Important Safety Information on the Authorization of Janssen COVID-19 Vaccine with English-only Vial and Carton Labels

2021/03/05

IMPORTANT: **Access to Canadian-specific labelling and expiration date information during the initial distribution of the Janssen COVID-19 Vaccine.**

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.

Innomar Strategies Inc. (Logistics Services Provider) is distributing Janssen COVID-19 Vaccine to vaccination locations where administration of the vaccine will occur, as outlined by provincial and territorial governments and public health authorities.

Key messages

- **On March 5, 2021, Janssen COVID-19 Vaccine (DIN 02513153) was authorized in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.**
- **Janssen COVID-19 Vaccine is indicated for active immunization for the prevention of coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.**
- **At this time, Janssen Inc. is providing vaccine supplies with global English-only labels on the vials and cartons in order to expedite the global distribution of Janssen COVID-19 Vaccine (see Appendix A).**
- **Health Canada has imposed terms and conditions on the authorization of the vaccine requiring that Janssen Inc. develop Canadian-specific labelling in French and English for the vaccine vials and cartons. Janssen Inc. has agreed that vaccine supplies with Canadian-specific labelling in French and English will be available as soon as feasible given the need to ensure a rapid global supply of the vaccine.**

- **Healthcare professionals are advised that:**
  - **Important Canadian-specific information is absent from the vial and carton labels (see the Information for healthcare professionals section).**
  - **The expiration date is not printed on vial or carton labels. The date printed on the outer carton is the product manufacture date (Mfg. date). The expiration date can be obtained by scanning the QR code on the outer carton or carton insert using a smart device, by going to www.vaxcheck.jnj, or by calling: 1-800-565-4008 (toll free) or 1-908-455-9922 (US toll). Janssen Inc. will also distribute an instruction sheet to provide directions on accessing the expiration date and recording the expiration date information to prevent confusion post-recording.**
  - **The Canadian Product Monograph, which is available in French and English on Health Canada's Drug Product Database, the federal government's covid-vaccine.canada.ca website, or at www.vaxcheck.jnj, should be referenced for complete product information.**
  - **Other Canadian-specific labelling information can be accessed at www.vaxcheck.jnj. This information is also available on the federal government's covid-vaccine.canada.ca website.**
  - **Janssen Inc. will develop Health Canada approved vial and carton labels in French and English, and make them available at www.vaxcheck.jnj in the coming weeks.**
  - **Paper copies of the Canadian Product Monograph and Patient Handout in French and English will be available as needed for healthcare professionals and patients.**
  - **Paper copies of the Health Canada approved vial and carton labels in French and English will also be made available as needed, once finalized in the coming weeks, for reference by healthcare professionals.**

What is the issue?

Janssen COVID-19 Vaccine was authorized for use in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. As an extraordinary measure to provide earlier access to vaccine supplies in the context of the global pandemic, Janssen Inc. is providing, at this time, vaccine vials and cartons labelled with the global label. This label is presented in English-only and is missing some important Canadian-specific information normally found on Health Canada approved labels, including the expiration date (see the Information for healthcare professionals section).

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.

Given the public health emergency resulting from the current pandemic, Health Canada has authorized the importation, sale, and advertising of Janssen COVID-19 Vaccine with vial and carton labels that are in English-only, and that do not include an expiration date, for the initial global distribution of the vaccine. This allows earlier access to the vaccine for the Canadian population ahead of the Canadian-labelled Janssen COVID-19 Vaccine being available, and facilitates the global deployment of this vaccine across many countries given the high demand.

Janssen COVID-19 Vaccine with global labels is the same as the Health Canada authorized Janssen COVID-19 Vaccine in all aspects (i.e., formulation, strength, route of administration) and should be used in Canada for the same indication and vaccination schedule. The Canadian Product Monograph for Janssen COVID-19 Vaccine, which is approved by Health Canada and available in French and English, should be used for complete product information. The Product Monograph is available on Health Canada's Drug Product Database, on the federal government's covid-vaccine.canada.ca website, or at www.vaxcheck.jnj.

