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

2021/04/26

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

Please note: Important safety information on the Janssen COVID-19 Vaccine and the risk of thrombosis with thrombocytopenia was also published on April 26, 2021.

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

- **Further to the March 5, 2021 authorization of the Janssen COVID-19 Vaccine, Janssen Inc. is providing vaccine supplies with two types of English-only vial and carton labels (referred to herein as Non-US White Label and Non-US Orange Label; see Appendix A) in order to expedite the distribution of the vaccine in Canada.**
- **There are some key differences between the Non-US White Label and Non-US Orange Label (see Table 1 in the Information for healthcare professionals section). However, both products are the same as the Health Canada authorized Janssen COVID-19 Vaccine in all other aspects (i.e., formulation, strength, route of administration).**
- **Healthcare professionals are advised that:**
  - **Important Canadian-specific information is absent from both types of English-only vial and carton labels (see the Information for healthcare professionals section).**
  - **The brand name, the method of determining the expiry date and**

the method for recording date and time on the vial label differs with the type of English-only label (see Table 1 in the Information for healthcare professionals section).

- **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 for reference by healthcare professionals.**
- **Paper copies of the Canadian Product Monograph and the Patient Medication Information, 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 vaccine vials and cartons labelled with two types of English-only labels (Non-US Orange and Non-US White labels). These labels are presented in English-only and are missing some important Canadian-specific information normally found on Health Canada approved labels, including the expiry date on some labels (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 two types of vial and carton labels that are in English-only, and that may not include an expiry date, for the initial 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. On March 5, 2021, Health Canada permitted the use of Janssen COVID-19 Vaccine with one type of English-only vial and carton label (Non-US White Label). On April 23, 2021, Health Canada permitted the use of Janssen COVID-19 Vaccine with another type of English-only vial and carton label (Non-US Orange Label).

There are some differences between the Non-US White Label and Non-US Orange Label. However, both products are the same as the Health Canada authorized Janssen COVID-19 Vaccine 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 labelled with two types of English-only labels 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
    - expiry date (absent from Non-US White labelled product)
- **The brand name, the method of determining the expiry date and the method for recording date and time on the vial label differs with the type of English-only label:**

TABLE 1 Janssen COVID-19 Vaccine		
	Non-US Orange Label – Product with an orange panel sticker on the carton	**Non-US White Label – Product with all white carton panels**
Brand name	COVID-19 Vaccine Janssen	Janssen COVID-19 Vaccine
Method of determining the expiry date	• The correct expiry date is printed on the orange panel of the carton. • The expiry date on the vial label should be disregarded because it reflects the expiry of the product when stored in a frozen state and not the expiry of the product when received by immunization centres (i.e., stored at 2 to 8°C). • The information on the package insert contains non-Canadian specific information and should also be disregarded.	• The expiry date is not printed on the carton or vial label. The date printed on the carton is the product manufacture date (Mfg. date). • The expiry date can be obtained by scanning the QR code on the carton or leaflet 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 and recording the expiry date information.
Method of recording date and time on the vial label	The vial label includes a space for recording date and time to discard after puncture.	The vial label includes a space for recording date and time of first use.

- 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 the 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 two types of English-only carton and vial labels, without the expiry date printed on one type of label, 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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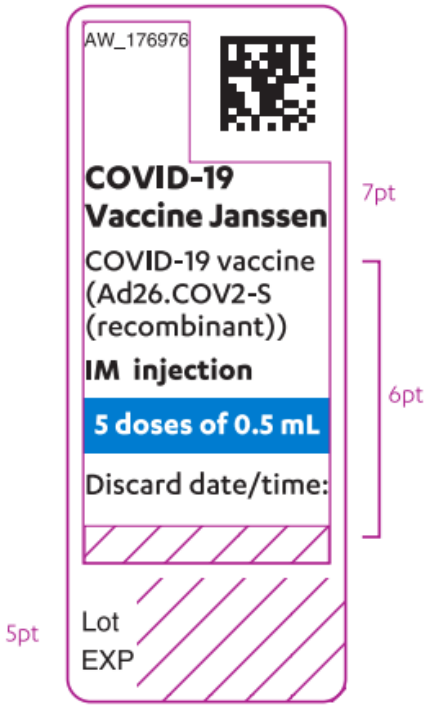
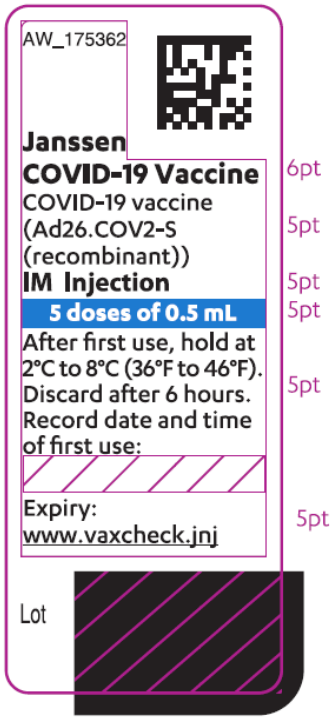
Vice President Regulatory Affairs
Janssen Inc.

