

**Important Safety Information on
the Importation of AstraZeneca COVID-19 Vaccine
with English-only Vial and Carton Labels (US-Labelled Supply)**



2021/03/31

IMPORTANT: Access to Canadian-specific labelling information during the initial distribution of the AstraZeneca COVID-19 Vaccine (US-labelled vaccine supplies).

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

- **Further to the February 26, 2021 authorization of the AstraZeneca COVID-19 Vaccine in accordance with the [Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19](#), AstraZeneca is providing US-labelled vaccine supplies with English-only vial and carton labels (see [Appendix A](#)) in order to expedite the distribution of AstraZeneca COVID-19 Vaccine in Canada.**
- **AstraZeneca COVID-19 Vaccine with US labels is the same as the Health Canada authorized AstraZeneca COVID-19 Vaccine in all aspects (i.e., formulation, strength, route of administration).**
- **Healthcare professionals are advised that:**
 - **Important Canadian-specific information is absent from the US vial and carton labels (see the Information for healthcare professionals section).**
 - **The expiration date is not printed on the US vial and carton labels. Healthcare professionals must verify the expiration date prior to vaccination. The expiration date for the corresponding batches/lots can be found in the 'Products affected' section of this document, by going to www.AZCOVID-19.com website, or by scanning the QR code on the US English-only carton label.**

- **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](#), or by scanning the QR code on the US English-only carton label. 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.**
- **On February 26, 2021, Health Canada also permitted the use of AstraZeneca COVID-19 Vaccine, [COVAX English-only vials and carton labels](#).**

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 Canada in the context of the global pandemic, AstraZeneca is providing the vaccine with US vial and carton 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

Product Name	Dosage Form, Strength, and Route of Administration	Country of Origin and Identifying Code	Manufacturer	Importer and Supplier in Canada
AstraZeneca COVID-19 Vaccine, (ChAdOx1-S [recombinant])	Suspension for Intramuscular Injection 10 Multi-dose vials (each vial contains 10 doses of 0.5 mL)	USA NDC 0310-1222-10 (vial) NDC 0310-1222-15 (carton)	AstraZeneca Pharmaceuticals LP	AstraZeneca Canada Inc.

Expiration date information for the US-labelled batches/lots	
Batch Number	Expiry Date
MT0055	31-May-2021
MT0056	31-May-2021
NA0079	30-Jun-2021

Background information

AstraZeneca COVID-19 Vaccine is indicated for active immunization of individuals 18 years of age and older 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 US-labelled 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 US English-only 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.

Information for healthcare professionals

In order to provide rapid access to AstraZeneca COVID-19 Vaccine for Canadians, AstraZeneca will provide US-labelled vaccine supplies with 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 US 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
- The expiration date is not printed on the vial and carton labels. Healthcare professionals must verify the expiration date prior to vaccination. The expiration date for the corresponding batches/lots can be found in the 'Products affected' section of this document, by going to www.AZCOVID-19.com website, or by scanning the QR code on the US English-only carton label.
- The vial and/or carton labels for the initial supplies of vaccines may include the text "Emergency Use Authorization", reference to the FDA-authorized fact sheet, and National Drug Code number, "NDC 0310-1222-10" (vial) and "NDC 0310-1222-15" (carton). This should be disregarded as this is not relevant to the Canadian authorization.
- The Canadian-specific labelling information, in French and English, can be accessed at www.AZCOVID-19.com, or by scanning the QR code on the US English-only carton label. 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.
- On February 26, 2021, Health Canada also permitted the use of AstraZeneca COVID-19 Vaccine, [COVAX English-only vials and carton labels](#).
- 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 US English-only labels for a limited period. Health Canada also permitted the use of [COVAX English-only](#) vials and carton labels.

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](https://www.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

For any medical questions related to AstraZeneca COVID-19 Vaccine, contact Medical Information at 1-800-668-6000) or submit a form online at www.azcovid-19.com.

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

A handwritten signature in blue ink, appearing to read "Neil Maresky".