The use of Janssen COVID-19 Vaccine is permitted under an interim authorization in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.

Patients should be advised of the nature of the authorization.

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 labelled in English-only for a limited time period (see Appendix A).

Healthcare professionals are advised that:

- The approved Canadian Product Monograph, which is available in French and English on Health Canada's Drug Product Database, the federal government's covid-vaccine.canada.ca website or at www.vaxcheck.jnj, should be used for complete product information.
- The following important Canadian-specific information is absent from the vial

and carton labels:
    - 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
    - expiration date
- The expiration date is not printed on vial or carton labels. The date printed on the outer carton is the product manufacture date (Mfg. date). The expiration date can be obtained by scanning the QR code on the outer carton or carton insert using a smart device, by going to www.vaxcheck.jnj, or by calling: 1-800-565-4008 (toll free) or 1-908-455-9922 (US toll). Janssen Inc. will also distribute an instruction sheet to provide directions on accessing the expiration date and recording the expiration date information to prevent confusion post-recording.
- The Canadian-specific labelling information can be accessed at www.vaxcheck.jnj. This information is also available on the federal government's covid-vaccine.canada.ca website.
- Paper copies of the Canadian Product Monograph and Patient Medication Information will be made available to healthcare professionals, as needed.
- Janssen Inc. will develop Health Canada approved vial and carton labels in French and English, and make them available on the www.vaxcheck.jnj website in the coming weeks for reference by healthcare professionals. Once finalized, a paper copy of these labels will also be made available for reference as needed.
- For any medical information questions, contact Janssen Inc. Medical Information at 1-800-565-4008 (toll free), or 1-908-455-9922 (US toll), or by visiting www.janssenmedicalinformation.ca.

Action taken by Health Canada

On September 16, 2020, Canada's Minister of Health approved an Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 to expedite the authorization for the importation, sale, and advertising of drugs used in relation to COVID-19 while taking into consideration urgent public health needs. The Interim Order will expire after one year. Health Canada authorized the use of Janssen COVID-19 Vaccine under the Interim Order on March 5, 2021, and this vaccine has been added to the "List of authorized drugs, vaccines and expanded indications" for COVID-19.

Health Canada is permitting the use of global English-only carton and vial labels without expiration dates printed on the labels for a limited period. Health Canada has imposed terms and conditions requiring Janssen Inc. to provide vaccine supplies with Canadian-specific labels as soon as possible. Health Canada has made full labelling information available in French and English on the federal government's covid-vaccine.canada.ca website.

Health Canada has worked with Janssen Inc. to prepare this alert for the Janssen COVID-19 Vaccine. Health Canada is communicating this important safety information 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: hc.brdd.dgo.enquiries.sc@canada.ca

