Do not return any unused vaccine product with your shipping container.

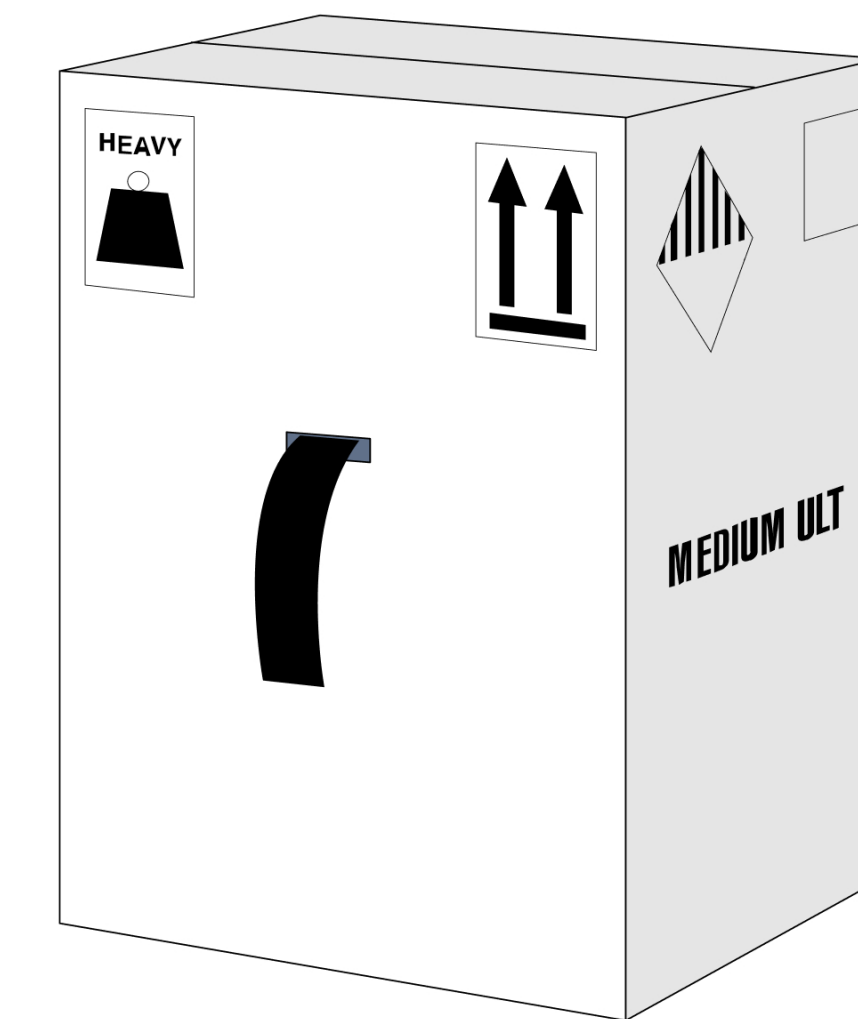
After use, the thermal shipping container, including the temperature-monitoring device, must be returned to the supplier to help Pfizer fulfill its commitment to reusable resources.

Do not use the product until you have received the quality disposition report from Controlant advising on further use.

For assistance on Controlant customer support, you can contact:

US number: 1-701-540-4039

[**pfizer.logistics@controlant.com**](mailto:pfizer.logistics@controlant.com)



[Click here](#) to learn more about returning the thermal shipping container or temperature-monitoring device.



ULT=ultra-low temperature.

Please see the [COMIRNATY® \(COVID-19 Vaccine, mRNA\) Full Prescribing Information and EUA Fact Sheets for Vaccination Providers and Recipients and Caregivers](#) or visit cvdvaccine-us.com.

