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

2021/02/26

IMPORTANT: **Access to Canadian-specific labelling information during the initial distribution of the AstraZeneca COVID-19 Vaccine.**

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

AstraZeneca Canada Inc. (AstraZeneca) (the Canadian importer and distributor) is initially distributing AstraZeneca COVID-19 Vaccine doses directly to locations where administration of the vaccine will occur, as outlined by provincial and territorial governments and public health authorities.

Key messages

- **On February 26, 2021, AstraZeneca COVID-19 Vaccine (DIN 02510847 [10 doses, 5 mL]) was authorized in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.**
- **AstraZeneca COVID-19 Vaccine is indicated for active immunization of individuals 18 years of age and over for the prevention of coronavirus disease 2019 (COVID-19).**
- **At this time, AstraZeneca is providing vaccine supplies with COVAX English-only labels on the vials and cartons (see Appendix A) in order to expedite the distribution of AstraZeneca COVID-19 Vaccine in Canada. Vaccine supply with Canadian-specific information will be implemented by June 2021.**
- **Healthcare professionals are advised that:**
    - **Important Canadian-specific information is absent from the COVAX vial and carton labels (see 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, and at**

www.AZCOVID-19.com, should be referenced for complete product information.

- **The Canadian-specific labelling information in French and English can be accessed at www.AZCOVID-19.com. This information is also available on the federal government's covid-vaccine.canada.ca website.**
- **AstraZeneca has developed Health Canada approved vial and carton labels in French and English (see Appendix B), and has made them available on the www.AZCOVID-19.com website. The labels are also available on the federal government's covid-vaccine.canada.ca website.**
- **Paper copies of the Canadian Product Monograph, including the Patient Medication information, in French and English will be made available at the points of use 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 (see Appendix B) for reference by healthcare professionals at the points of use.**

What is the issue?
AstraZeneca 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, AstraZeneca is providing, at this time, vaccine vials and cartons labelled with the COVAX labels. These labels are presented in English-only and are missing some important Canadian-specific information normally found on Health Canada approved labels (see the Information for healthcare professionals section).

Products affected
AstraZeneca COVID-19 Vaccine, COVID-19 Vaccine (ChAdOx1-S [recombinant]), 5 mL solution for intramuscular injection, multiple dose vials.
Each vial contains **10 doses** (each dose is 0.5 mL).
DIN: 02510847

Manufacturer: AstraZeneca Canada Inc.
Canadian Importer and Distributor: AstraZeneca Canada Inc.

Background information
AstraZeneca COVID-19 Vaccine is indicated for active immunization of individuals 18 years of age and over for the prevention of coronavirus disease 2019 (COVID-19).

Given the public health emergency resulting from the current pandemic, Health Canada has authorized the importation, sale, and advertising of AstraZeneca

COVID-19 Vaccine with vial and carton labels that are in English-only for the initial distribution of the vaccine. This allows earlier access to the vaccine for the Canadian population ahead of the Canadian-labelled AstraZeneca COVID-19 Vaccine being available, and facilitates the global deployment of this vaccine across many countries given the high demand.

AstraZeneca COVID-19 Vaccine with COVAX labels is the same as the Health Canada authorized AstraZeneca COVID-19 Vaccine in all aspects (i.e., formulation, strength, route of administration) and should be used in Canada for the same indication and per the same vaccination schedule. The Canadian Product Monograph for AstraZeneca 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.AZCOVID-19.com.

AstraZeneca has also developed Health Canada approved vial and carton labels in French and English (see Appendix B), and has made them available on the www.AZCOVID-19.com website. The labels are also available on the federal government's covid-vaccine.canada.ca website. Vaccines with Canadian-specific labelling information will be implemented by June 2021.

The use of AstraZeneca 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 AstraZeneca COVID-19 Vaccine for Canadians, AstraZeneca will provide product vials and cartons labelled in English-only for a limited time period.

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.AZCOVID-19.com, should be used for complete product information.
- The following important Canadian-specific information is absent from the COVAX 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
- The brand name of the vaccine on the COVAX labels is COVID-19 Vaccine AstraZeneca.

