UN SYSTEM-WIDE COVID-19 VACCINATION PROGRAMME

DEPLOYMENT OF COVID-19 VACCINE JANSSEN (FROZEN)

VERSION 1 – 06 MAY 2022

BACKGROUND

1. The UN System-wide COVID-19 Vaccination Programme acquired a batch of COVID-19 Vaccine Janssen[1] (Ad26.COV2-S [recombinant]), which is being allocated to Local Vaccine Deployment Teams for administration as primary vaccination or booster to eligible individuals as indicated in the Eligibility Document[2].

2. The COVID-19 Vaccine Janssen is a suspension for intramuscular injection. The vaccine purchased by the Programme is from lot number 1885153, which **expires on 31 October 2023** (the "Expiry Date"). It is supplied in 2.5mL multiple-dose vials, which allows for 5 doses of 0.5mL to be extracted per vial. Each carton includes 10 vials.

3. The vaccine is stored frozen at -25ºC to -15ºC at the central warehouse in Denmark. It is being shipped frozen to the destination countries. Once thawed, the vaccine can be stored at 2° to 8°C and used for **up to 11 months after thawing, not exceeding the Expiry Date**.

4. Upon reaching the Expiry Date, all unused vials must be discarded following appropriate protocols outlined in this document.

PRIMARY VACCINATION, BOOSTER DOSE, MIX & MATCH

5. **Primary Vaccination**: The primary vaccination regimen for the COVID-19 Vaccine Janssen is a single-dose (0.5 mL) administered to individuals 18 years of age and older by intramuscular injection only.

6. **Booster Dose**: A single COVID-19 Vaccine Janssen booster dose (second dose) of 0.5 mL may be administered intramuscularly at least 2 months after primary vaccination with the COVID-19 Vaccine Janssen, to individuals 18 years of age and older. A single booster dose of the COVID-19 Vaccine Janssen (0.5 mL) may also be administered to individuals 18 years of age and older as a heterologous (mix and match) booster dose following completion of primary vaccination with another WHO EUL approved inactivated (such as Sinopharm) or mRNA vaccine (such as Moderna).

[1] The product name under the EMA authorization was recently changed to Jcovden in April 2022.
https://www.ema.europa.eu/en/medicines/human/EPAR/jcovden-previously-covid-19-vaccine-janssen
[2] https://www.un.org/sites/un2.un.org/files/un_system-wide_covid-19_vaccination_programme_-_eligibility.pdf

ADMINISTRATION

7. **Inspection**:
   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, for cracks and any other abnormalities, prior to administration. If any of these should exist, do not administer the vaccine.

8. **Administration**
   Swirl: 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). A maximum of 5 doses can be withdrawn from the multi-dose vial. Discard any remaining vaccine in the vial after 5 doses.
   Administer by intramuscular injection preferably into the deltoid muscle of the upper arm. Do not inject the vaccine intravenously, subcutaneously or intradermally.

CONTRAINDICATIONS

9. **Severe Allergic Reactions**: Do not administer to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to any component of the COVID-19 Vaccine Janssen.

10. **Thrombosis with Thrombocytopenia (TTS)**: Do not administer to individuals with a history of thrombosis with thrombocytopenia following the COVID-19 Vaccine Janssen or any other adenovirus-vectored COVID-19 vaccines (e.g., AstraZeneca/Covishield COVID-19 vaccine).

11. Healthcare professionals should be alert to the signs and symptoms of TTS in individuals who receive the COVID-19 Vaccine Janssen. In individuals with suspected TTS following administration of the COVID-19 Vaccine Janssen, the use of heparin may be harmful and alternative treatments may be needed. Consultation with hematology specialists is strongly recommended.

STORAGE AND TRANSPORTATION

VACCINE DELIVERED FROZEN TO COUNTRY TEAMS

12. At this time, the Programme delivers the vaccine frozen at -25°C to -15°C from the central warehouse. Depending on the local storage capacity, country teams can either store the vaccine frozen until the expiry date, or thawed at 2°C to 8°C for up to 11 months not exceeding the original expiry date.