Time and Temperature Considerations

Do NOT store contents in standard freezer

- **Do not open vial or prefilled syringe* cartons until there is a need to remove vials or prefilled syringes for transfer, thawing, or use**
 - **Upon delivery:**
 - Inspect the thermal shipping container to confirm that ordered vial or prefilled syringe cartons were received
 - Do not stack or place anything on top of the thermal shipping container
 - **Handling the vial or prefilled syringe carton between storage environments:**
 - Once an individual vial or prefilled syringe is removed from a carton at room temperature, it should not be returned to frozen storage and should be thawed for use.
- Do not refreeze thawed vials or prefilled syringes¹**

Originating Temperature Environment ¹	Maximum Time at Room Temperature (up to 25 °C or up to 77 °F) During Storage or Transfer
 <p>From ULT Freezer -90 °C to -60 °C (-130 °F to -76 °F)</p> <p style="font-size: 2em; color: blue; margin: 10px 0;">OR</p>  <p>From Thermal Shipping Container[†] -90 °C to -60 °C (-130 °F to -76 °F)</p>	<p>Unopened Vial or Prefilled Syringe Carton Transfer Times</p> <p>Once removed from thermal shipping container, if transferring vial or prefilled syringe cartons to a ULT freezer, unopened cartons may be at room temperature ($\leq 25\text{ °C}$ [$\leq 77\text{ °F}$]) for up to 5 minutes.</p> <p>Thawing and Storage of Prefilled Syringes</p> <p>Frozen COMIRNATY prefilled syringes should be thawed in the carton, preferably at 2 °C to 8 °C (35 °F to 46 °F) for 2 hours. A full carton of prefilled syringes may also be thawed at room temperature [up to 25 °C (77 °F)] for 60 minutes. Prefilled syringes thawed in the carton by either method may be stored in the refrigerator for 10 weeks and at room temperature [8 °C to 25 °C (46 °F to 77 °F)] for 12 hours prior to use. If individual frozen prefilled syringes are thawed at room temperature outside of the carton, they can be kept at room temperature and must be used within 4 hours of thawing.¹</p>

Safe Disposal of Vaccine Vials or Prefilled Syringes

Discard vaccine vials or prefilled syringes that:

- Have had the maximum number of complete doses extracted to administer vaccinations (multiple dose vial)
- Are more than 12 hours from time of puncture (multiple dose vial)
- Past the expiration date based on storage conditions

Discard vaccine vials or prefilled syringes in a sharps container as medical waste to ensure they are permanently destroyed.

Discard vial cartons as medical waste so they cannot be reused.

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.

*Prefilled syringes may be available for select product presentations.
[†]The thermal shipping container should not be opened for more than 3 minutes at a time.

ULT=ultra-low temperature.

Please see the COMIRNATY® (COVID-19 Vaccine, mRNA) Full Prescribing Information and EUA Fact Sheets for Vaccination Providers and Recipients and Caregivers or visit cvdvaccine-us.com.

Time and Temperature Considerations

Storage of Vials and Prefilled Syringes Prior to Use¹

Cartons of COMIRNATY single dose vials and prefilled syringes may arrive frozen at ultra-cold conditions in thermal containers with dry ice.

Once received, frozen vials and prefilled syringes may be immediately transferred to the refrigerator at 2 °C to 8 °C (35 °F to 46 °F), thawed and stored for up to 10 weeks. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. Cartons of 10 vials or cartons of 10 single dose prefilled syringes may take up to 2 hours to thaw at this temperature.

Alternatively, frozen vials and prefilled syringes may be stored in an ULT freezer at -90 °C to -60 °C (-130 °F to -76 °F). Do not store vials and prefilled syringes at -25 °C to -15 °C (-13 °F to 5 °F). Once thawed, they should not be refrozen.

If cartons of COMIRNATY vials and prefilled syringes are received at 2 °C to 8 °C (35 °F to 46 °F), they should be stored at 2 °C to 8 °C (35 °F to 46 °F). Check that the carton has been previously updated to reflect the 10-week refrigerated expiry date.

ULT=ultra-low temperature.

Please see the COMIRNATY® (COVID-19 Vaccine, mRNA) Full Prescribing Information and EUA Fact Sheets for Vaccination Providers and Recipients and Caregivers or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com).

Below are answers to some commonly asked questions about the shipping and handling of COVID-19 vaccines from BioNTech and Pfizer.

