Ministry of Health

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

Version 2.2 – October 13, 2022

Highlights of Changes:
- Addition of the grey cap/grey border bivalent Omicron-containing mRNA COVID-19 vaccine

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

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

<table>
<thead>
<tr>
<th>Purple Cap</th>
<th>Orange Cap</th>
<th>Grey Cap/Grey Border</th>
<th>Maroon Cap</th>
</tr>
</thead>
<tbody>
<tr>
<td>For ages 12 years and older</td>
<td>For ages 5 years through 11 years</td>
<td>For ages 12 years and older</td>
<td>for ages 6 months through 4 years</td>
</tr>
<tr>
<td>*Will be discontinued in 2022</td>
<td></td>
<td>Monovalent vaccine</td>
<td>AND Bivalent Original &amp; Omicron BA.4/BA.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Purple Cap</th>
<th>Orange Cap</th>
<th>Grey Cap/Grey Border</th>
<th>Maroon Cap</th>
</tr>
</thead>
<tbody>
<tr>
<td>30mcg/0.3mL (after dilution)</td>
<td>10mcg/0.2mL (after dilution)</td>
<td>30mcg/0.3mL (do not dilute)</td>
<td>3mcg/0.2mL (after dilution)</td>
</tr>
</tbody>
</table>
Health care providers and organizations should also follow the:

- Direction from the manufacturer’s site: [https://www.cvdvaccine.ca/](https://www.cvdvaccine.ca/)
- [COVID-19 Vaccine Storage and Handling Guidelines](https://www.cvdvaccine.ca/)
- [Vaccine Storage Handling Guidelines](https://www.cvdvaccine.ca/)
- 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

### Storage and Handling of Pfizer-BioNTech’s COVID-19 Vaccines

#### Storage and Handling

**Table 2. Storage and Handling for Pfizer-BioNTech (Purple Cap)**

<table>
<thead>
<tr>
<th>Storage Condition</th>
<th>Pfizer-BioNTech (Purple Cap)</th>
</tr>
</thead>
</table>
| Frozen Vials Prior to Use           | - Kept between -90°C to -60°C (-130°F to -76°F) until expiry date indicated on the vial label.  
  - For information regarding vaccine expiry extensions visit, [www.cvdvaccine.ca](http://www.cvdvaccine.ca) or Health Canada’s website  
  - Protected from light, in the original packaging, until ready to use.  
  - Can store in a freezer between -25°C to -15°C for up to two weeks. Vials stored between -25°C to -15°C for up to 2 weeks may be returned one time to storage condition of between -90°C to -60°C. Track the total time vials are stored between -25°C to -15°C. Cumulative total of 2 weeks should not be exceeded. |
| Thawed, unpunctured vials          | - Prior to dilution, thaw and store between +2°C to +8°C for up to 31 days or at room temperature (up to +25°C) for no more than 2 hours.  
  - During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.  
  - Thawed vials can be handled in room light conditions.  
  - Do not refreeze thawed vials.                                                                                                                                                                                                 |
### Storage Condition: Pfizer-BioNTech (Purple Cap)

- After dilution, store between +2°C to +25°C and use within 6 hours from time of first puncture.
- During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.
- After dilution, can be handled in room light conditions.

### 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, providing diluent is stored in a temperature stable environment.
- Diluent may be stored between +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](http://www.cvdvaccine.ca)