FROZEN VACCINE: STORAGE, THAWING, UPDATING THE EXPIRY DATE

13. Store and transport vaccine frozen at -25°C to -15°C. The expiry date for storage at -25°C to -15°C is **31 October 2023**, as printed on the vial and outer carton after “EXP”

14. When stored frozen at -25°C to -15°C, the vaccine **can be thawed** either at 2°C to 8°C or at room temperature:
    a. at 2°C to 8°C: a carton of 10 or 20 vials will take approximately 13 hours to thaw, and a single vial will take approximately 2 hours to thaw.
    b. at room temperature (maximally 25°C): a carton of 10 or 20 vials will take approximately 4 hours to thaw, and a single vial will take approximately 1 hour to thaw.

15. **Do not re-freeze** vaccine once thawed.

16. Once **thawed**, the vaccine can be stored in a refrigerator at 2°C to 8°C for a single period of **up to 11 months**, **not exceeding the original expiry date (EXP).**
    a. It is recommended to store the vials in their original cartons to protect them from light.
    b. 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.

TRANSPORTATION AT THE COUNTRY LEVEL

17. Frozen vaccine must be transported at -25°C to -15°C. Thawed vaccine must be transported at 2° to 8°C.

18. The thermal boxes used by the Programme to ship vaccines to the destination countries, both at -25°C to -15°C and at 2° to 8°C (in previous shipments of other vaccine types), **may be re-used** for transportation within the country, provided that they have not been damaged during transit. Please follow the applicable SOP for **pre-conditioning the cooling elements (in advance)** and loading them in the box at packing (see Annex 2 and Annex 3).

INFORMATION TO VACCINE RECIPIENTS, PHARMACOVIGILANCE, REPORTING OF ADVERSE EVENTS

19. Vaccine recipient must be provided information consistent with the factsheet[3] prior to receiving each dose of vaccine including benefits/risks of vaccination. Vaccine recipients must be provided with adverse event reporting instructions.

20. Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of vaccine. See DHMOSH guidance[4] for reference.

21. Adverse events following vaccination that are beyond the normal side effect profile and require treatment are to be recorded as part of the clinic visit for that vaccination in Everbridge. The UN has an obligation to cooperate with the manufacturer with respect to pharmacovigilance and the occurrence of adverse events and safety reports in the administration of the COVID-19 Vaccine Janssen under the Programme.

EVERBRIDGE

22. The Everbridge platform has been updated to allow the recording of individuals' additional doses. The new lot number has been added to the platform. Changes have been made to the platform to allow for all medical personnel within a country to be able to update the records of the vaccine candidate across the clinics within the country.

23. Further guidance has been published on our SharePoint site, which highlights the recent enhancements that have developed (e.g., "walk-in clinic" functionality) to improve the usability of the platform for local teams, improving visibility and flexibility.

[3] https://www.who.int/news-room/feature-stories/detail/the-j-j-covid-19-vaccine-what-you-need-to-know
[4] https://www.un.org/sites/un2.un.org/files/coronavirus_vaccination_anaphylaxisguidelines.pdf

DESTRUCTION OF USED, EXPIRED OR UNUSABLE VIALS, AND ANCILLARIES

24. Used COVID-19 vaccine vials and ancillary supply should be disposed of according to medical waste management best practices. See guidance here for reference: https://www.afro.who.int/sites/default/files/2021-05/SOP%20Waste%20management%20of%20Covid-19%20Vaccines%20%281%29.pdf

25. Unused vials: Any vial of vaccine that exceeds the shelf life indicated by the manufacturer should be disposed of as **regulated medical waste**.

26. Certificates of destruction must be issued and collected by each local vaccine deployment team. Upon expiration of the vaccine batch, a record of all destructions of expired or otherwise unusable vaccines must be provided to the Global Vaccine Deployment Support Team (GVDST). A template is available here. The GVDST will provide the manufacturer with written confirmation of the destruction or disposition of such unused vaccines.

