

# COVID-19 Pfizer Pediatric Vaccine (Orange / Maroon Cap)

## Shipping, Storage, Thawing and Use Guidelines

### A. Formulations

- Orange Cap 10 mcg/0.2ml – intended population: 5 years to <12 years
- Maroon Cap 3 mcg/0.2ml – intended population: 6 months to <5 years

### 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 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

### C. 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 for 12 months after manufacturing date printed on the vial/carton.

2°C to 8°C Refrigerator (thawed):

- 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):

- Vials may be stored for up to 24 hours at temperatures up to 25°C, with no more than 12 hours from the time of dilution (first puncture). After dilution the vials should be stored at 2°C to 25°C
- Thawed vials can be handled in room light conditions.

## D. Thawing:

Regular Use (2°C to 8°C Refrigerator)

- A carton of 10 vials of Orange Cap (5 years to <12 years) may take up to 4 hours to thaw.
- A carton of 10 vials of Maroon Cap (6 months to <5 years) may take up to 2 hours to thaw
- Product needs to reach room temperature prior to dilution.<sup>1</sup>

Immediate Use

- Thaw at room temperature (up to 25°C) for 30 minutes.
- Product needs to reach room temperature before dilution.<sup>1</sup>

Handling Frozen Vials

- Cartons containing 10 vials removed from frozen storage may be at room temperature for up to **5 minutes**
- If at room temperature for close to, but not over 5 (full carton) minutes, place back in ULT freezer for **2 hours** before they can be removed again.
- If 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 **24 hours** at temperatures up to 25°C with no more than 12 hours from the time of dilution (first puncture).
- Vials and cartons may state that vials be discarded 6 hours after dilution. This information is **incorrect**, and has been updated to **12 hours**.

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<sup>1</sup> It is not required that the vaccine reach room temperature prior to dilution, however the vaccine must be fully thawed.

## F. Vaccine Stability

ULT	2°C to 8°C	Room temperature
 <p data-bbox="598 397 808 552">-90°C to -60°C for 30 days (replenish dry ice q 5 days)</p>  <p data-bbox="598 641 829 787">-90°C to -60°C for 12 months from manufacturer date</p>	 <p data-bbox="1134 454 1270 527">10 weeks (70 days)</p>	<p data-bbox="1491 487 1732 836">Vials may be stored for up to 24 hours at temperatures up to 25°C with no more than 12 hours from the time of dilution (first puncture)</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.cvdvaccine.ca](http://www.cvdvaccine.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

<b>Date</b>	<b>Section</b>	<b>Description</b>	<b>Author</b>
November 24, 2021	A, B, C, D, E, F	SOP developed based on product monograph and information provided by Pfizer	Calvin Kaila
November 26, 2021	A	Added hyperlink to preloaded syringes	Calvin Kaila
December 15, 2021	B, D, E	Information on storage at room temperature updated	Calvin Kaila
January 31, 2022	B, E	Shelf life extension from 6 to 9 months at ULT updated	Calvin Kaila
May 3, 2022	B, E	Shelf life extension from 9 to 12 months at ULT updated	Calvin Kaila
Sept 22	Title, A,B,C,D,E,F,G	Inclusion of Maroon Cap information	Calvin Kaila