### Table 3. Storage and Handling for Pfizer-BioNTech (Orange and Grey Cap)

<table>
<thead>
<tr>
<th>Storage Condition</th>
<th>Pfizer-BioNTech (Orange Cap)</th>
<th>Pfizer-BioNTech (Grey Cap)</th>
</tr>
</thead>
</table>
| Frozen Vials Prior to Use          | - Kept between -90°C to -60°C up to 12 months after manufacturing date printed on the vial label.  
- Do not store between -25°C to -15°C.  
- Keep protected from light, in the original packaging, until ready to use. | - Kept between -90°C to -60°C up to 12 months after manufacturing date printed on the vial label.  
- Do not store between -25°C to -15°C.  
- Keep protected from light, in the original packaging, until ready to use. |
<table>
<thead>
<tr>
<th>Storage Condition</th>
<th>Pfizer-BioNTech (Orange Cap)</th>
<th>Pfizer-BioNTech (Grey Cap)</th>
</tr>
</thead>
</table>
| Thawed Unpunctured Vials | • Thawed vials may be stored between +2°C to +8°C for up to 10 weeks or at room temperature (up to +25°C) for no more than 24 hours prior to dilution.  
• During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.  
• Thawed vials can be handled in room light conditions.  
• Do not refreeze thawed vials. | • Thawed vials may be stored between +2°C to +8°C for up to 10 weeks within the 12-month shelf-life. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer.  
• Do not refreeze thawed vials. |
<table>
<thead>
<tr>
<th>Storage Condition</th>
<th>Pfizer-BioNTech (Orange Cap)</th>
<th>Pfizer-BioNTech (Grey Cap)</th>
</tr>
</thead>
</table>
| Thawed Punctured Vials            | • After dilution, store between +2°C to +25°C and use within 24 hours from time of first puncture.  
  o Additional stability data has been provided from the manufacturer which supports an additional 12 hours of cumulative storage in vials or syringes to total 24 hours (12 hours as listed in the product monograph plus an additional 12-hours excursion time). | • Do not dilute  
  • After first puncture, the vial should be stored between +2°C to +25°C. Vials should be discarded 12 hours after first puncture including any thaw time.  
  o Vial labels and cartons may state that a vial should be discarded 6 hours after the first puncture. However, the information in the Product Monograph supersedes the number of hours printed on vial labels and cartons.  
  • Thawed vials can be handled in room light conditions. |
| Syringe Stability                 | • Additional stability data from Pfizer supports storage of diluted vaccine in syringes for  
  o up to 24 hours in refrigerated temperatures (+2°C to +8°C)  
  o up to 12 hours at room temperature (+8°C to +25°C)  
  • Total cumulative time post-dilution cannot exceed 24 hours. During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. |
### Table 4. Storage and Handling for Pfizer-BioNTech (Maroon Cap)

<table>
<thead>
<tr>
<th>Storage Condition</th>
<th>Pfizer-BioNTech (Maroon Cap)</th>
</tr>
</thead>
</table>
| Frozen Vials Prior to Use          | • Frozen vials may be stored in ultra-low temperature freezer at -90°C to -60°C for up to 12 months from the date of manufacture.  
• Do not store vials at -25°C to -15°C.  
• Do not re-freeze thawed vials. |
| Thawed, unpunctured vials         | • Thawed vials may be stored at +2°C to +8°C for up to 10 weeks. The 10-week refrigerated expiry date should be recorded on the carton at the time of transfer from freezer.  
• Vaccine may be stored at room temperature +8°C to +25°C for a total of 12 hours prior to dilution (including any thaw time).  
• Thawed vials can be handled in room light conditions. |
### Storage Condition

<table>
<thead>
<tr>
<th>Pfizer-BioNTech (Maroon Cap)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thawed, punctured vials</td>
</tr>
<tr>
<td>• Record the date and time of dilution on the vial label. Store between +2°C to +25°C.</td>
</tr>
<tr>
<td>• Discard any unused vaccine 12 hours after dilution.</td>
</tr>
</tbody>
</table>

### Diluent

- Stored between +20°C to +25°C; storage outside of this range must be tracked.
- Excursions at +15°C to +30°C are permitted, providing 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](http://www.cvdvaccine.ca)

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### Thawing Pfizer-BioNTech Vaccine