ADDITIONAL INFORMATION AND RESOURCES

27. The product information is published on the European Medicines Agency's website:
    ENGLISH: https://www.ema.europa.eu/en/documents/product-information/jcovden-previously-covid-19-vaccine-janssen-epar-product-information_en.pdf
    FRENCH: https://www.ema.europa.eu/en/documents/product-information/jcovden-previously-covid-19-vaccine-janssen-epar-product-information_fr.pdf

28. You may also contact the GVDST for additional guidance at covidvaccines@un.org

ANNEXES

- Annex 1: EMA's infographic on storage, handling and administration
- Annex 2: SOP on pre-conditioning cooling elements (Va-Q-Pads type -21G) for transportation at -25°C to -15°C
- Annex 3: SOPs on pre-conditioning cooling elements (Va-Q-Pads type +05G) for transportation at 2°C to 8°C

Annex 1 – EMA's infographic on storage, handling and administration

Source: European Medicines Agency product information

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

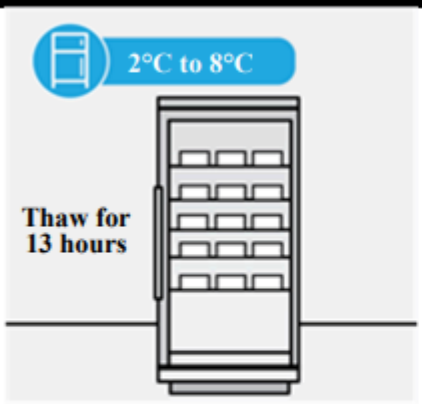
- The vaccine can also be stored and transported at **2°C to 8°C** for a single period of **up to 11 months**, not exceeding the original expiry date (EXP).
- Upon moving the product **to a refrigerator at 2°C to 8°C**, the updated expiry date must be written on the outer carton and the vaccine should 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:

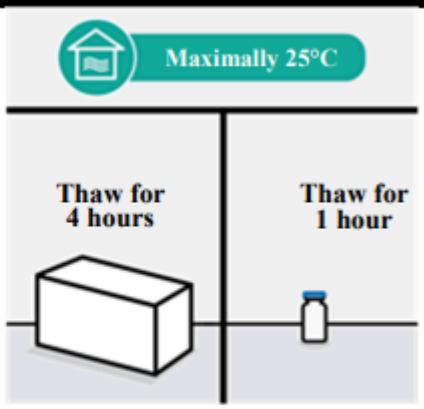
Do not re-freeze if the product is received already thawed at 2°C to 8°C.

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



OR



Thaw in refrigerator

- When stored frozen at -25°C to -15°C, a carton of 10 or 20 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 or 20 vials or individual vials should be thawed at room temperature maximally **25°C**.
- A carton of 10 or 20 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

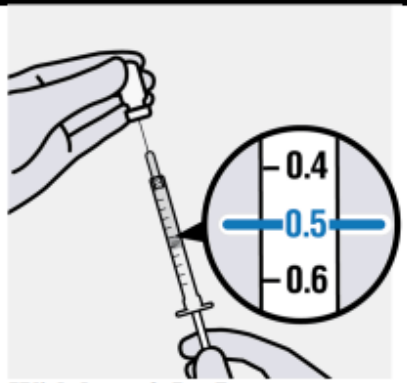
- JCOVDEN is a colorless to slightly yellow, clear to very opalescent suspension (pH 6-6.4).
- The vaccine should be inspected visually for particulate matter and discoloration prior to administration.
- The vial should be inspected visually for cracks or any abnormalities, such as evidence of tampering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

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

d. Prepare and administer vaccine

Swirl the vial gently

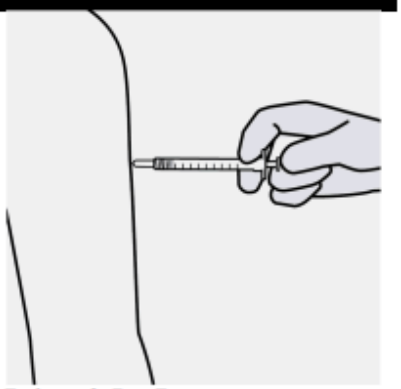
- Before administering a dose of vaccine, swirl the vial gently **in an upright position for 10 seconds**.
- **Do not** shake.



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).

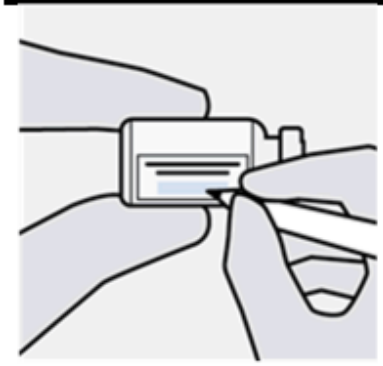
⚠ **A maximum of 5 doses can be withdrawn from the multi-dose vial**. Discard any remaining vaccine in the vial after 5 doses have been extracted.