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

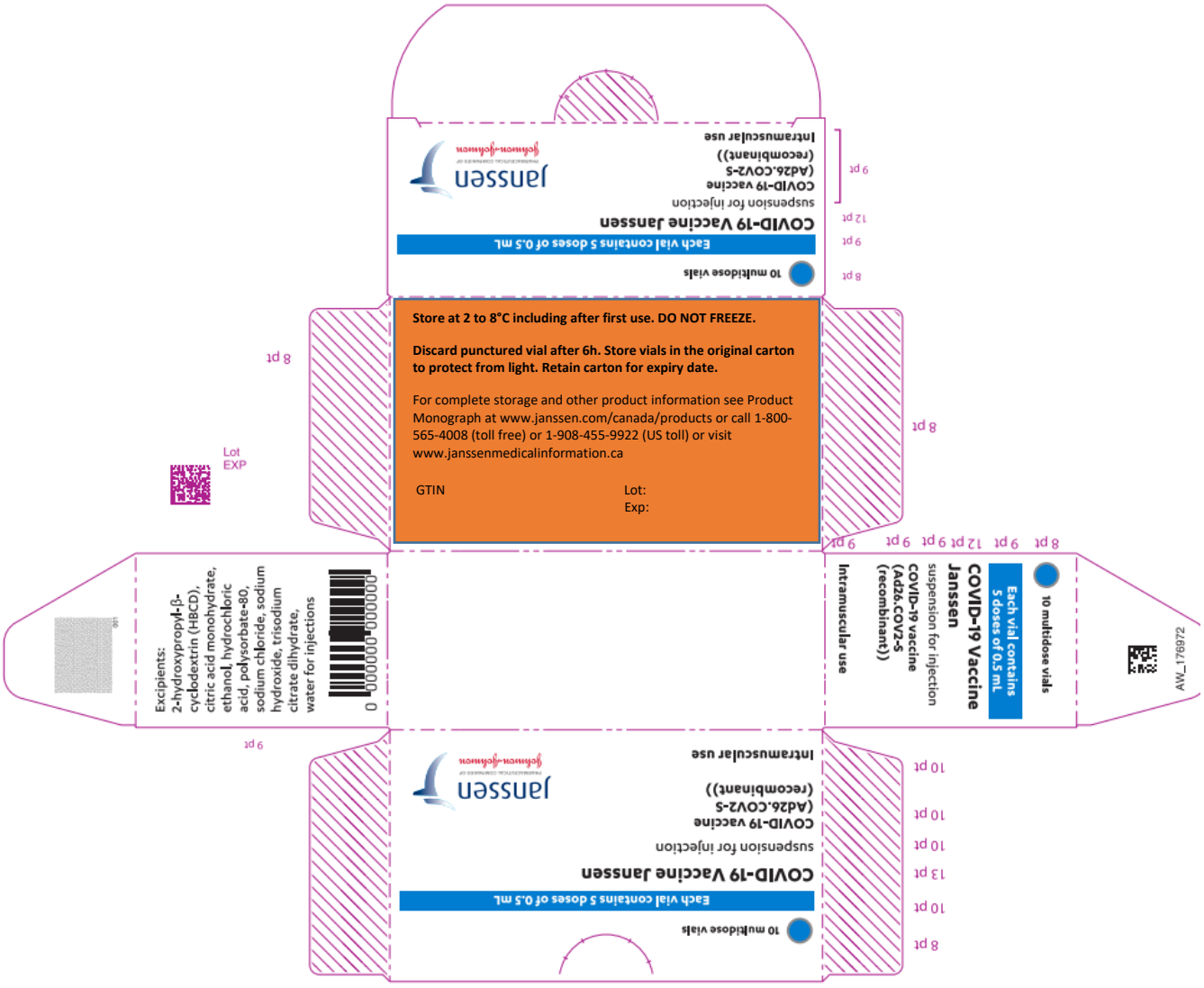
Vial

Non-US Orange Label – Product with an orange panel sticker on the carton: Vial label	**Non-US White Label – Product with all white carton panels:** 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 EXT	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 (36°F to 46°F). Discard after 6 hours. Record date and time of first use: Expiry: www.vaxcheck.jnj Lot