Original signed by

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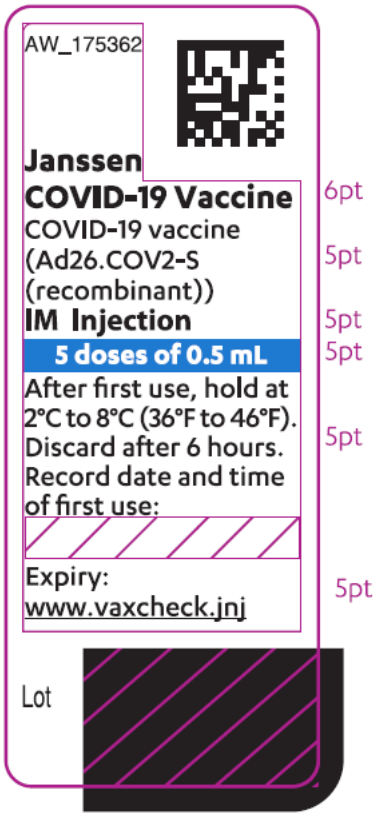
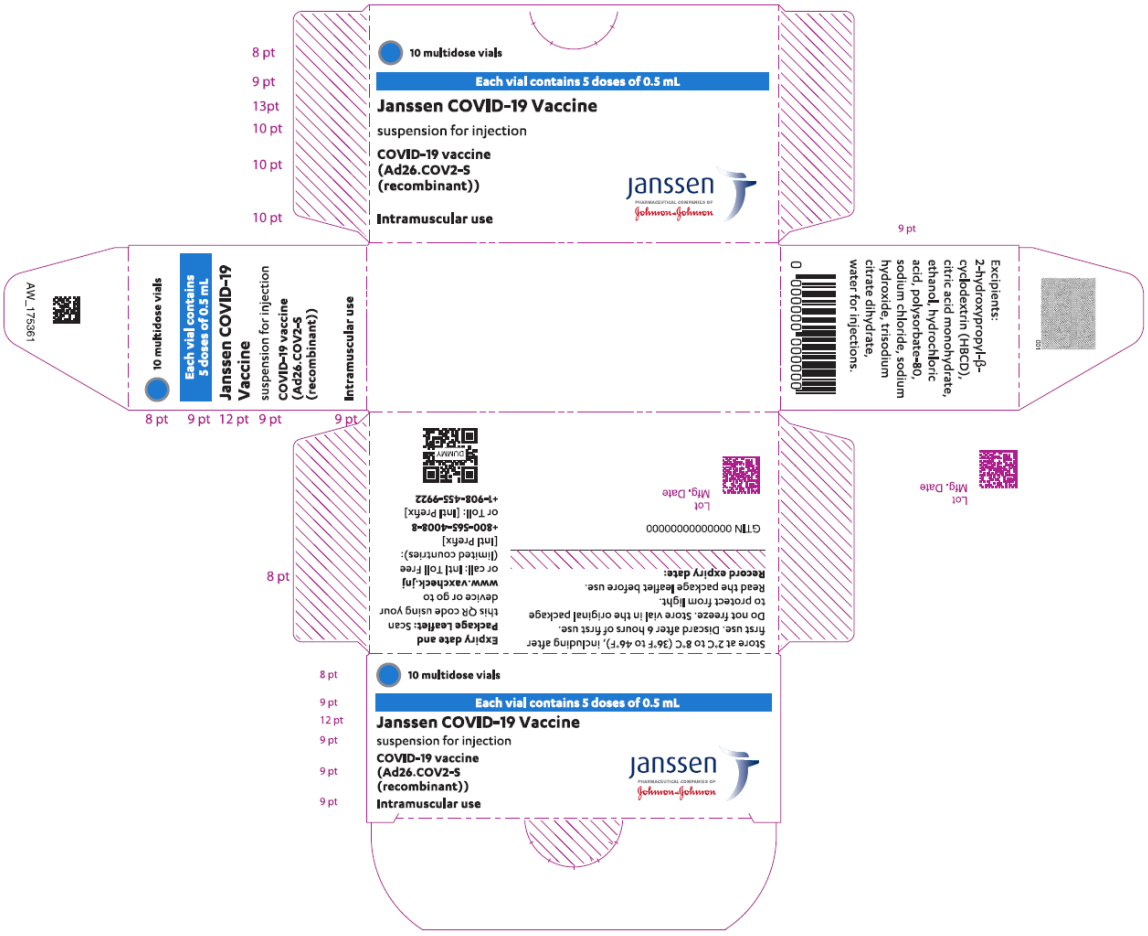
Appendix A – Vial and carton labels for Janssen COVID-19 Vaccine with English-only labelling

Vial



Janssen COVID-19 Vaccine
COVID-19 vaccine
(Ad26.COV2-S) (recombinant))
IM Injection
5 doses of 0.5 mL
After first use, hold at 2°C to 8°C (35°F to 46°F).
Discard after 6 hours.
Record date and time of first use:
Expiry:
www.vaxcheck.jnj
Lot:

Carton



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

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 2°C to 8°C (35°F to 46°F), including after first use. Discard after 6 hours of first use. Do not freeze. Store vial in the original package to protect from light.
Read the package leaflet before use.
Record expiry date:

Expiry date and package leaflet: Scan this QR code using your device or go to www.vaxcheck.jnj or call Intl toll free (limited countries):
[intl prefix] +800-565-4008-8 Or Toll: [Intl prefix] +1-908-455-9922