Inject 0.5 mL

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

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.

- 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

- 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.

Annex 2 – SOP on pre-conditioning cooling elements for transportation at -25°C to -15°C

Keep Va-Q-Pads (**type -21G**) at -25°C for at least 72 hrs.

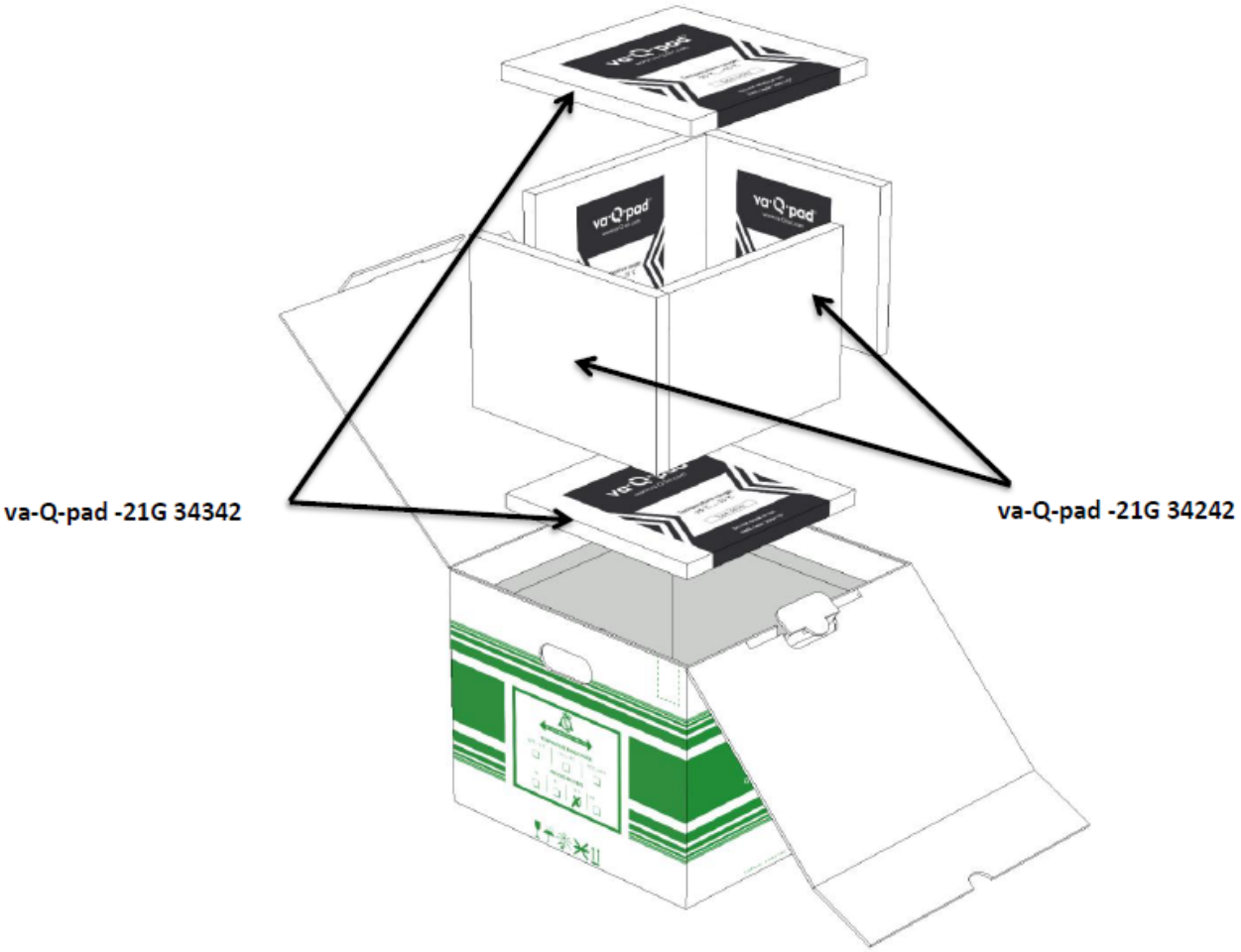
va-Q-tec
ALWAYS THE RIGHT TEMPERATURE

3.4 PCM, container and good pre-conditioning

Table 12: Pre-conditioning Data

PCM pre-conditioning	PCM-Type	Temperature	Duration
	-21G	≤-25.0°C	≥72 hrs
Good pre-conditioning	**Good**	**Temperature**	**Duration**
	va-Q-gel 48 M	-20.0 °C ±0.5 °C	≥72 hrs