Carton

Non-US Orange Label – Product with an orange panel sticker on the carton:

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

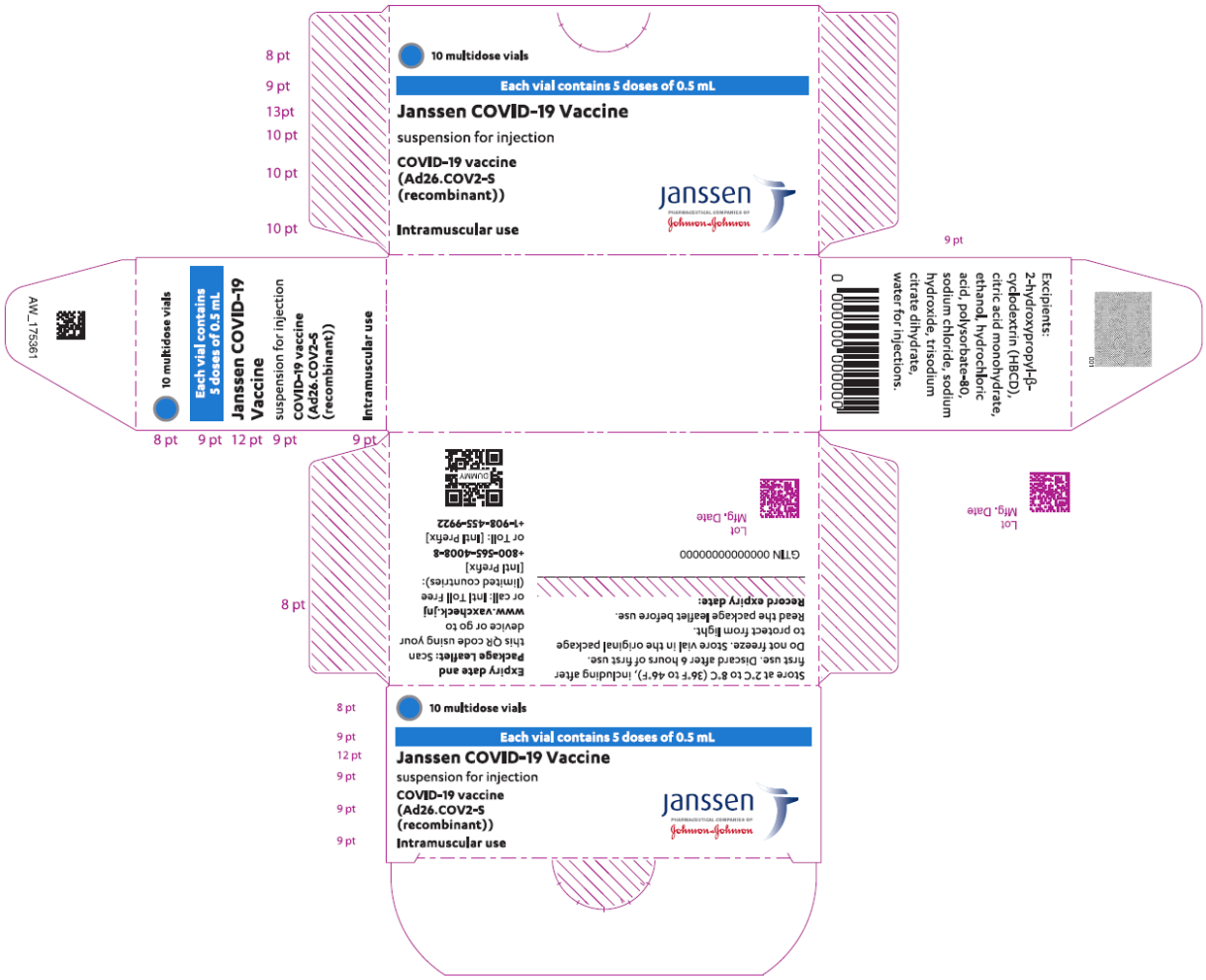
Store at 2 to 8°C including after first use. DO NOT FREEZE.

Discard punctured vial after 6h. Store vials in the original carton to protect from light. Retain carton for expiry date.

For complete storage and other product information see Product Monograph at www.janssen.com/canada/products or call 1-800-565-4008 (toll free) or 1-908-455-9922 (US toll) or visit www.janssenmedicalinformation.ca

GTIN
Lot:
EXP:

Non-US White – Product with all white carton panels: Carton label



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 (36°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:

GTIN
Lot
Mfg. 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