

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



2021/11/18

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

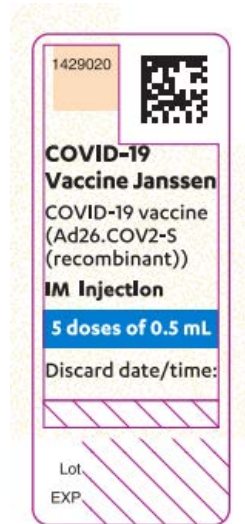


Katherine Tsokas
Vice President Regulatory Affairs
Janssen Inc.

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.COVS2-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