

Ministry of Health

Chapter 1: Storage and Handling of Pfizer-BioNTech's COVID-19 Vaccines

Version 4.1 – March 1, 2023

Highlights of Changes:

- Updates to Table 2
- Addition of *Rounding Principles* section

The scope for this chapter includes information pertaining to the storage and handling of Pfizer-BioNTech's COVID-19 Vaccine.

The intended audience for this guidance document includes hospitals, and public health units that are:




- Storing, distributing and/or administering COVID-19 vaccines;
- Involved in the assessment of temperature excursions, including the vaccine return process;

Providing education for the storage and handling of ultra-low temperature (ULT) and frozen vaccines and the use of temperature monitoring devices, such as data loggers. Additional resources available:

- Pfizer-BioNTech: <https://www.cvdvaccine.ca/>
- [COVID-19 Vaccine Storage and Handling Guidelines](#)
- [Vaccine Storage Handling Guidelines](#);
- Individual product monographs on the [Government of Canada website](#).

In addition, health care providers and organizations who have questions should contact their [local public health unit](#) or the ministry of health at vacpro@ontario.ca.

Table 1. Pfizer-BioNTech formulations of the COMIRNATY® vaccine authorized for use in Canada

Maroon Cap	Orange Cap ¹	Grey Cap ¹
6 months to 4 years	5 years to 11 years Monovalent vaccine AND Bivalent Original & Omicron BA.4/BA.5	12 years and older Monovalent vaccine AND Bivalent Original & Omicron BA.4/BA.5
 <p data-bbox="293 1083 505 1178">3 mcg/0.2mL (after dilution)</p>	 <p data-bbox="695 1083 922 1178">10 mcg/0.2mL (after dilution)</p>	 <p data-bbox="1105 1083 1341 1178">30 mcg/0.3mL (do not dilute)</p>

 ¹ Please use caution: Both monovalent and bivalent Pfizer vials have the same cap and label colour. They also have the same vial concentration. Ensure the correct product is used.

Storage and Handling of Pfizer-BioNTech's COVID-19 Vaccines

Storage and Handling

Table 2. Storage and Handling for Pfizer-BioNTech (Maroon, Orange (monovalent & bivalent), and Grey Cap (monovalent & bivalent) Vials)

Storage Condition	Maroon Cap	Orange Cap	Grey Cap
Frozen Vials Prior to Use	<ul style="list-style-type: none"> • Store monovalent and bivalent formulations (maroon, orange, and grey caps) at ultra-low temperature freezer at -90°C to -60°C for up to 18 months from the date of manufacture. • Do not store vials at -25°C to -15°C. • Keep protected from light, in the original packaging, until ready to use. 		
Thawed Unpunctured Vials	<ul style="list-style-type: none"> • Thawed vials may be stored in the fridge between +2°C to +8°C for a single period of up to 10 weeks within the 18-month self-life for monovalent formulations and 12-month shelf-life for bivalent formulations. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer. • Vaccine may be stored at room temperature +8°C to +25°C up to a maximum of 12 hours. • Thawed vials can be handled in room light conditions. • Do not refreeze thawed vials. 		
Thawed Punctured Vials or Syringes	<ul style="list-style-type: none"> • Record the date and time of first vial puncture (time of dilution for maroon and orange cap vials) on the vial label. Store between +2°C to +25°C. After first puncture, the vial should be stored between +2°C to +25°C. • Vials should be discarded 12 hours post-puncture. 		

Storage Condition	Maroon Cap	Orange Cap	Grey Cap
Diluent	<ul style="list-style-type: none"> • Dilution required. • Diluent stored between +20°C to +25°C; storage outside of this range must be tracked. • Excursions between +15°C to +30°C are permitted, provided diluent is stored in a temperature stable environment. • Diluent may be stored at +2°C to +20°C for up to five (5) days. • Diluent stored outside of these temperature ranges must be assessed by the manufacturer prior to use. For further information visit: http://www.cvdvaccine.ca 		<ul style="list-style-type: none"> • Do not dilute.

Rounding Principles

Based on information from Pfizer-BioNTech; COVID-19 vaccines at refrigerated temperatures may be rounded to the nearest whole degree:

- Temperatures between +1.5°C and +1.9°C are rounded to +2.0°C
- Temperatures between +8.1°C and +8.4°C are rounded to +8.0°C

Pfizer BioNTech COVID-19 vaccines exposed to temperatures between +1.5°C and +8.4°C are considered to be in refrigerated temperatures and the incident does not need to be recorded as a temperature excursion and entered in COVAX_{ON}. Troubleshooting should occur to ensure that temperatures are corrected and maintained between +2°C to +8°C.