1 When product is shipped at ULT, what does the packaging contain?

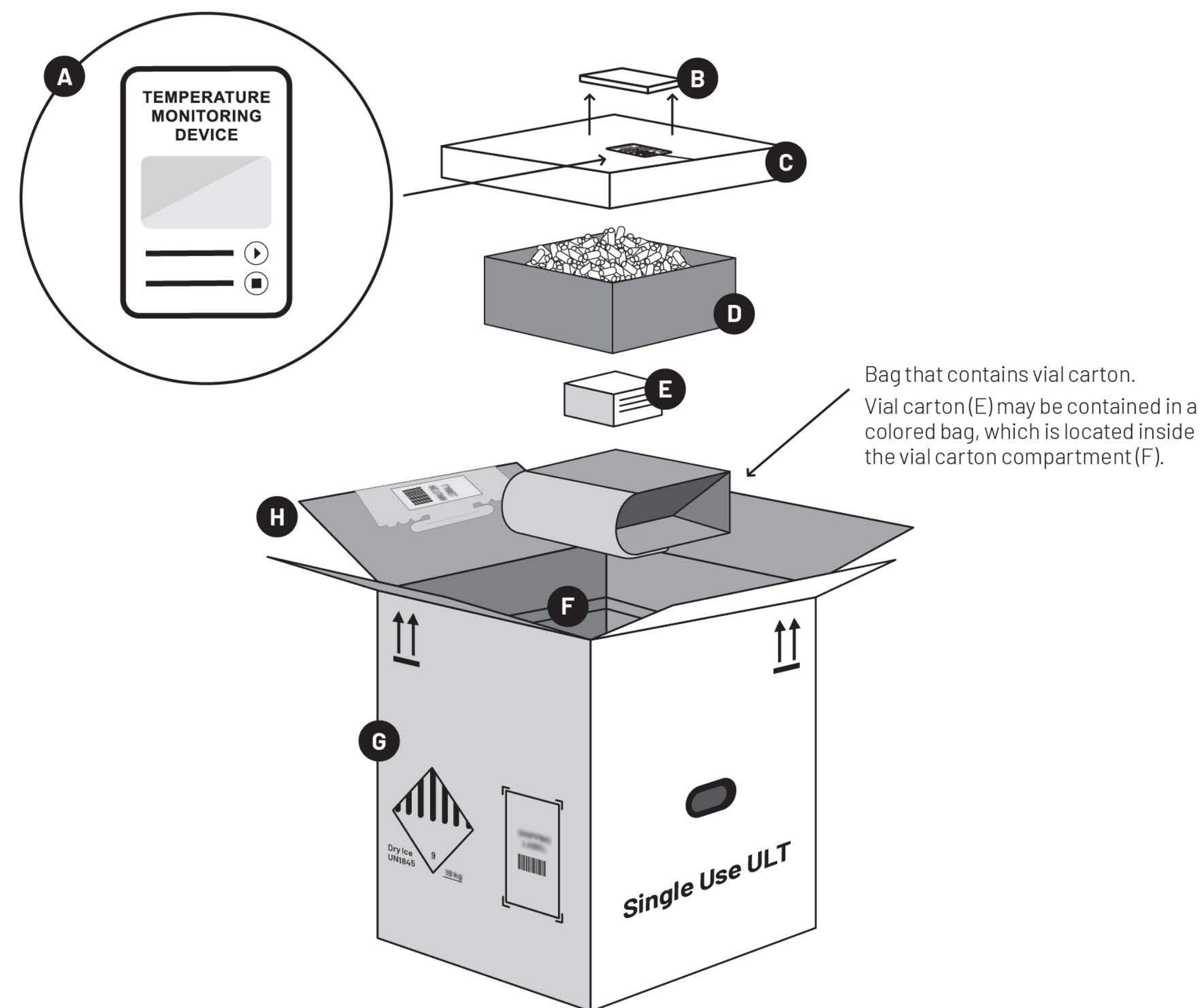
For Single-Use ULT Thermal Shippers:

Contents and Packaging

There are multiple types of thermal shipping containers and vial or prefilled syringe carton sizes, all with similar components.

The example shown below is for illustrative purposes only and may not exactly replicate the thermal shipping container you receive.

Be sure to read all instructions that are included with the thermal shipping container and its components.