**Table 5. Thawing conditions for Pfizer BioNTech COVID-19 Vaccines**

<table>
<thead>
<tr>
<th>Thawing Condition</th>
<th>Purple Cap For ages 12 years and older</th>
<th>Orange Cap For age 5 years through 11 years</th>
<th>Grey Cap For ages 12 years and older</th>
<th>Maroon Cap for ages 6 months through 4 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thawing in a refrigerator</td>
<td>Thaw Pfizer-BioNTech vaccine in the refrigerator between +2°C to +8°C. A carton of 10 vials may take up to 3 hours to thaw.</td>
<td>Allow vial(s) to thaw in the refrigerator between +2°C to +8°C. A carton of 10 vials may take up to 4 hours to thaw.</td>
<td>Allow vial(s) to thaw in the refrigerator between +2°C to +8°C. A carton of 10 vials may take up to 6 hours to thaw.</td>
<td>Allow vial(s) to thaw in the refrigerator between +2°C to +8°C. A carton of 10 vials may take up to 2 hours to thaw.</td>
</tr>
<tr>
<td><strong>Thawing Condition</strong></td>
<td><strong>Purple Cap</strong> For ages 12 years and older</td>
<td><strong>Orange Cap</strong> For age 5 years through 11 years</td>
<td><strong>Grey Cap</strong> For ages 12 years and older</td>
<td><strong>Maroon Cap</strong> for ages 6 months through 4 years</td>
</tr>
<tr>
<td>----------------------</td>
<td>------------------------------------------</td>
<td>---------------------------------------------</td>
<td>------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Thawing at room temperature</td>
<td>Vials may thaw at room temperature (up to +25°C) for 30 minutes.</td>
<td>Vials may thaw at room temperature (up to +25°C) for 30 minutes.</td>
<td>Vials may thaw at room temperature (up to +25°C) for 30 minutes.</td>
<td>Vials may thaw at room temperature (up to +25°C) for 30 minutes.</td>
</tr>
<tr>
<td><strong>Notes:</strong></td>
<td>Using either thawing method, vials must reach room temperature before dilution and must be diluted within 2 hours of exposure to room temperature.</td>
<td>Undiluted vials may be stored between +8°C to +25°C for up to 24 hours prior to mixing (including thaw time). The product monograph outlines a 12-hour storage time at +8°C to +25°C, however, additional stability data from the manufacturer allows for an additional 12 hours for a total of 24 hours. Evaluation of excursions of undiluted vials stored beyond the labeled 12-hour allowance at room temperature must consider total storage time of vials pre and post dilution.</td>
<td>Each vial must be thawed prior to administration.</td>
<td>Vials may be stored at room temperature up to +25°C for up to 12 hours prior to use.</td>
</tr>
</tbody>
</table>
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 should be adhered to.

**Table 6. Transport Conditions for Pfizer-BioNTech Purple Cap**

<table>
<thead>
<tr>
<th>Storage Condition</th>
<th>For ages 12 years and older (purple cap)</th>
</tr>
</thead>
</table>
| Vaccine During Transport (by vehicle on ground, air, or water) | Air and water transport should be done in a frozen state  
- Transport in ULT.  
- **If not possible**, then  
  - between -25°C to -15°C  
    - time counts toward the 2-week storage limit for returning to ULT  
  - or  
    - between +2°C to +8°C  
      - time counts toward the one-month (31 day) storage limit  
      - If 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.  
      - these doses need to be used within 31 days, minus any time in the container.  
  - 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 and vibration.  
  - 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. |
Table 7. Transport Conditions for Pfizer-BioNTech Grey, Orange and Maroon Caps

<table>
<thead>
<tr>
<th>Storage Condition</th>
<th>Orange, Grey, and Maroon Caps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine During Transport (by vehicle on ground, air, or water)</td>
<td>• Transport in ULT.</td>
</tr>
<tr>
<td></td>
<td>• <strong>If not possible</strong>, then between +2°C to +8°C</td>
</tr>
<tr>
<td></td>
<td>o time counts toward the 10-week storage limit</td>
</tr>
<tr>
<td></td>
<td>• Do not pack vaccine that is between +2°C and +8°C with frozen vaccine.</td>
</tr>
<tr>
<td></td>
<td>• Store upright and protect from light.</td>
</tr>
<tr>
<td></td>
<td>• Label as fragile.</td>
</tr>
<tr>
<td></td>
<td>• Protect from shocks, drops, vibration, etc.</td>
</tr>
</tbody>
</table>

**Transport of Open (Punctured) Vials or Syringes Containing Pfizer-BioNTech COVID-19 Vaccine**

While Pfizer-BioNTech has conducted limited studies to understand the stability of diluted vaccines, it is recommended that transport is undertaken in a pre-filled syringe.

The vaccine does not contain a preservative, therefore special attention should be given to handling and packaging of the syringe to prevent contamination.

While not suggested as routine practice, in exceptional circumstances it is recommended that diluted (if applicable) Pfizer-BioNTech vaccine be transported in a syringe.

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). When at all possible, it is recommended that unpunctured vials of vaccine be transported and the entire vial of vaccine administered in one location over transporting syringes filled with vaccine.

It is advised that vaccine is transported in a syringe as the potential for agitation (physical stress) of the mRNA in the vaccine is more likely in an open vial; this is caused by a change in air in the vial pressure once it has been punctured.

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 (6 hours after puncture):
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. For the purple cap vial stored at freezer temperatures of -25°C to -15°C, the vaccine may be returned to a frozen storage unit only once. Any hours used for transport at this temperature range are cumulative and should be tracked to ensure the 2-week limit for storage at -25°C to -15°C is followed (purple cap). 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.