Thawing Pfizer-BioNTech Vaccine

Table 3. Thawing conditions for Pfizer BioNTech COVID-19 Vaccines

Thawing Condition	Maroon Cap	Orange Cap	Grey Cap
Thawing in a refrigerator	<ul style="list-style-type: none"> Thaw in the refrigerator at +2°C to +8°C. A carton of 10 vials may take up to 2 hours to thaw and thawed vials can be stored in the refrigerator for up to 10 weeks. 	<ul style="list-style-type: none"> Thaw in the refrigerator at +2°C to +8°C. A carton of 10 vials may take up to 4 hours to thaw and thawed vials can be stored in the refrigerator for up to 10 weeks. 	<ul style="list-style-type: none"> Thaw in the refrigerator at +2°C to +8°C. A carton of 10 vials may take up to 6 hours to thaw and thawed vials can be stored in the refrigerator for up to 10 weeks.
Thawing at room temperature	<ul style="list-style-type: none"> If not previously thawed at +2°C to +8°C, allow vial(s) to thaw at room temperature (up to +25°C) for 30 minutes prior to dilution. Thawed vials may be stored at room temperature (up to +25°C) for up to 12 hours² prior to first puncture. 		

² Table 2 has additional stability information for vaccine in punctured vials and/or syringes.

Transport Conditions for Pfizer-BioNTech Vaccines

Transport time vaccine movement should not exceed **12 hours of cumulative time**. This includes a limit of 3 hours by air and 9 hours by road.

Table 4. Transport Conditions for Pfizer-BioNTech Grey, Orange and Maroon Caps

Storage Condition	Maroon Cap	Orange Cap	Grey Cap
Vaccine During Transport (by vehicle on ground, air, or water)	<ul style="list-style-type: none"> • Transport in ULT. • If not possible, then between +2°C to +8°C <ul style="list-style-type: none"> ○ This time counts toward the 10-week storage limit • Do not pack vaccine that is between +2°C and +8°C with frozen vaccine. • Store upright and protect from light. • Label as fragile. • Protect from shocks, drops, vibration, etc. • No data is available regarding the stability of punctured vials or pre-drawn syringes during transportation. 		

Transportation Of Pfizer-BioNTech COVID-19 Vaccine in Syringes

When at all possible, it is recommended that Pfizer-BioNTech COVID-19 vaccine be transported in an unpunctured vial and that the entire vial be administered in one location rather than transporting syringes filled with vaccine.

However, while not suggested as routine practice, in exceptional circumstances, diluted (if applicable) vaccine maybe transported in a syringe.

- Pfizer-BioNTech has conducted limited studies to understand the stability of diluted vaccines.
- The vaccine does not contain a preservative, therefore special attention should be given to handling and packaging of the syringe to prevent contamination.

Exceptional circumstances may include situations in which a few doses are needed to support the immunization and series completion of small numbers of individuals residing in congregate settings (i.e., one or two residents) and for those who are home bound (e.g., those who may be unable to attend a community-based clinic due to physical limitations).

Example of pre-drawn syringe and container labels:

Pfizer-BioNTech COMIRNATY COVID-19 Vaccine <insert age indication>

Facility name and phone number:

Quantity of syringes:

Date prepared & Time to discard:

Lot #:

Initials of preparer:

Transport Scenarios

The following scenarios may assist planning for the onward transport of the vaccine.

Scenario 1: Ground Transport between Locations

Transport from a hospital to another hospital for longer term storage (ULT or frozen).

Transport of the vaccine for storage at another facility should be done in the frozen state at ultra-cold temperature.

Scenario 2: Ground Transport between Locations or Facilities

Transport from a hospital to a congregate living setting.

ULT, frozen transport or liquid state transport, see product monograph and above for details and recommendations.

Scenario 3: Medium and Long Duration Ground PLUS Air Transport

It is recommended that any transport that involves air, be done in a frozen state at this time, ultra-cold temperature, but may also be done at -25°C to -15°C per product monograph and details and recommendations above.

Scenario 4: Short Duration Movement within a Facility or Campus

Movement of the vaccine that is stored at a long-term care home but needs to be walked over to an attached retirement home (e.g., on the same campus/property).

Movement in a Playmate cooler using a well-functioning wheeled cart on a relatively smooth pathway. Transport may also be conducted as a hand-carry (walked only, no running). Following general precautions described above, such movement may be conducted for a short period (i.e., up to 15 minutes).

Vaccine storage post temperature excursion or unit malfunction.

If placed in an ULT portable unit (-90°C to -60°C) vaccines can go back into an ULT unit. To the extent possible, vials should be kept in the tray during transport. If this is not possible, the vials need to be securely stored (not rolling around) in the storage device.

- If vaccines are placed in an insulated container for +2°C to +8°C temperature range, the vaccines should go back into a refrigerator and not be refrozen.
 - Time in fridge temperatures counts toward the 10-week storage limit for orange, grey and maroon caps.

If the purpose-built vaccine storage unit is unable to maintain the required storage temperature range, maintain the vaccines in the assigned container and continue to monitor temperatures inside the container. Place the vaccine back into the purpose-built unit once it is able to maintain the temperature range as specified by the vaccine manufacturer(s) in the product monograph.

For manufacturer contact information please see the [General Covid Vaccine Storage and Handling Guidance document](#).