Important Safety Information on the Importation of Janssen COVID-19 Vaccine with European Union (EU) English-only Vial and Carton Labels

2021/11/09

IMPORTANT: **Access to storage and expiry date instructions during the distribution of the Janssen COVID-19 Vaccine with EU English-only labels.**

Audience

Healthcare professionals including infectious disease physicians, pharmacists, family physicians, public health officials, nurses and nurse practitioners. Healthcare professionals at the identified points of use.

Key messages

- **Further to the authorization of Janssen COVID-19 Vaccine, under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*, Janssen Inc. is providing vaccine supplies with EU English-only vial and carton labels (referred to as EU White Label in Appendix A) in order to expedite distribution of the vaccine in Canada.**
- **There are some differences in the storage and expiry date instructions between the Janssen COVID-19 Vaccine with EU English-only labelling and the Health Canada authorized Janssen COVID-19 Vaccine. However, both products are the same in all other aspects (i.e., formulation, strength, route of administration).**
- **Healthcare professionals are advised that:**
  - **Important Canadian-specific information is absent from the EU English-only vial and carton labels (see Information for healthcare professionals section).**
  - **At the time of this communication, the storage and expiry date instructions for the Janssen COVID-19 Vaccine with EU English-only labels are NOT included in the Canadian Product Monograph available on Health Canada's Drug Product Database, or the federal government's covid-vaccine.canada.ca website.**
  - **The Storage, Expiry, Dosage and Administration Guide, developed by Janssen Inc., should be used as a reference along with this communication for storage and expiry date instructions (see Information for healthcare professionals section) for the Janssen COVID-19 Vaccine with EU English-only labels.**

- **The Janssen guide can be accessed by scanning the QR code on the carton, or visiting http://www.covid19vaccinejanssen.com as referenced on the carton. It can also be accessed by visiting https://www.janssenmedicalinformation.ca/covid-19_vaccine_resources, or by contacting Janssen Inc. Medical Information at 1-800-565-4008 (toll free), or 1-908-455-9922 (US toll).**

What is the issue?
As an extraordinary measure to provide immediate access to vaccine supplies in the context of the global pandemic, Janssen Inc. is providing vaccine vials and cartons labelled with EU English-only labels. These labels are presented in English-only and are missing some important Canadian-specific information normally found on Health Canada approved labels.

Products affected
Janssen COVID-19 Vaccine (5×10^{10} virus particles/0.5 mL) suspension for intramuscular injection, multiple dose vials. Each vial contains 5 doses (each dose is 0.5 mL).
DIN: 02513153

Manufacturer, Importer and Distributor: Janssen Inc.
Logistics Services Provider: Innomar Strategies Inc.

Background information
Janssen COVID-19 Vaccine 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.

Further to the authorization of Janssen COVID-19 Vaccine under the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*, Janssen Inc. is providing vaccine supplies with EU English-only vial and carton labels (referred to as EU White Label in Appendix A) in order to expedite distribution of the vaccine in Canada.

There are some differences in the storage and expiry date instructions between the Janssen COVID-19 Vaccine with EU English-only labelling and the Health Canada authorized Janssen COVID-19 Vaccine. However, both products are the same in all other aspects (i.e., formulation, strength, route of administration).

Information for healthcare professionals
In order to provide rapid access to Janssen COVID-19 Vaccine for Canadians, Janssen Inc. will provide product vials and cartons with EU English-only labels for a limited time period (see Appendix A).

Healthcare professionals are advised that:

- The following important Canadian-specific information is absent from the vial and carton labels:
  - Canadian brand name “Janssen COVID-19 Vaccine”

    - Drug Identification Number (DIN)
    - Name and address of the Canadian DIN holder
    - Name and address of the Canadian importer and distributor
    - All corresponding text in French
- At the time of this communication, the storage and expiry date instructions for the Janssen COVID-19 Vaccine with EU English-only labels are **NOT** included in the Canadian Product Monograph available on Health Canada's Drug Product Database, or the federal government's covid-vaccine.canada.ca website.
- **Specific storage and expiry date instructions should be followed:**
    - The vaccine can be stored and transported frozen at -25°C to -15°C.
    - The expiry date is printed on the vial and carton after "EXP".
    - After thawing, the vaccine can be stored and transported at 2°C to 8°C for a single period of up to 6 months, not exceeding the original expiry date (EXP) on the labels.
    - Upon thawing the product to 2°C to 8°C, the updated expiry date must be written on the carton and vial label. The vaccine should be used or discarded by the updated expiry date. The original expiry date should be made unreadable.
- The Storage, Expiry, Dosage and Administration Guide, developed by Janssen Inc., should be used as a reference along with this communication for the storage and expiry date instructions for the Janssen COVID-19 Vaccine with EU English-only labels.
- The Janssen guide can be accessed by scanning the QR code on the carton, or visiting http://www.covid19vaccinejanssen.com as referenced on the carton. It can also be accessed by visiting https://www.janssenmedicalinformation.ca/covid-19_vaccine_resources, or by contacting Janssen Inc. Medical Information at 1-800-565-4008 (toll free), or 1-908-455-9922 (US toll).