Item	Description
A TEMPERATURE-MONITORING DEVICE	The temperature-monitoring device will be embedded in the foam lid and may be concealed by a removable compartment cover
B COMPARTMENT COVER	A removable cover that may sit atop the temperature-monitoring device to protect it from over-freezing
C FOAM LID	Removable top foam lid that includes an embedded temperature-monitoring device
D DRY ICE POD	Holds the top layer of dry ice
E VIAL CARTONS	Each carton contains vials and may appear different, depending on the size of your order
F VIAL CARTON COMPARTMENT	Area that holds the vial cartons within the Single-Use Thermal Shipping Container
G THERMAL SHIPPING CONTAINER	Outer box of the Single-Use Thermal Shipping Container
H RETURN KIT FOR THE TEMPERATURE-MONITORING DEVICE	The temperature-monitoring device must be returned in the enclosed kit

ULT=ultra-low temperature.

Please see the **COMIRNATY® (COVID-19 Vaccine, mRNA) Full Prescribing Information and EUA Fact Sheets for Vaccination Providers and Recipients and Caregivers** or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com).

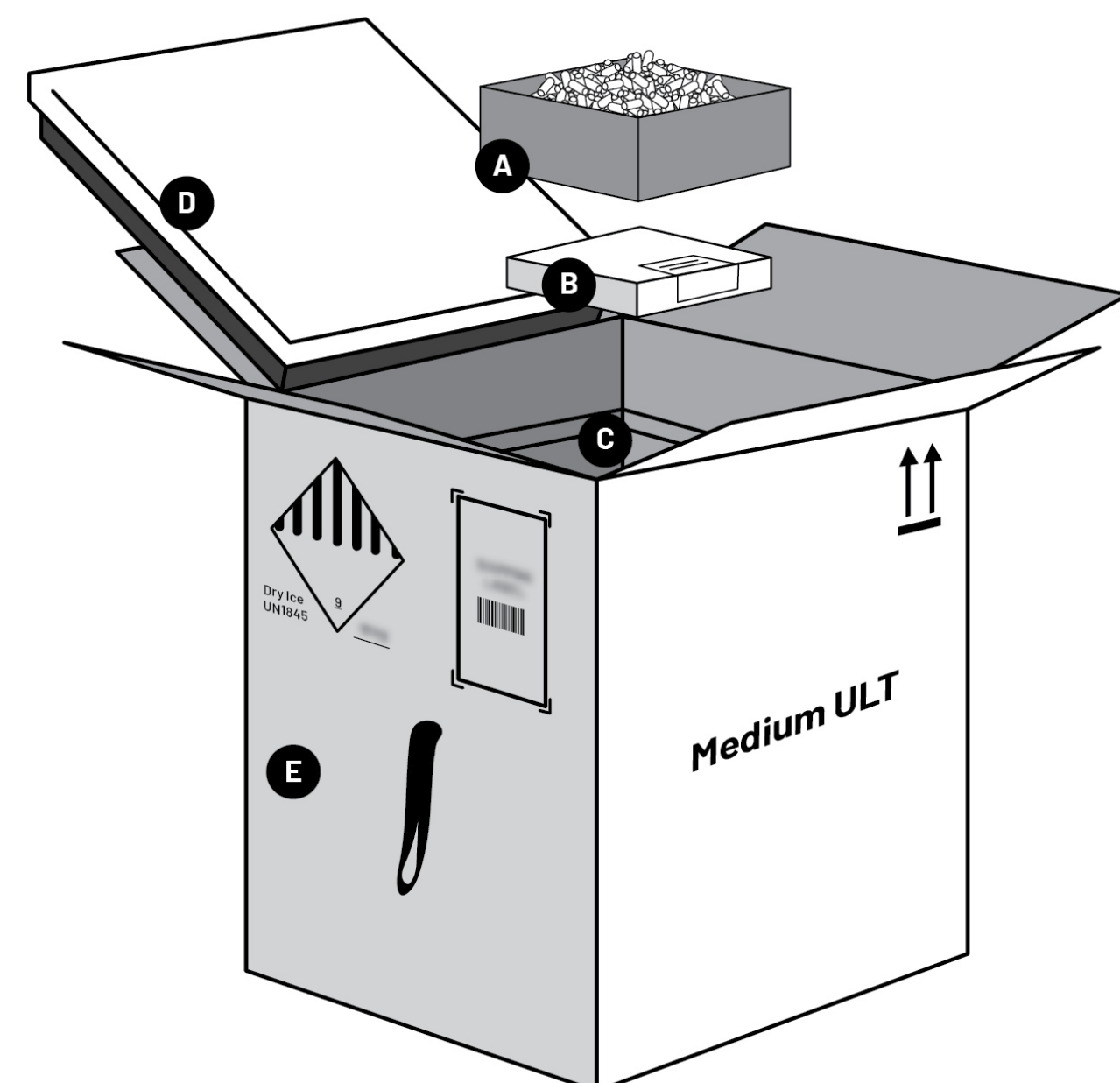
1 When product is shipped at ULT, what does the packaging contain? (cont'd)