- The vial and/or carton labels for the initial supplies of vaccines may include the text "COVAX Supply" and a QR code. This should be disregarded as this is not relevant to the Canadian authorization and the QR code leads to non-Canadian information.
- The Canadian-specific labelling information, in French and English, can be accessed at www.AZCOVID-19.com. This information is also available on the federal government's covid-vaccine.canada.ca website.
- Paper copies of the Canadian Product Monograph, including the Patient Medication Information, in French and English will be made available at the points of use for this vaccine.
- AstraZeneca has developed French and English vial and carton labels that Health Canada has approved (see Appendix B), and has made them available on the www.AZCOVID-19.com website for reference by healthcare professionals. The labels are also available on the federal government's covid-vaccine.canada.ca website.
- Paper copies of the Health Canada approved vial and carton labels in French and English will also be made available (see Appendix B), for reference by healthcare professionals at the points of use.
- For any product or general inquiries, contact AstraZeneca Medical Information at 1-800-668-6000, or email medinfo.canada@astrazeneca.com.

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 AstraZeneca COVID-19 Vaccine under the Interim Order on February 26, 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 COVAX English-only labels for a limited period. Health Canada has imposed terms and conditions requiring AstraZeneca to provide vaccine supplies with Canadian-specific labels as soon as possible. Vaccines with Canadian-specific labelling information will be implemented by June 2021. 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 AstraZeneca to prepare this alert for the AstraZeneca COVID-19 Vaccine and 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 AstraZeneca COVID-19 Vaccine should be reported to your local Health Unit or AstraZeneca.

AstraZeneca Canada Inc.
1004 Middlegate Road, Suite 5000
Mississauga
Ontario L4Y 1M4

To correct your mailing address or fax number, contact AstraZeneca at 1-800-668-6000

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. Alternatively, you can report adverse events to AstraZeneca online at https://contactazmedical.astrazeneca.com.

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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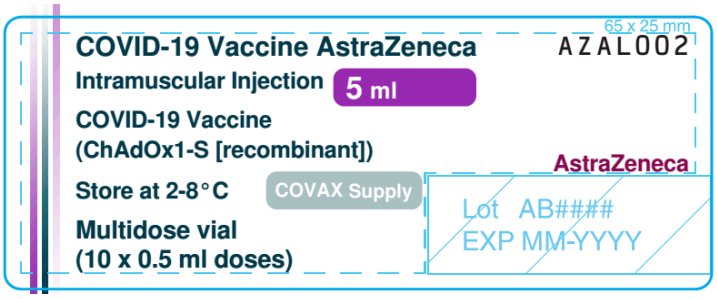
Vice President, Scientific Affairs

- Appendix A: Vial and carton labels for 5 mL AstraZeneca COVID-19 Vaccine with English-only labelling (COVAX-labelled supply)
- Appendix B: Vial and carton labels for 5 mL AstraZeneca COVID-19 Vaccine with Health Canada approved English and French labelling (Canadian-labelled supply)

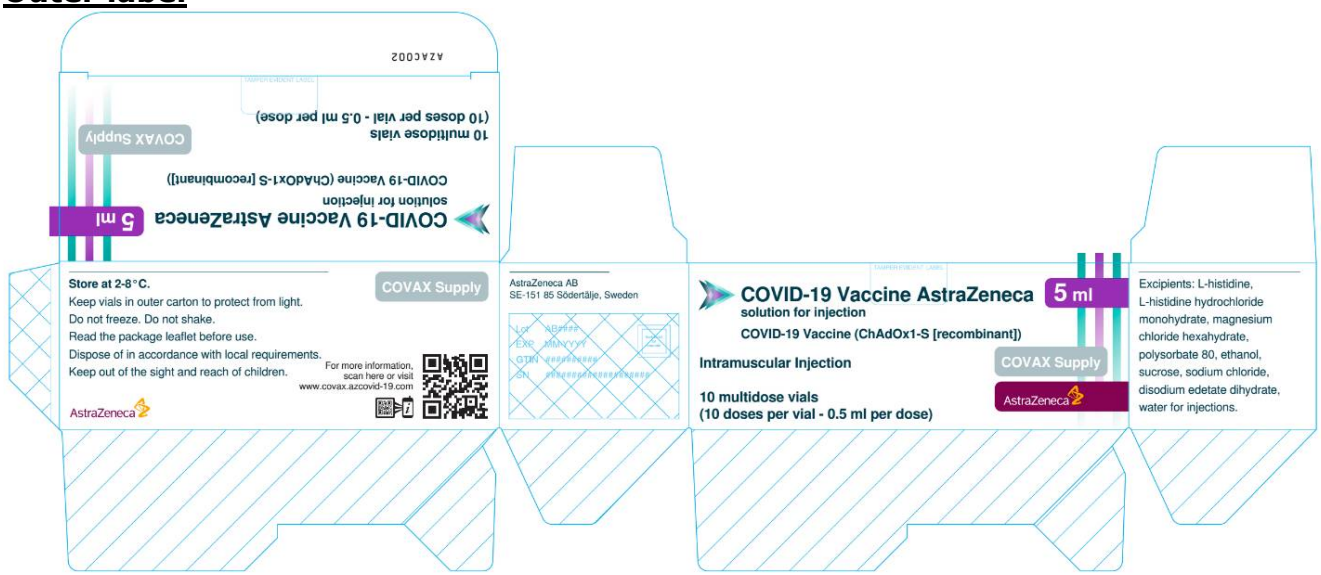
Appendix A: Vial and carton labels for AstraZeneca COVID-19 Vaccine with English-only labelling (COVAX-labelled supply)

