

Ministry of Health

# Chapter 3: Storage and Handling of Janssen's COVID-19 Vaccine

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The scope for this chapter includes information pertaining to the storage and handling of the Janssen COVID-19 Vaccine.

Health care providers and organizations should also follow the:

- [COVID-19 Vaccine Storage and Handling Guidelines](#)
- [Vaccine Storage Handling Guidelines](#)
- Individual product monographs can be found on the [Government of Canada website](#).

Janssen Medical Information can be found at:

[https://www.janssenmedicalinformation.ca/covid-19\\_vaccine\\_resources](https://www.janssenmedicalinformation.ca/covid-19_vaccine_resources)

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](mailto:vacpro@ontario.ca)

## Storage and Handling of the Janssen COVID-19 Vaccine

### Storage and Handling

**Table 1. Storage and Handling for the Janssen COVID-19 Vaccine**

Storage Condition	Janssen
Frozen Vials Prior to Use	<ul style="list-style-type: none"> <li>• Vaccines can be kept frozen between -25°C to -15°C until expiry.</li> <li>• Protect from light</li> <li>• Expiry date for storage is printed on the vial and carton after "EXP"</li> </ul>

<b>Storage Condition</b>	<b>Janssen</b>
Thawed, Unpunctured Vials	<ul style="list-style-type: none"><li>• The vaccine can also be stored and transported between +2°C to +8°C for a single period of up to 11 months, not exceeding the original expiry date.</li><li>• Upon moving the product to a refrigerator between +2°C to +8°C the updated expiry date must be written on the carton and the vaccine should be used or discarded by the updated expiry date. In this case the original expiry date should be made unreadable.</li><li>• Do not re-freeze if product is received thawed between +2°C to +8°C. Check that the expiry date has been updated.</li><li>• The vaccine is stable for a total of 12 hours between 9°C to 25°C. It is not a recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions.</li></ul>

<b>Storage Condition</b>	<b>Janssen</b>
Thawed, Punctured Vials	<ul style="list-style-type: none"> <li>• It is preferred that the vaccine is used immediately after first puncture.</li> <li>• Once punctured the vial/filled syringe can be held between +2°C to +8°C for up to 6 hours. Discard if the vaccine is not used within this time.</li> <li>• Once punctured, the vial/filled syringe can also be held at room temperature (maximally +25°C) for a single period of up to 3 hours. Discard if the vaccine is not used within this time.</li> <li>• Note: Maximum hold times for these 2 temperature ranges are not cumulative (i.e., the vaccine cannot be held at room temperature for 3 hours and then held refrigerated for another 6 hours). <ul style="list-style-type: none"> <li>○ If 3-hour time limit at room temperature is not reached, the punctured vial may be transferred to a refrigerated storage unit (+2°C to +8°C) for the remaining time, up to 3 hours.</li> <li>○ For example, a vial held at room temperature for 1 hour after first puncture can be stored in the refrigerator (+2°C to +8°C) for no more than 2 hours before using or discarding. If the 3-hour time limit at room temperature has been met, it must be discarded and cannot be transferred to the refrigerator.</li> </ul> </li> </ul>

# Thawing

**Table 2. Thawing Janssen Vaccine**

Thawing conditions	Janssen Vaccine
Thawing in refrigerator	<ul style="list-style-type: none"><li>• When stored frozen between -25°C to -15°C, a carton of 10 vials will take approximately 13 hours to thaw.</li><li>• Individual vials will take approximately 2 hours between +2°C to +8°C.</li><li>• The vial must be kept in the original carton to protect from light and to record the expiry for the different storage conditions of applicable.</li><li>• Do not re-freeze once thawed.</li></ul>
Thawing at room Temperature	<ul style="list-style-type: none"><li>• When stored between -25°C to -15°C, a carton of 10 vials or individual vials should be thawed at room temperature maximally +25°C.</li><li>• A carton of 10 vials will take approximately 4 hours to thaw.</li><li>• Individual vials will take approximately 1 hour to thaw.</li><li>• The vaccine is stable for a total of 12 hours between +9°C to +25°C. It is not a recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions.</li></ul>

# Transport Conditions for the Janssen COVID-19 Vaccine

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 3. Janssen vaccine transport by storage condition**

Storage Condition	Janssen COVID-19 Vaccine
Vaccine During Transport (by vehicle on ground, air, or water)	<ul style="list-style-type: none"><li>• Frozen state, or</li><li>• Can be transported between +2°C to +8°C<ul style="list-style-type: none"><li>◦ Do not pack thawed vaccine with frozen vaccines, or allow contact with frozen packs</li></ul></li></ul>
Syringe Transport	<ul style="list-style-type: none"><li>• In exceptional circumstances it is recommended the Janssen vaccine be transported in a single dose syringe. It is not recommended to transport punctured vials.</li><li>• The vaccine is stable for a total of 12 hours between +9°C to +25°C. It is not a recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions.</li><li>• Drawn up vaccine must be administered within 6 hours from the time the vial was first punctured if stored between +2°C to +8°C or within 3 hours when held at room temperature, maximally at +25°C.</li></ul>

# Transport of Open-Vials or Syringes Containing Janssen

While not recommended as routine practice, in exceptional circumstances a single dose of Janssen vaccine may be transported in a syringe.

Exceptional circumstances could 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 recommended that vaccine is transported in a syringe as once a vial has been punctured the air pressure in the vial will have been changed and the potential for agitation (physical stress) of the vaccine is more likely.

Example of pre-drawn syringe and container labels:

**Janssen COVID-19 Vaccine (0.5 mL) IM suspension**

Facility name and phone number:

Quantity of syringes:

Date prepared & Time to discard:

Lot #:

Initials of preparer:

## Scenarios

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

### **Scenario 1: 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).

### **Scenario 2: Ground Transport between Locations or Facilities**

Transport from one public health unit to a congregate living setting.

Transport in a Playmate cooler may be carried out using a car, van or truck on paved, smooth gravel, or smooth dirt roads, following the general precautions described above. Avoid sudden movements/braking as much as possible.

The vaccine should preferably be used immediately after the first puncture of the vial; however, the product can be stored and/or transported between 2°C to 8°C for up to 6 hours or at room temperature (maximally 25°C) for up to 3 hours after first puncture of the vial.

Such transport may be conducted for up to 12 hours for unpunctured vials.

## Vaccine Storage Post Temperature Excursion or Unit Malfunction

- If placed in a portable freezer unit (-25°C to -15°C), the vaccines can go back into a freezer unit. To the extent possible, vials should be kept in the boxes during transport. If this is not possible, any individual vials need to be securely stored (not rolling around) in the portable storage device.

- Upon moving the product to a refrigerator between +2°C to +8°C, the updated expiry date must be written on the carton and the vaccine should be used or discarded by the updated expiry date. The original expiry date should be made unreadable.
- If an alternative storage facility cannot be identified within a reasonable timeframe, place the vaccine in the portable freezer unit and/or insulated containers with appropriate packaging material and digital temperature monitoring devices and record the temperature at the facility by:
  - Labelling the insulated containers; and
  - Continuing to monitor the temperatures inside the insulated container at 30-minute intervals using a temperature monitoring device that allows temperature viewing without opening the insulated container (e.g., in/out thermometer).