

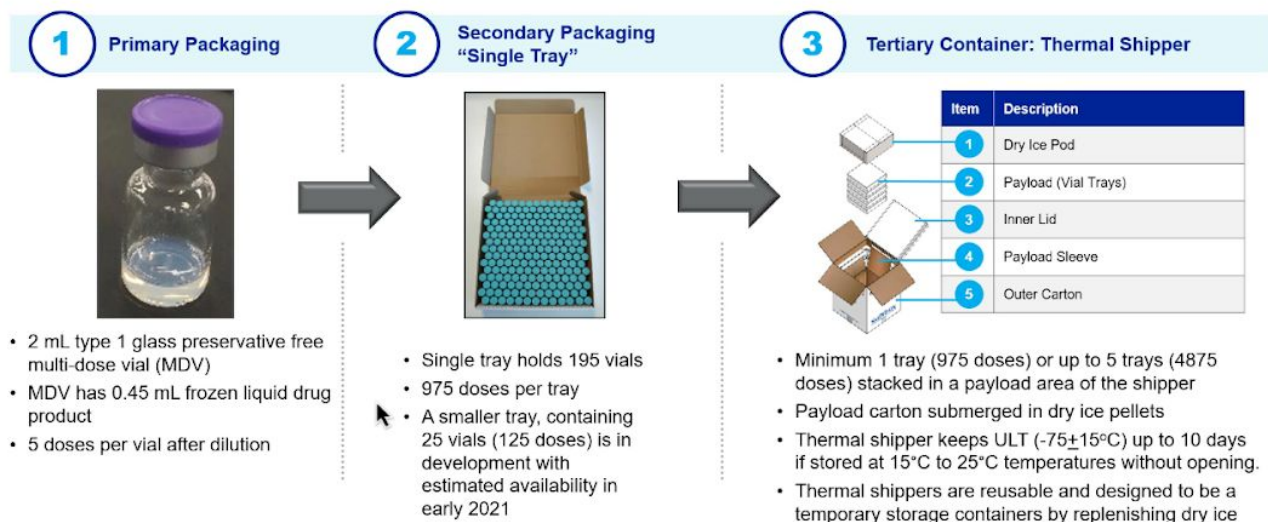
COVID-19 Ultra Cold Vaccine Logistics

The following planning assumptions and logistic considerations apply to the mRNA COVID-19 vaccine manufactured by Pfizer. This document is intended to assist healthcare facilities, local public health agencies and other partners in planning for receipt, storage and administration of ultra cold COVID-19 vaccine.

Vaccine and diluent will be shipped separately and mixed onsite.


- Vaccine
 - Shipped directly to site from Pfizer in a thermal shipping container packed with dry ice (riced or pelleted).
 - Specifications of thermal shipping container:
 - Tare weight = 8.5 kg (18.7 lb), weight including dry ice = 31.5 kg (69.4 lb)
 - Volumetric weight = 15 kg (33.1 lb)
 - Payload space L x W x H = 245x245x241 mm (9.6x9.6x9.5 in)
 - Shipper dimensions L x W x H = 400x400x560 mm (15.7x15.7x22 in)
 - Preservative-free multidose vials (5 doses per vial)
 - Minimum order 975 doses, maximum order 4,875 doses
- Diluent (0.9% Sodium Chloride Injection, USP)
 - Shipped directly to site at room temperature.
- [Ancillary supply kits](#) (for onsite mixing and vaccine administration)
 - Shipped directly to site at room temperature.
 - Does NOT include gloves, bandages or sharps containers.
 - Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs.

Product Packaging Overview




Direct Shipments to Vaccination Sites and Temperature/Location Tracking

Direct Shipments* to Vaccination Center by Transport Courier



- Pfizer has designed a distribution model which is built on a flexible just in time system to ship the vaccine from manufacturing site and/or storage facility directly to the points of vaccination.

Temperature & Location Tracking During Transportation




- Each thermal shipper has reusable GPS enabled temperature monitoring device which will be enabled when the shipper is packed.
- All shipments will be tracked via the onboard GPS monitoring device to ensure end-to-end distribution within required temperatures.
- Shipments will be executed under the management of Pfizer Quality processes and controls to ensure that upon ownership transfer, product has arrived under acceptable conditions.
- Temperature records of the shipments can be shared with upon request.