For Medium ULT Thermal Shippers:

Contents and Packaging

There are multiple types of thermal shipping containers and vial or prefilled syringe carton sizes, all with similar components. The example shown below is for illustrative purposes only and may not exactly replicate the thermal shipping container you receive.

Be sure to read all instructions that are included with the thermal shipping container and its components.



Item	Description
A DRY ICE POD	Holds the top layer of dry ice
B VIAL CARTONS	Each carton contains either vials or prefilled syringes and may appear different, depending on the size of your order
C VIAL CARTON COMPARTMENT	Fixed compartment within the thermal shipping container that holds the vial cartons
D FOAM LID	Top foam lid that includes an embedded temperature-monitoring device and remains connected to the box
E THERMAL SHIPPING CONTAINER	Outer box of the thermal shipping container

Please see Medium ULT Thermal Shipping Update Full Page Insert regarding ULT PFS Shipping on next page.

PFS=prefilled syringe; ULT=ultra-low temperature.

Please see the [COMIRNATY® \(COVID-19 Vaccine, mRNA\) Full Prescribing Information and EUA Fact Sheets for Vaccination Providers and Recipients and Caregivers](#) or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com).

1 When product is shipped at ULT, what does the packaging contain? (cont'd)

For Medium ULT Thermal Shippers:

NOTE: ULT PFS SHIPPING & HANDLING

FOR MEDIUM THERMAL SHIPPING CONTAINERS ONLY

The administration of the COVID-19 vaccine is no longer limited to government-authorized vaccination venues. Moving forward, the COVID-19 vaccine can be administered by a range of immunization providers, in accordance with federal and state laws.

Beginning September 2023, Pfizer will directly ship COVID-19 vaccine PFS at ULT in select markets. Please be aware that the instructions in the Shipping and Handling Guidelines for Medium Thermal Shipping Containers apply to vaccine vials and PFS.

Note: ULT PFS cases and cartons will be wrapped in two bags, an exterior blue bag, and an interior silver bag. Medium Thermal Shipping Containers are not recommended to be used as temporary storage for ULT PFS. These images are for illustrative purposes only and may not exactly replicate the thermal shipping container.

PLEASE PERFORM A VISUAL CHECK OF THE INTERIOR SILVER BAG BEFORE USE

- 1 Open thermal shipping container to view the exterior blue bag



- 2 Open the exterior blue bag to view the enclosed silver bag



- 3 Remove the enclosed silver bag



- 4 Visually check the silver bag for openings, punctures, tears, and air pockets

EXAMPLES OF SUITABLE AND NOT SUITABLE SILVER BAGS

No/Small Damage: Potentially Suitable for Use

An acceptable pouch is defined as:

- An aluminum bag where the air is removed/expelled (vacuum seal is maintained)



Large Damage: Potentially Not Suitable for Use

A potentially not suitable pouch is defined as:

- An aluminum bag where the air is not removed/expelled (vacuum seal is not maintained)



If it is determined that the product is potentially not suitable for use, please contact Customer Service at 1-800-666-7248

Reminder: Please read all Instructions included with the thermal shipping container and its components. Do not use product until you have received, via email, the Quality Disposition Report. Do NOT return any dry ice or unused vaccine product in your shipping container.

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PFS=prefilled syringe; ULT=ultra-low temperature.