Action taken by Health Canada
Health Canada is working with Janssen Inc. to develop Canadian-specific vial and carton labels in French and English.

Health Canada is communicating this important safety information from Janssen Inc. to healthcare professionals and Canadians via the Recalls and Safety Alerts Database on the Healthy Canadians Web Site. This communication will be further distributed through the MedEffect™ e-Notice email notification system, as well as through social media channels, including LinkedIn and Twitter.

Report health or safety concerns
Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any serious or unexpected side effects in patients receiving Janssen COVID-19 Vaccine should be reported to your

local Health Unit or Janssen Inc.

Janssen Inc.
19 Green Belt Drive
Toronto, ON
M3C 1L9

To correct your mailing address or fax number, contact Janssen Inc. at 1-800-565-4008 (toll free) or 1-908-455-9922 (US toll).

If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (https://www.canada.ca/en/public-health/services/immunization/reporting-adverse-events-following-immunization/form.html) and send it to your local Health Unit.

For other health product inquiries related to this communication, contact Health Canada at:

Biologic and Radiopharmaceutical Drugs Directorate
E-mail: brdd.dgo.enquiries@hc-sc.gc.ca

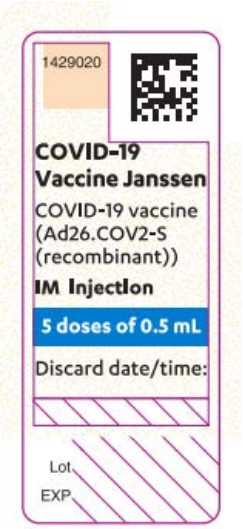
Original signed by

Katherine Tsokas
Vice President Regulatory AffairsJanssen Inc.

Appendix A – Vial and carton labels for Janssen COVID-19 Vaccine with English-only labelling

Vial

EU White Label: Vial label



COVID-19 Vaccine Janssen
COVID-19 vaccine
(Ad26.COV2-S
(recombinant))
IM Injection
5 doses of 0.5 mL
Discard date/time:

Lot
EXP

Carton

EU White Label: Carton label

10 multidose vials
Each vial contains 5 doses of 0.5 mL
COVID-19 Vaccine Janssen
suspension for injection
COVID-19 vaccine
(Ad26.COV2-S (recombinant))
Intramuscular use

Excipients: 2-hydroxypropyl-β-cyclodextrin (HBCD), citric acid monohydrate, ethanol, hydrochloric acid, polysorbate-80, sodium chloride, sodium hydroxide, trisodium citrate dihydrate, water for injections

Store at -25°C to -15°C. Can also be stored at 2°C to 8°C.
See package leaflet for shelf-life at 2°C to 8°C.

Store vial in the original carton to protect from light and to record expiry date when stored at 2°C to 8°C, below:

Read the package leaflet before use:
Scan this QR code using your device or go to **www.covid19vaccinejanssen.com**

SN
EXP
Lot
GTIN 05413968119794

Janssen COVID-19 Vaccine

Storage, Expiry, Dosing and Administration

Janssen COVID-19 Vaccine (SARS-CoV-2 Vaccine [Ad26.COV2.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.

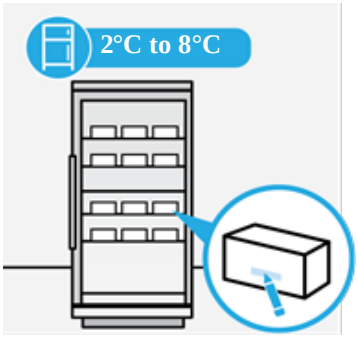
This vaccine should be handled by a healthcare professional using aseptic technique to ensure the sterility of each dose.

- 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



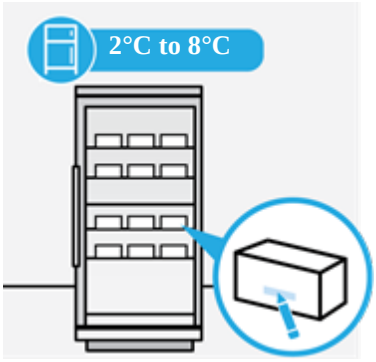
Store in a freezer

- 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 carton after "EXP".

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 6 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 carton and the vaccine should be used or discarded by the updated expiry date. **The original expiry date should be made unreadable**.

