COVID-19 Pfizer COMIRNATY Vaccine

Shipping, Storage, Thawing and Use Guidelines



A. Shipping:

- Ideally, vaccine will be shipped frozen between -60°C to -90°C.
- Vaccine may be shipped thawed at 2°C to 8°C.
- <u>Single-dose preloaded syringes</u> 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 <u>guidelines for dry ice</u> 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: 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):

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

C. Thawing:

Environment	Time
Thawed at 2°-8°C	6 hours
Thawed at room temp (up to 25°C)	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.	
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D. 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

E. Vaccine Stability

ULT	2*C to 8*C	Room temperature	
-90*C to -60*C for 30 days (replenish dry ice q 5 days) -90*C to -60*C Can be stored until written expiry	10 weeks (70 days)	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. 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

- Pfizer Product Monograph
- Pfizer COVID Vaccine Resources
- Pfizer Dry Ice Safety Data Sheet
- Pfizer instructions on dry ice replenishment

Any questions or requests for revision of this document should be sent to IBCOC_Operations@phsa.ca

List of Amendments

Date	Section	Description	Author
Oct 11, 2023	A, B, C, D, E,	SOP developed based on product monograph and information provided by	Calvin Kaila
	F,G	Pfizer	
Oct 4, 2024	A,C,D,E,G	Updated for KP.2 formualtion	Calvin Kaila