Please see the **COMIRNATY® (COVID-19 Vaccine, mRNA) Full Prescribing Information and EUA Fact Sheets for Vaccination Providers and Recipients and Caregivers** or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com).

2 Do customers have to return the thermal shipping containers?

For Single-Use ULT Thermal Shippers:

- The Single-Use ULT shipper should not be returned.
- The temperature-monitoring device must be returned to the supplier to help Pfizer fulfill its commitment to reusable resources. Remove the temperature-monitoring device and the temperature-monitoring return kit from the Single-Use Thermal Shipping Container.
- After removal of the temperature-monitoring device and temperature-monitoring return kit, the Single-Use Thermal Shipping Container should be disposed of at your facility.

For complete instructions on how to return the temperature-monitoring device using the included temperature-monitoring return kit, please refer to the Return Instructions downloadable resource available at [cvdvaccine-us.com](https://www.cvdvaccine-us.com).

Do NOT return any dry ice or unused vaccine product in your shipping container.

For assistance on returns, you can contact:

- US number: 1-701-540-4039
- pfizer.logistics@controlant.com

For Medium ULT Thermal Shippers:

- The Medium ULT shipper and temperature-monitoring device should be returned.
- 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 Medium ULT 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.
- When coordinating the return of the thermal shipping container, apply the preprinted return shipping label over the existing shipping label. Some thermal shipping containers have a peel-away tape backing under the flaps to seal the container closed.

Elements Required for Return

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

3 What is a temperature logger?

A temperature logger is a temperature-monitoring device. The temperature-monitoring device is used to monitor the temperature of product throughout its transportation journey to ensure quality of product is tracked.

ULT=ultra-low temperature.

Please see the [COMIRNATY® \(COVID-19 Vaccine, mRNA\) Full Prescribing Information and EUA Fact Sheets for Vaccination Providers and Recipients and Caregivers](#) or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com).

4 How does Pfizer track product?

Shipments are tracked by Controlant. You will receive shipment and delivery confirmations.

1. **IMPORTANT:** Do not use any product until you have received, via email, the Quality Disposition Report.
2. **FOR PFS SHIPMENTS:** Perform a visual check of interior silver bag and ensure the vacuum seal is maintained. Please see Medium ULT Thermal Shipping Update Full Page Insert enclosed in shipping container and page 8 of this FAQ.

5 How do you properly handle dry ice?

Please see the Dry Ice Handling Guidelines included in your shipping container and referenced below.

Safe Handling Dry Ice Guidelines

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 -109 °F (-80 °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 resulting in asphyxiation. Exposed skin should be protected from contact with dry ice. To ensure appropriate controls are in place, **review the enclosed Safety Data Sheet (SDS) and consult with your EHS/Occupational Health department.**

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. Leave area containing dry ice immediately if you start to pant and breathe quickly, feel short of breath, develop a headache, notice that your fingernails or lips start to turn blue, or experience other symptoms of asphyxiation. These signs can indicate that you have inhaled too much carbon dioxide. Carbon dioxide is heavier than air and accumulates in low, poorly ventilated spaces.

BURN TREATMENT

Dry ice may cause cold burns to the skin. Seek medical care as directed by the SDS.

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.

GENERAL SAFETY GUIDANCE FOR DRY ICE CAUTION



DO NOT TOUCH - AVOID EYE CONTACT

Use insulated gloves when removing or adding dry ice to prevent cold burns and frostbite. Avoid contact with face and eyes. Wear eye protection.



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 (-80 °C).

ULT=ultra-low temperature.

Please see the **COMIRNATY® (COVID-19 Vaccine, mRNA) Full Prescribing Information and EUA Fact Sheets for Vaccination Providers and Recipients and Caregivers** or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com).

6 What temperature will product be shipped to me from each distribution channel?

Product delivery temperatures vary between products and distributors. Product can be received by POUs at either ULT, which is -90 °C to -60 °C (-130 °F to -76 °F), or refrigerated, which is 2 °C to 8 °C (35 °F to 46 °F).¹

7 Is there Customer Service available to help address questions?

The number for Pfizer Customer Service is 1-800-666-7248.

8 What is the QDR and the process?

The QDR is the Quality Disposition Report and is only created for ULT shipments which contain a temperature monitor. It is important to review this report before administering any product. Below are examples of communications that POUs will receive regarding shipments and QDRs.