COVAX supply (5 mL – 10 doses)

Inner label



Outer label



Inner label
COVID-19 Vaccine AstraZeneca
Intramuscular Injection 5 ml
COVID-19 Vaccine (ChAdOx1-S [recombinant])
Store at 2-8°C
Multidose vial (10 x 0.5 ml doses)
COVAX Supply
AstraZeneca

Outer label
COVID-19 Vaccine AstraZeneca

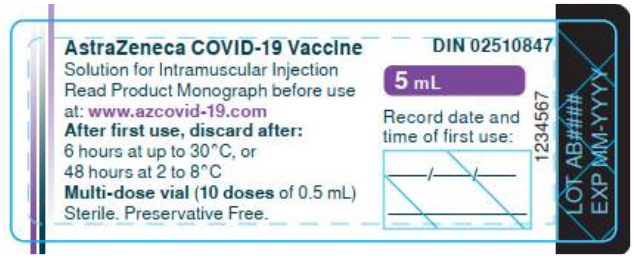
COVAX supply (5 mL – 10 doses)

solution for injection 5 ml
COVID-19 Vaccine (ChAdOx1-S [recombinant])
Intramuscular Injection
10 multidose vials (10 doses per vial - 0.5 ml per dose)
COVAX Supply
AstraZeneca
Excipients: L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80, ethanol, sucrose, sodium chloride, disodium edetate dihydrate, water for injections.
Store at 2-8°C.
Keep vials in outer carton to protect from light.
Do not freeze. Do not shake.
Read the package leaflet before use.
Dispose of in accordance with local requirements.
Keep out of the sight and reach of children.
For more information, scan here or visit
www.covax.azcovid-19.com
AstraZeneca AB
SE-151 85 Södertälje, Sweden

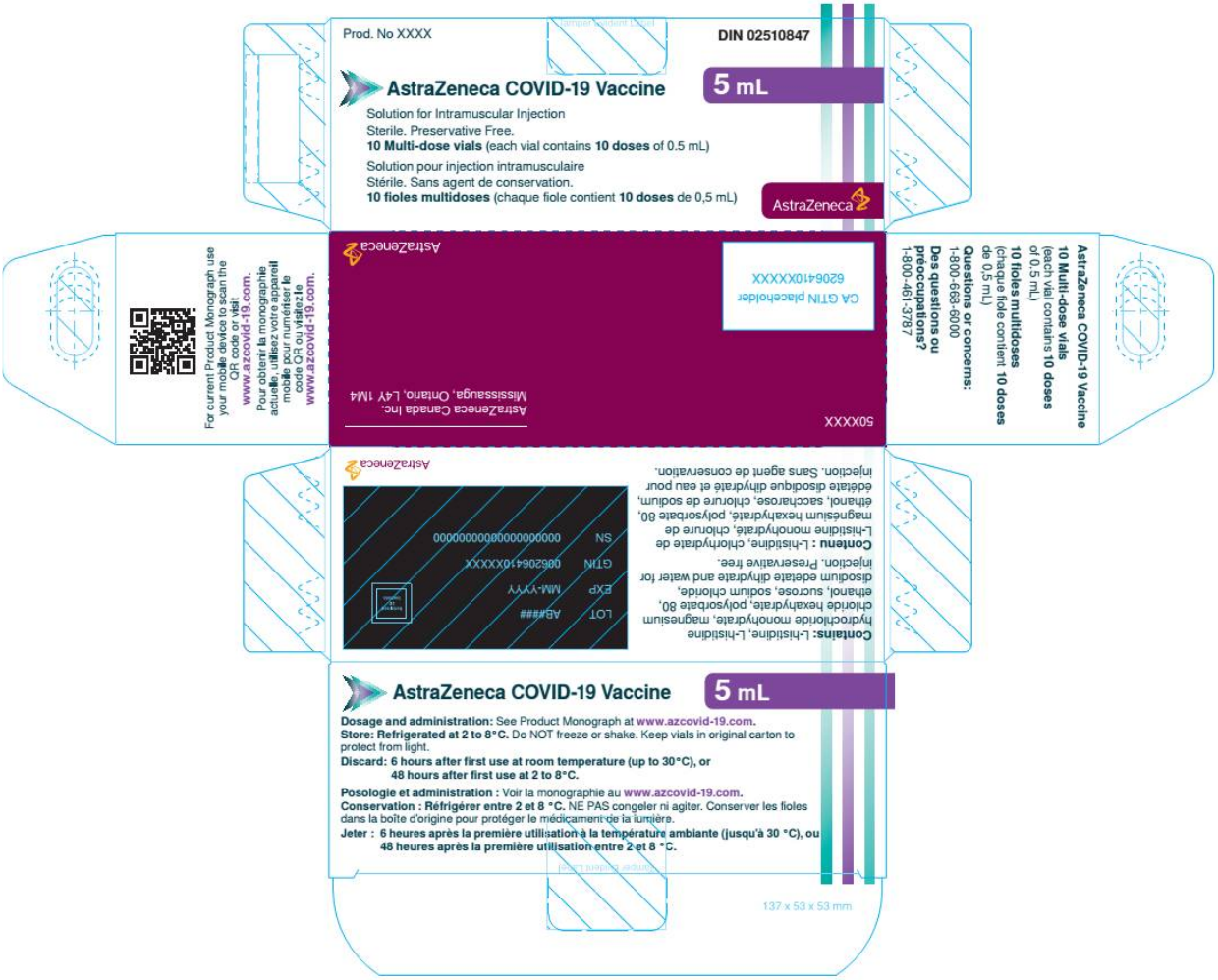
Appendix B: Vial and carton labels for AstraZeneca COVID-19 Vaccine with Health Canada approved English and French labelling (Canadian-labelled supply)