Vaccine Storage Options at the Point of Vaccination


1 Ultra-Low Temperature Freezer

- Store as frozen liquid at $-75^{\circ}\text{C} \pm 15^{\circ}\text{C}$ for long term storage.
 - Emergency Use vials are labeled as $-70^{\circ}\text{C} \pm 10^{\circ}\text{C}$, however they can be safely stored in a freezer set to $-75^{\circ}\text{C} \pm 15^{\circ}\text{C}$
- Different size of ULT freezers are available in the market.

A small size (under or over the countertop ULT Freezers can store as much as 30K doses)



2 Thermal Shipper Designed for Temporary Storage





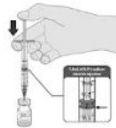






- Within 24 hours of receipt and after opening the thermal shipper, replenish/inspect with dry ice (using proper personal protective equipment and dry ice handling).
- With every re-icing, thermal shipper can maintain ultra-low temperature storage for 5 days with 2 openings per day.
- Multiple dry ice replenishments possible; up to 3 re-icings.
- Local dry ice suppliers can be used for re-icing the thermal shipper.
- The thermal shipper to be returned within 10 business days and no later than 20 business days including temperature data logger (picked up by Pfizer/BioNTech contracted supplier)
- Apply appropriate dry ice monitor

3 2 to 8°C Refrigerator



- Can be stored at 2 to 8°C up to 5 days
- Room temperature hold time is no more than 2 hours.
- Thawing: 3 hours at 2 to 8°C or 30 min at room temperature.
- Post-dilution in use period is 6 hours.

Vaccine Preparation and Administration

Removing the Vials to Thaw	Dilute the Vaccine	Preparing the Dose	Vaccine Administration
 <p>From storage, remove 1 vial for every 5 recipients according to planned vaccinations schedule.</p> <p>Vials may be stored in the refrigerator for 5 days (120 hours).</p>	<p>Obtain 0.9% Sodium Chloride Injection, USP for use as a diluent. Do not use any alternate diluents.</p>  <p>Dilute the thawed vial by adding 1.8 mL of 0.9% Sodium Chloride Injection into the vial.</p>  <p>Ensure vial pressure is equalized by withdrawing 1.8 mL air into the empty diluent syringe before removing the needle from the vial.</p> 	 <p>Draw up 0.3 mL of the diluted dosing solution into a new sterile dosing syringe with a needle appropriate for intramuscular injection.</p>  <p>For each additional dose, use a new sterile syringe and needle and ensure the vial stopper is cleansed with antiseptic before each withdrawal.</p> 	 <p>Diluted vials must be used within 6 hours from the time of dilution and stored between 2°C to 25°C (35°F to 77°F).</p> <p>Pfizer BioNTech COVID-19 Vaccine 30 mcg/0.3 mL</p> <p>A single 30 mcg/0.3 mL dose followed by a second dose 21 days later.</p>  <p>21 DAYS</p>

Thawing Guidance

- When removing a tray from the thermal shipper, minimize the time the shipper is open (no more than one minute).
- If less than a full tray (975 doses) is needed, remove the number of vials needed from the tray as quickly as possible and return the tray to frozen storage. Trays should not be exposed to room temperature for more than a few minutes, as the vials can thaw very quickly.
 - Vials should be transferred to a secondary container for safe transportation.
 - Gloves allowing manual dexterity should be worn while handling frozen vials.
- Transfer the frozen vials immediately to a refrigerator (2 to 8°C).
 - An entire tray (975 doses) will take about 3 hours to thaw; a smaller number of vials may thaw more quickly.
 - Vials needed for near-immediate use can be thawed at room temperature for 30 minutes.
 - Vials thawed at room temperature form condensation, so thawing in a secondary container is recommended.
- Vials may be stored in the refrigerator prior to dilution for up to 5 days (120 hours).
- Vials may be held at room temperature for no more than 2 hours prior to dilution.

Vaccine Administration

- 2 dose series, 21 days apart
- Onsite mixing, reconstitute with diluent just prior to administration
- Administered by intramuscular injection