

# Janssen COVID-19 Vaccine

## Storage, Expiry, Dosing and Administration



*Janssen COVID-19 Vaccine (Ad26.COVID-S [recombinant]) is indicated for active immunization for the prevention of coronavirus disease-2019 (COVID-19) caused by SARS-CoV-2 virus in individuals 18 years of age and older.*

For the primary vaccination, Janssen COVID-19 Vaccine should be administered intramuscularly as a single dose of 0.5 mL in individuals 18 years of age and older.

A booster dose of 0.5 mL of Janssen COVID-19 Vaccine may be administered intramuscularly at least 2 months after the primary vaccination in individuals 18 years of age and older.

This vaccine should be handled by a healthcare professional using aseptic technique to ensure the sterility of each dose.

- The vaccine comes ready to use once thawed.
- The vaccine may be supplied frozen at  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$  or thawed at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$ .
- Do not re-freeze vaccine once thawed.
- Keep the vials in the original carton in order to protect from light and to record the expiry for the different storage conditions, if applicable.

### a. Storage upon receipt of vaccine

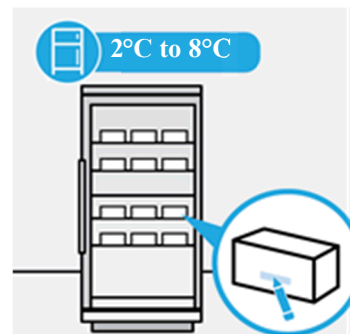
**IF YOU RECEIVE YOUR VACCINE FROZEN AT  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$  you may:**



#### Store in a freezer

- The vaccine can be stored and transported frozen at  $-25^{\circ}\text{C}$  to  $-15^{\circ}\text{C}$ .
- The expiry date for storage is printed on the vial and carton after "EXP".

OR



#### Store in a refrigerator

- The vaccine can also be stored and transported at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  for a single period of **up to 6 months**, not exceeding the original expiry date (EXP).
- Upon moving the product to a refrigerator at  $2^{\circ}\text{C}$  to  $8^{\circ}\text{C}$ , 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.**

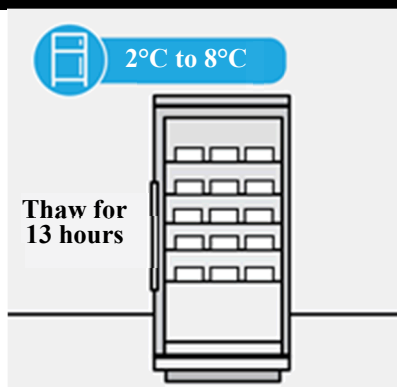
**IF YOU RECEIVE YOUR VACCINE THAWED AT 2°C to 8°C you should store in a refrigerator:**



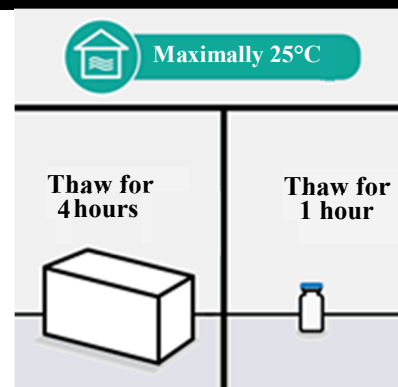
**⚠ Do not re-freeze** if the product is received already thawed at 2°C to 8°C.

**Note:** If the vaccine is received refrigerated at 2°C to 8°C, check that the expiry date has been updated by the local supplier upon receipt. If you cannot find the new EXP date, contact the local supplier to confirm the refrigerated EXP date. Write the **new expiry date** on the carton before the vaccine is stored in the refrigerator. **The original expiry date should be made unreadable.**

**b. If stored frozen, thaw vial(s) either in a refrigerator or at room temperature before administration**



OR



#### Thaw in refrigerator

- When stored frozen at -25°C to -15°C, a carton of 10 vials will take approximately 13 hours to thaw or individual vials will take approximately 2 hours to thaw **at 2°C to 8°C.**
- If the vaccine is not used immediately, refer to the instructions in section 'Store in a refrigerator'.
- The vial must be kept in the original carton in order to protect from light and to record the expiry for the different storage conditions, if applicable.

**⚠ Do not re-freeze** once thawed.

#### Thaw at room temperature

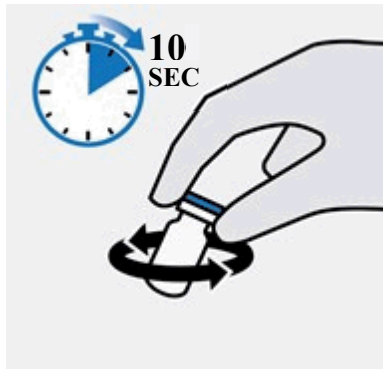
- When stored frozen at -25°C to -15°C, a carton of 10 vials or individual vials should be thawed at room temperature maximally **25°C.**
- A carton of 10 vials will take approximately **4 hours** to thaw.
- Individual vials will take approximately **1 hour** to thaw.
- The vaccine is stable for a total of **12 hours at 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.
- If the vaccine is not used immediately, refer to the instructions in section Store in a refrigerator.
- **⚠ Do not re-freeze** once thawed.

**c. Inspect vial and vaccine**

- Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension (pH 6-6.4).
- The vaccine should be inspected visually for particulate matter and discoloration prior to administration.
- The vial should be inspected visually for cracks or any abnormalities, such as evidence of tampering prior to administration.

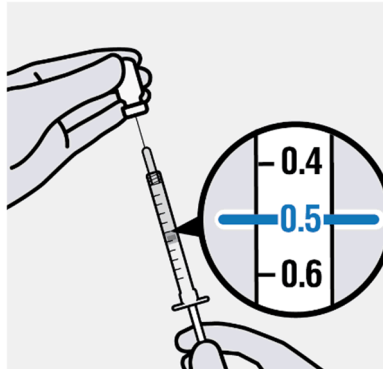
If any of these should exist, do not administer the vaccine.

**d. Prepare and administer vaccine**



**Swirl the vial gently**

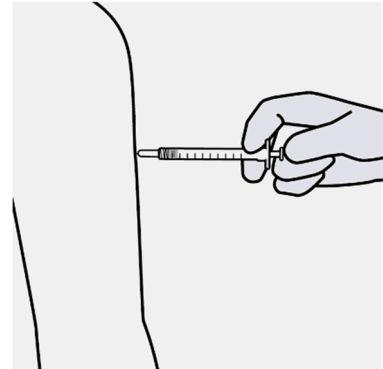
- Before administering a dose of vaccine, swirl the vial gently **in an upright position for 10 seconds**.
- **Do not** shake.



**Withdraw 0.5 mL**

- Use a sterile needle and sterile syringe to extract a single-dose of **0.5 mL** from the multi-dose vial.

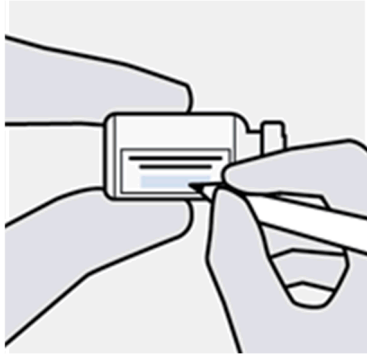
**⚠ A maximum of 5 doses can be withdrawn from the multidose vial.** Discard any remaining vaccine in the vial after 5 doses have been extracted.



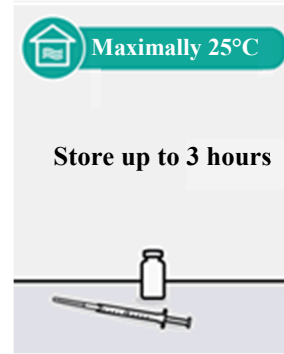
**Inject 0.5 mL**

- Administer by **intramuscular injection only** into the deltoid muscle of the upper arm.

e. Storage after first puncture



OR



**Record date and time the vial should be discarded**

- After first puncture of the vial record the date and time the vial should be discarded on each vial label.



Preferably, use immediately after first puncture.

- After the first puncture of the vial, the vaccine can be held at **2°C to 8°C** for **up to 6 hours**.

Discard if vaccine is not used within this time.

- After the first puncture of the vial, the vaccine can be held at **room temperature (maximally 25°C)** for a single period of **up to 3 hours**.

Discard if vaccine is not used within this time.

Indication:

Janssen COVID-19 Vaccine (Ad26.CO2-S [recombinant]) is indicated for active immunization for the prevention of coronavirus disease-2019 (COVID-19) caused by SARS-CoV-2 virus in individuals 18 years of age and older.

Contraindications:

Janssen COVID-19 Vaccine is contraindicated in individuals who are hypersensitive to the active ingredient, any other adenovirus-based vaccines, or to any ingredient in the formulation, including any non-medicinal ingredient, or component of the container.

Janssen COVID-19 Vaccine is contraindicated in individuals with a history of thrombosis with thrombocytopenia following vaccination with Janssen COVID-19 Vaccine or any other adenovirus-vectored COVID-19 vaccine.

Janssen COVID-19 Vaccine is contraindicated in individuals with a history of Capillary Leak Syndrome (CLS).

**For additional information consult the Product Monograph at [www.janssen.com/canada/products](http://www.janssen.com/canada/products), call Janssen Inc. at: 1-800-567-3331 or visit [www.janssenmedicalinformation.ca](http://www.janssenmedicalinformation.ca).**