POU Communications Process Overview

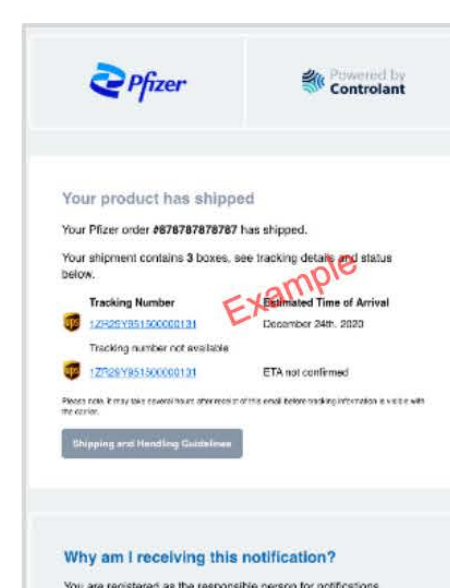
Order Created Order Shipped During Transit Order Delivered to Site

Pre-Shipment Email



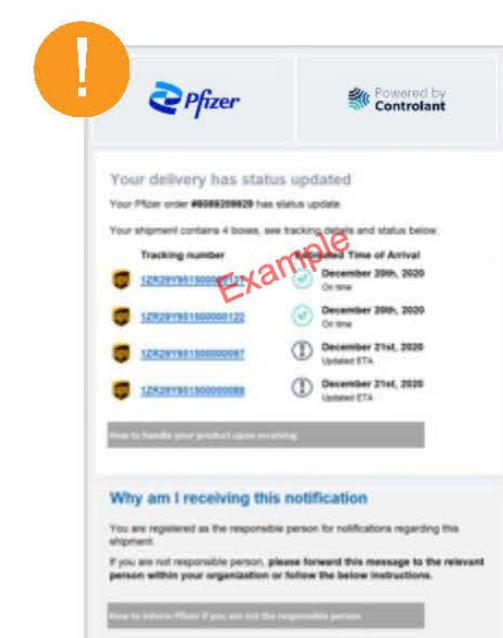
Order confirmation and advance info on how to prepare for shipment

Vaccine Shipment Confirmation Email



Vaccine shipment tracking information

Exception Email *Only if ETA changes during shipments*



Status update regarding shipment new ETA

Shipment Delivery Email*



Quality disposition report **GOOD** if there are **no exceptions** associated with the shipment



Quality disposition report **UNDECIDED** if there is an **exception** associated with the shipment **currently under Pfizer review**



Quality disposition report **BAD** if there is an **exception** associated with the shipment resulting in a **rejection of the shipment and pending Pfizer instructions**

POU=point of use; ULT=ultra-low temperature.

Please see the COMIRNATY® (COVID-19 Vaccine, mRNA) Full Prescribing Information and EUA Fact Sheets for Vaccination Providers and Recipients and Caregivers or visit cvdvaccine-us.com.

9 If storing at 2 °C to 8 °C upon receiving ULT product, what is the new expiration?

Storage of Thawed Product:

- Thawed product can be stored in the refrigerator between 2 °C and 8 °C (35 °F and 46 °F) for up to **10 weeks prior to use**, not exceeding the printed expiration date on carton and product labels.¹
- Do not refreeze.¹

Please refer to the [cvdvaccine-us.com](https://www.cvdvaccine-us.com) website for storage conditions and product fact sheets.

ULT=ultra-low temperature.

Please see the COMIRNATY® (COVID-19 Vaccine, mRNA) Full Prescribing Information and EUA Fact Sheets for Vaccination Providers and Recipients and Caregivers or visit [cvdvaccine-us.com](https://www.cvdvaccine-us.com).

1. COMIRNATY® (COVID-19 Vaccine, mRNA). Full Prescribing Information. Pfizer and BioNTech; September 11, 2023.

BIONTECH



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

Manufactured by
Pfizer Inc.
New York, NY 10001

COVID-19 vaccines from BioNTech and Pfizer, which are based on BioNTech proprietary mRNA technology, were developed by both BioNTech and Pfizer.

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