CANADIAN supply (5 mL – 10 doses)

Inner label



Outer label



CANADIAN supply (5 mL – 10 doses)

Inner label
AstraZeneca COVID-19 Vaccine
DIN 02510847
Solution for Intramuscular Injection 5 mL
Read Product Monograph before use
at: www.azcovid-19.com
After first use, discard after:
6 hours at up to 30°C, or
48 hours at 2 to 8°C
Multi-dose vial (10 doses of 0.5 mL)
Sterile. Preservative Free.
Record date and time of first use:

Outer label
Prod. No XXXX DIN 02510847
AstraZeneca COVID-19 Vaccine
Solution for Intramuscular Injection 5 mL
Sterile. Preservative Free.
10 Multi-dose vials (each vial contains 10 doses of 0.5 mL)
Solution pour injection intramusculaire
Stérile. Sans agent de conservation.
10 fioles multidoses (chaque fiole contient 10 doses de 0,5 mL)
AstraZeneca

Dosage and administration: See Product Monograph at www.azcovid-19.com.
Store: Refrigerated at 2 to 8°C. Do NOT freeze or shake. Keep vials in original carton to protect from light.
Discard: 6 hours after first use at room temperature (up to 30°C), or
48 hours after first use at 2 to 8°C.
Posologie et administration : Voir la monographie au www.azcovid-19.com.
Conservation : Réfrigérer entre 2 et 8 °C. NE PAS congeler ni agiter. Conserver les fioles dans la boîte d'origine pour protéger le médicament de la lumière.
Jeter : 6 heures après la première utilisation à la température ambiante (jusqu'à 30 °C), ou 48 heures après la première utilisation entre 2 et 8 °C.

Contains: L-histidine, L-histidine hydrochloride monohydrate, magnesium chloride hexahydrate, polysorbate 80, ethanol, sucrose, sodium chloride, disodium edetate dihydrate and water for injection. Preservative free.
Contenu : L-histidine, chlorhydrate de L-histidine monohydraté, chlorure de magnésium hexahydraté, polysorbate 80, éthanol, saccharose, chlorure de sodium, édétate disodique dihydraté et eau pour injection. Sans agent de conservation.

Questions or concerns: 1-800-668-6000
Des questions ou préoccupations? 1-800-461-3787

CANADIAN supply (5 mL – 10 doses)
For current Product Monograph use your mobile device to scan the QR code or visit www.azcovid-19.com. Pour obtenir la monographie actuelle, utilisez votre appareil mobile pour numériser le code QR ou visitez le www.azcovid-19.com. AstraZeneca Canada Inc. Mississauga, Ontario, L4Y 1M4