3.5 va-Q-pad and good loading



Annex – SOPs Preconditioning cooling elements (Va-Q-Tec) for 2°C to 8°C shipments

OPTION 1: Keep Va-Q-Pads (**type +05G**) at 3°C for at least 72 hrs.

va-Q-tec AG
Alfred-Nobel-Straße 33
D-97080 Würzburg
Tel: +49 (0)931 35 942 -0
www.va-Q-tec.com

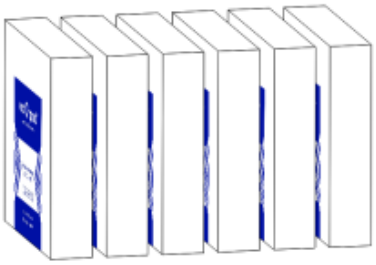
va-Q-tec
ALWAYS THE RIGHT TEMPERATURE

SOP: Preconditioning va-Q-pads for va-Q-one 4, va-Q-one 8, va-Q-one 23 and va-Q-one 43 for +2 °C to +8 °C shipments

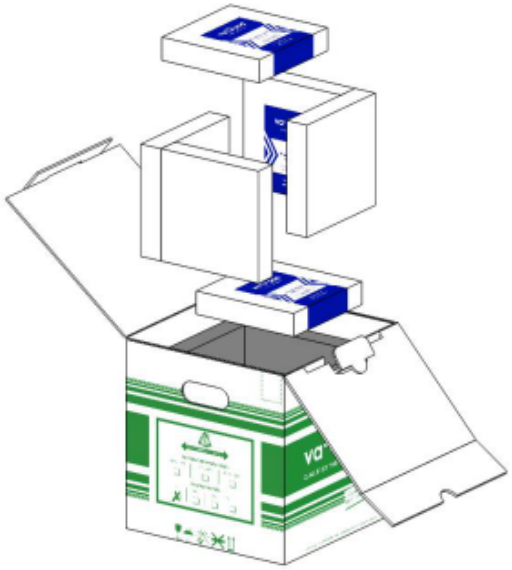
PCM type +05G (color code: blue)

Step 1
Place the va-Q-pads (short "pads") in a row with the distance of approximately 15 mm to each other.

Store the pad bundles in a cool room at a temperature of +3.0 ± 0.5 °C for at least 72 hours.



Step 2
Load the pads into the box as per the respective Loading SOP instructions.



OPTION 2: Keep Va-Q-Pads (**type +05G**) at -20°C for at least 24 hrs. then at 2°C to 8°C for 9 hrs.

va-Q-tec AG
Alfred-Nobel-Straße 33
D-97080 Würzburg
Tel: +49 (0)931 35 942 -0
www.va-Q-tec.com

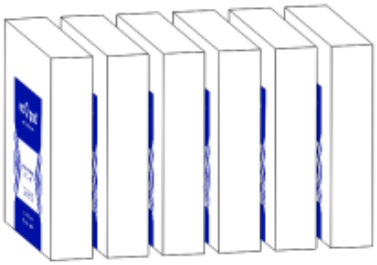
ALWAYS THE RIGHT TEMPERATURE

SOP: Preconditioning va-Q-pads for va-Q-one 4 for +2 °C to +8 °C shipments

va-Q-pad size 20204 with PCM type +05G (color code: blue)

Step 1
Place the va-Q-pads (short "pads") in a row with the distance of approximately 15 mm to each other.

Store the pad bundles in a freezer at a freezer temperature of -20.0 ± 5 °C for at least 24 hours.



Step 2
Take the pads out of the freezer and store the pads in a cool room at +5 ± 3°C for 9 ± 1 hours.

Step 3
Load the pads into the va-Q-one 4 as per the respective Loading SOP instructions.