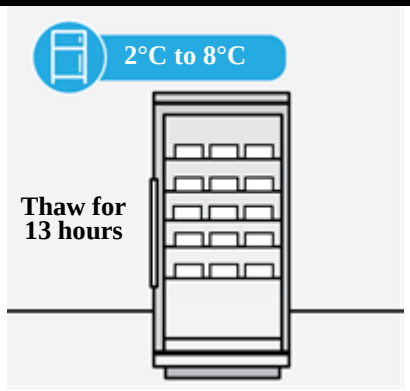
IF YOU RECEIVE YOUR VACCINE THAWED AT 2°C to 8°C you should store in a refrigerator:



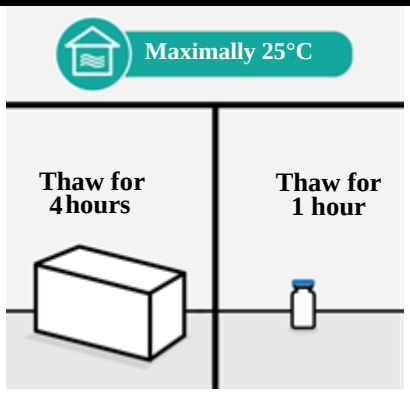
Do not re-freeze if the product is received already thawed at 2°C to 8°C.

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

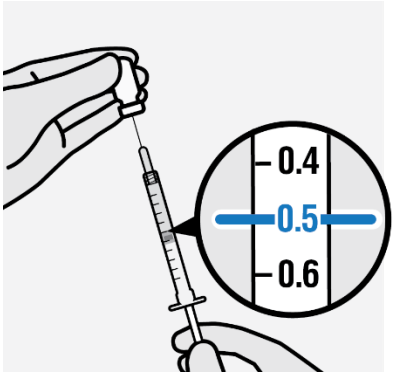
- Janssen COVID-19 Vaccine is a colorless to slightly yellow, clear to very opalescent suspension (pH 6-6.4).
- The vaccine should be inspected visually for particulate matter and discoloration prior to administration.
- The vial should be inspected visually for cracks or any abnormalities, such as evidence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

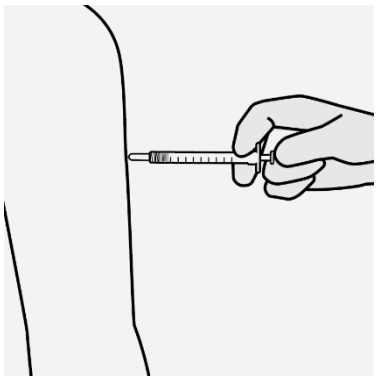
- Before administering a dose of vaccine, swirl the vial gently **in an upright position for 10 seconds**.
- **Do not** shake.



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.

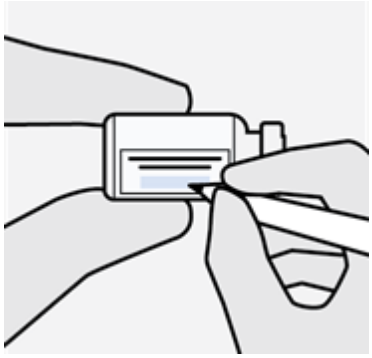
A maximum of 5 doses can be withdrawn from the multidose vial. Discard any remaining vaccine in the vial after 5 doses have been extracted.



Inject 0.5 mL

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

e. Storage after first puncture



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**.

Discard if vaccine is not used within this time.

Indication:
Janssen COVID-19 Vaccine (SARS-CoV-2 Vaccine [Ad26.COV2.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 Capillary Leak Syndrome (CLS).

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

Additional Q&A's: meeting on Janssen COVID 19 Vaccine and Materials Nov 2, 2021

1. **Which Product Monograph should be referenced?**
    a. Please reference current Product Monograph dated Aug 18, 2021. As this PM has not been updated for -20C product, please refer to Storage, Expiry, Dosing and Administration guide for information on thawing frozen product.

2. **Is the product name changing?**
    a. No, the product name is not changing, however product from EU will have name **COVID-19 Vaccine Janssen** on packaging

3. **What is the DIN?**
    a. **DIN 02513153**

4. **What is the outline of package dimensions?**
    a. 93mm x 38mm x 54 mm
    Approximately 10cm x 4cm x 5.5cm

5. The timeframes regarding product handling:

- **Storage of punctured vials/filled syringes in the fridge vs. room temperature**
    a. After the first dose has been withdrawn, the punctured vial/filled syringe can be held at 2°C to 8°C for up to 6 hours **or** at room temperature (maximally 25°C) for up to 3 hours.
    b. The vaccine should be discarded if not used within these times
        i. 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).
            - If you do not reach the 3-hour time limit at room temperature, you may transfer the punctured vial to a refrigerated storage unit between 2°C to 8°C for the remaining time, up to 3 hours. For example, a vial held at room temperature for 1 hour after first puncture can be stored in the refrigerator (between 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.
        ii. If stored refrigerated after the first puncture, the vaccine can be moved to room temperature for brief periods of time for dose withdrawal. This does not impact the maximum 6-hour hold period in the refrigerator.
- **Stability of Punctured vial/filled syringes during transport (i.e. in a vehicle).**
    a. The vaccine should preferably be used immediately after 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.

- **Stability of unpunctured vial at 9°C to 25°C**
    a. Unopened vaccine is stable for a total of 12 hours at 9°C to 25°C. The 12 hours at this temperature is considered cumulative (e.g. a single 12-hour duration or multiple shorter durations adding up to 12 hours cumulatively).
    b. It is not a recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions.