

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 for how to report adverse reactions.

1. NAME OF THE MEDICINAL PRODUCT

COVID-19 Vaccine Janssen suspension for injection
COVID-19 vaccine (Ad26.COVS-S [recombinant])

4.2 Posology and method of administration

Posology

Individuals 18 years of age and older

COVID-19 Vaccine Janssen is administered as a single-dose of 0.5 mL by intramuscular injection only.

Paediatric population

The safety and efficacy of COVID-19 Vaccine Janssen in children and adolescents (less than 18 years of age) have not yet been established. No data are available.

Elderly

No dose adjustment is required in elderly individuals ≥ 65 years of age. See also sections 4.8 and 5.1.

Method of administration

COVID-19 Vaccine Janssen is for intramuscular injection only, preferably in the deltoid muscle of the upper arm.

The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.

For precautions to be taken before administering the vaccine, see section 4.4.

For instructions on handling and disposal of the vaccine, see section 6.6.

6.6 Special precautions for disposal and other handling

Handling instructions and administration

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

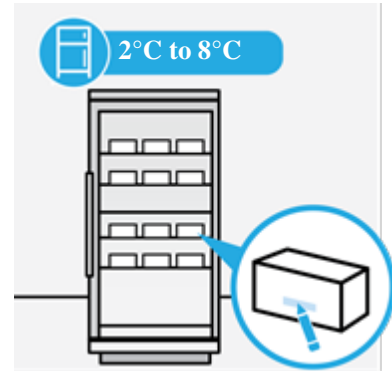
- The vaccine comes ready to use once thawed.
- The vaccine may be supplied frozen at -25°C to -15°C or thawed at 2°C to 8°C .
- Do not re-freeze vaccine once thawed.
- Keep the vials in the original carton in order to protect from light and to record the expiry for the different storage conditions,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

a. Storage upon receipt of vaccine

IF YOU RECEIVE YOUR VACCINE FROZEN AT -25°C to -15°C you may:



OR



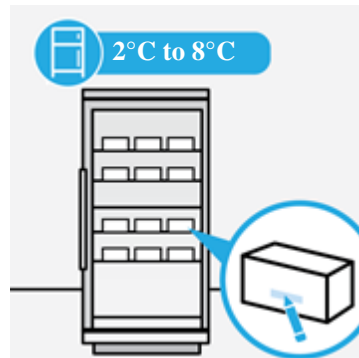
Store in a freezer

- The vaccine can be stored and transported frozen at **-25°C to -15°C**.
- The expiry date for storage is printed on the vial and outer carton after “EXP” (see section 6.4).

Store in a refrigerator

- The vaccine can also be stored and transported at **2°C to 8°C** for a single period of **up to 4.5 months**, not exceeding the original expiry date (EXP).
- Upon moving the product **to a refrigerator at 2°C to 8°C**, the updated expiry date must be written on the outer carton and the vaccine should be used or discarded by the updated expiry date. **The original expiry date should be crossed out** (see section 6.4).

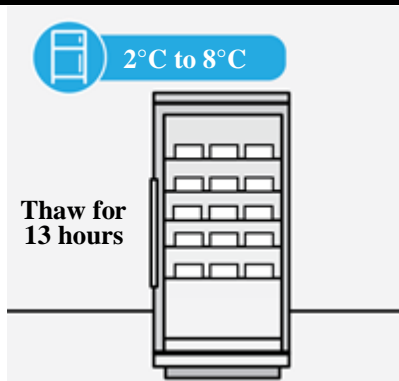
IF YOU RECEIVE YOUR VACCINE THAWED AT 2°C to 8°C you should store in a refrigerator:



⚠ 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 outer carton before the vaccine is stored in the refrigerator. **The original expiry date should be crossed out** (see section 6.4).

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

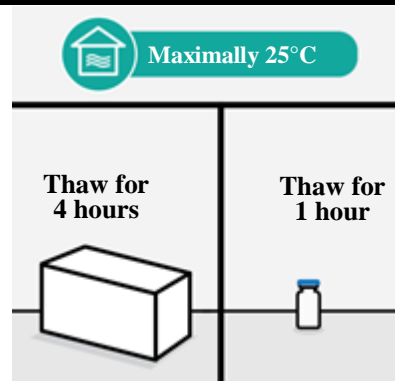


Thaw in refrigerator

- 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.

OR



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.

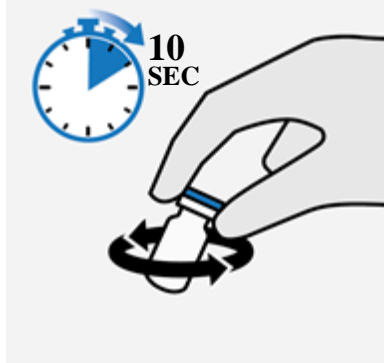
⚠ Do not re-freeze once thawed.

c. Inspect vial and vaccine

- COVID-19 Vaccine Janssen 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.

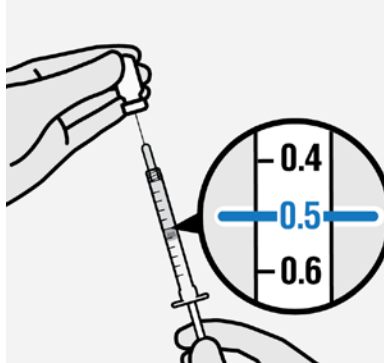
If any of these should exist, do not administer the vaccine.

d. Prepare and administer vaccine



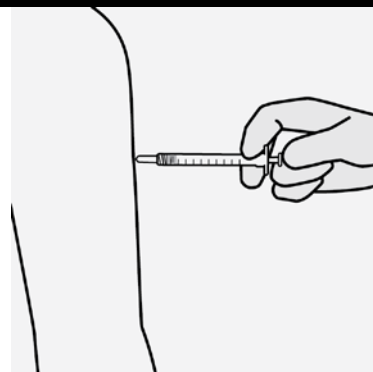
Swirl the vial gently

- 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 (see section 4.2).

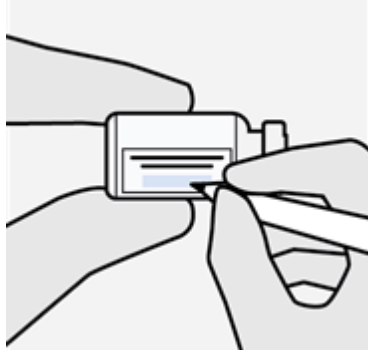


Inject 0.5 mL

- Administer by **intramuscular injection only** into the deltoid muscle of the upper arm (see section 4.2).

! A maximum of 5 doses can be withdrawn from the multi-dose vial. Discard any remaining vaccine in the vial after 5 doses have been extracted.

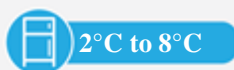
e. Storage after first puncture



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.



Store up to 6 hours



- 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.

OR



Store up to 3 hours



- 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**. (see section 6.3).
- Discard if vaccine is not used within this time.

f. Disposal

Any unused vaccine or waste material should be disposed of in compliance with local guidance for pharmaceutical waste. Potential spills should be disinfected with agents with viricidal activity against adenovirus.

10. DATE OF REVISION OF THE TEXT

14/02/2022