

COVID-19 Pfizer XBB.1.5 Adult/Pediatric/Infant

Shipping, Storage, Thawing and Use Guidelines

A. Formulations

- Adult ≥12 yo (Do Not Dilute) Grey Cap Grey Label Border
- Pediatric 5 yo-<12 yo (Do Not Dilute) Blue Cap Blue Label Border
- Infant 6 mo-<5 yo (Dilute Prior to use) Maroon Cap Maroon Label Border

B. Shipping:

- Ideally, vaccine will be shipped frozen between -60°C to -90°C.
- Vaccine may be shipped thawed at 2°C to 8°C.
- Single-dose preloaded syringes or punctured and diluted vials of vaccine may be transported in exceptional circumstances.
- Vials should be upright during transport, and tightly packed to reduce jostling of the vials.
- Validated containers must be used for transport.
- Temperature must be monitored continuously during transportation and documented

B. Storage:

-60°C to -90°C, Ultra-Low Temperature (ULT) **Shipper** (frozen):

- Carton may arrive packaged in thermal packing designed for temporary storage. The shipper can be used for temporary frozen storage for up to 30 days.
- If using the Pfizer-provided shipper upon receipt and after opening, dry ice should be replenished within 24 hours (maximum of 20-23 kg of dry ice pellets; recommended sizes: 9-16 mm). If transferring into a provincially/federally provided shipper, follow [guidelines for dry ice replenishment](#) to prepare shipper to store the vaccine.
- With every re-icing, shipper can maintain ULT storage for 5 days with 2 openings per day of 3 minutes or less, i.e. dry ice must be replenished every five days. **NOTE:** Additional openings of shipper will require more frequent dry ice replenishment (see resource link below).
- Temperature monitoring must be continually conducted while vaccine is stored in thermal shipper.

-60°C to -90°C, Ultra-Low Temperature (ULT) Freezer (frozen):

- Can be stored at ULT until the written expiry date printed on the vial/carton.

2°C to 8°C Refrigerator (thawed):

- Adult/Pediatric: Thawed vaccine can be stored for up to 10 weeks (70 days).
- Infant: Thawed and undiluted vaccine can be stored for up to 10 weeks (70 days).
- Once placed in 2°C to 8°C environment, the carton should be updated with the expiry information.

2°C to 25°C Room Temperature (thawed):

- Adult/Pediatric: Vials may be stored for up to 12 hours at temperatures up to 25°C prior to first puncture.
- Adult/Pediatric: Vials may be stored for up to 12 hours at temperatures up to 25°C after first puncture
- Infant: Vials may be stored for up to 12 hours at temperatures up to 25°C prior to dilution.
- Infant: Vials may be stored for up to 12 hours at temperatures up to 25°C after dilution.
- Thawed vials can be handled in room light conditions.

D. Thawing:

Environment	Adult ≥ 12 yo (Do Not Dilute) Grey Cap Grey Label Border	Pediatric 5 yo-<12 yo (Do Not Dilute) Blue Cap Blue Label Border	Infant 6 mo-<5 yo (Dilute Prior to use) Maroon Cap Maroon Label Border
Thawed at 2°-8°C	6 hours	6 hours	2 hours
Thawed at room temp (up to 25°C)	30 minutes	30 minutes	30 minutes

Handling Frozen Vials




- Cartons containing 10 vials removed from frozen storage may be at room temperature for up to **5 minutes**
- If a carton is at room temperature for close to, but not over 5 minutes, place back in ULT freezer for **2 hours** before it can be removed again.
- If a carton is at room temperature for over 5 minutes, consider it to be thawing and **do not place back in freezer**. Vials must be stored and moved into a refrigerated (2°C-8°C) container.
- Individual vials removed from a carton and left at room temperature should not be returned to frozen or refrigerated storage and must be thawed for use.

Thawed vaccine cannot be refrozen.

E. Use

- Vials may be stored for up to 12 hours at temperatures up to 25°C pre and post first puncture for a total of up to 24 hours

F. Vaccine Stability

ULT	2°C to 8°C	Room temperature
 <p data-bbox="590 354 793 500">-90°C to -60°C for 30 days (replenish dry ice q 5 days)</p>  <p data-bbox="590 573 793 743">-90°C to -60°C Can be stored until written expiry</p>	 <p data-bbox="1094 407 1220 480">10 weeks (70 days)</p>	<p data-bbox="1398 418 1734 602">Vials may be stored for up to 12 hours at temperatures up to 25°C pre and post first puncture for a total of up to 24 hours</p>

G. Helpful Resources

While specific links have been identified below, it is highly recommended that health authorities and sites familiarize themselves with the resources provided by Pfizer at www.cdvaccine.ca

- [Pfizer Product Monograph](#)
- [Pfizer COVID Vaccine Resources](#)
- [Pfizer Dry Ice Safety Data Sheet](#)
- [Pfizer Vaccine Shipping And Handling Guidelines](#)
- [Pfizer instructions on dry ice replenishment](#)

Any questions or requests for revision
of this document should be sent to
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List of Amendments

Date	Section	Description	Author
Oct 11, 2023	A, B, C, D, E, F,G	SOP developed based on product monograph and information provided by Pfizer	Calvin Kaila