

# COVID-19 Pfizer Adult/Adolescent Vaccine (Gray Cap; monovalent and bivalent)

## Shipping, Storage, Thawing and Use Guidelines

### A. Formulations:

- Monovalent – 30 mcg/0.3 ml - intended population: 12 years of age and older
- Bivalent – 30 mcg/0.3 ml - intended population: 12 years of age and older (booster dose only)

### B. Shipping:

- Ideally, vaccine will be shipped frozen between -60°C to -90°C.
- Vaccine may be shipped thawed in unpunctured vials at 2°C to 8°C.
- Single-dose preloaded syringes or punctured vials 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):

- Monovalent: Can be stored at ULT for 18 months after manufacturing date printed on the vial/carton.
- Bivalent: Can be stored at ULT for 18 months after manufacturing date printed on the vial/carton.

2°C to 8°C Refrigerator (thawed):

- Thawed 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 first puncture. After first puncture the vials should be stored at 2°C to 25°C
- Thawed vials can be handled in room light conditions.

## D. Thawing:

Regular Use

- A carton of 10 vials may take up to 6 hours to thaw in the refrigerator (2°C to 8°C)

Immediate Use

- Thaw at room temperature (up to 25°C) for 30 minutes.

Handling Frozen Vials




- Cartons containing 10 vials removed from frozen storage may be at room temperature for up to **5 minutes**
- 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 to 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 first puncture.

## F. Vaccine Stability

ULT	2°C to 8°C	Room temperature
 <p data-bbox="590 354 793 505">-90°C to -60°C for 30 days (replenish dry ice q 5 days)</p>  <p data-bbox="579 573 789 792">-90°C to -60°C  18 months from manufacturer date</p>	 <p data-bbox="1094 410 1220 483">10 weeks (70 days)</p>	<p data-bbox="1440 443 1661 776">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 Monovalent Product Monograph](#)
- [Pfizer Bivalent 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>
July 22, 2022	A, B, C, D, E, F	SOP developed based on product monograph and information provided by Pfizer	Calvin Kaila
Oct 11, 2022	A	Information added about Bivalent formulation	Calvin Kaila
Dec 14, 2022	G	Link to bivalent monograph added and other hyperlinks updated	Calvin Kaila
Jan 11 2023	C, F	Expiry information updated	Calvin Kaila
Mar 7 2023	C, F	Expiry information updated	Calvin Kaila