Dr. Neil Maresky, M.B., B.Ch.
Vice President, Scientific Affairs

- [Appendix A](#): Vial and carton labels for 5 mL AstraZeneca COVID-19 Vaccine with English-only labelling (US-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 (US-labelled supply)

US supply (5 mL – 10 doses)

Inner label

AstraZeneca COVID-19 Vaccine NDC 0310-1222-10
 For use under Emergency Use Authorization
 Suspension for Intramuscular Injection
After first use, discard after:
 6 hours at 20°-25°C (68°-77°F), or
 48 hours at 2°-8°C (36°-46°F)
 For Exp Date: see _____/_____/_____
 www.azcovid-19.com
 Multi-dose vial (10 doses of 0.5 mL)

3999151
LOT AB###

Outer label

AstraZeneca COVID-19 Vaccine
 For use under Emergency Use Authorization

10 Multi-dose vials
 (each vial contains 10 doses of 0.5 mL)

10 Multi-dose vials
 (each vial contains 10 doses of 0.5 mL)

AstraZeneca COVID-19 Vaccine

For Expiration Date and FDA-authorized Fact Sheet, scan here or visit www.azcovid-19.com

AstraZeneca Pharmaceuticals LP
 Wilmington, DE 19850

3999151
 NDC 0310-1222-15

Expiration Date: Please see additional information.
 See FDA-authorized Fact Sheet for 0.5 mL, No preservative.
 Contents: 10 Multi-dose vials (each vial contains 10 doses of 0.5 mL). No preservative.

www.azcovid-19.com

LOT AB###

AstraZeneca COVID-19 Vaccine
 For use under Emergency Use Authorization
 Suspension for Intramuscular Injection
 Store at 2°-8°C (36°-46°F) in original carton to protect from light.
 Do not freeze or shake. No preservative.
 Discard 6 hours after first use when held at 20°-25°C (68°-77°F).
 Discard 48 hours after first use when held at 2°-8°C (36°-46°F).

10 Multi-dose vials
 (each vial contains 10 doses of 0.5 mL)

AstraZeneca

137 x 53 x 53 mm

US supply (5 mL – 10 doses)

Inner label

AstraZeneca COVID-19 Vaccine NDC 0310-1222-10

For use under Emergency Use Authorization

Suspension for Intramuscular Injection

After first use, discard after:

6 hours at 20°-25°C (68°-77°F), or

48 hours at 2°-8°C (36°-46°F)

For Exp Date: see www.azcovid-19.com

Multi-dose vial (10 doses of 0.5mL)

3999151

No preservative.

Record date and time of first use:

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Outer label

NDC 0310-1222-15

AstraZeneca COVID-19 Vaccine

For use under Emergency Use Authorization

Suspension for Intramuscular Injection

Store at 2°-8°C (36°-46°F) in original carton to protect from light.

Do not freeze or shake. No preservative.

Discard 6 hours after first use when held at 20°-25°C (68°-77°F).

Discard 48 hours after first use when held at 2°-8°C (36°-46°F).

10 Multi-dose vials (each vial contains 10 doses of 0.5 mL)

For Expiration Date and FDA authorized Fact Sheet, scan here or visit www.azcovid-19.com

Contents: 10 Multi-dose vials (each vial contains 10 doses of 0.5 mL). No preservative.

See FDA-authorized Fact Sheet for additional information.

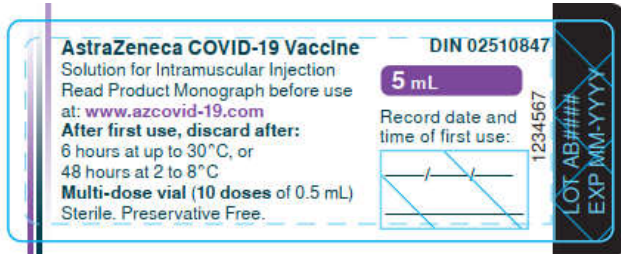
Expiration Date: Please see www.azcovid-19.com

AstraZeneca Pharmaceuticals LP Wilmington, DE 19850

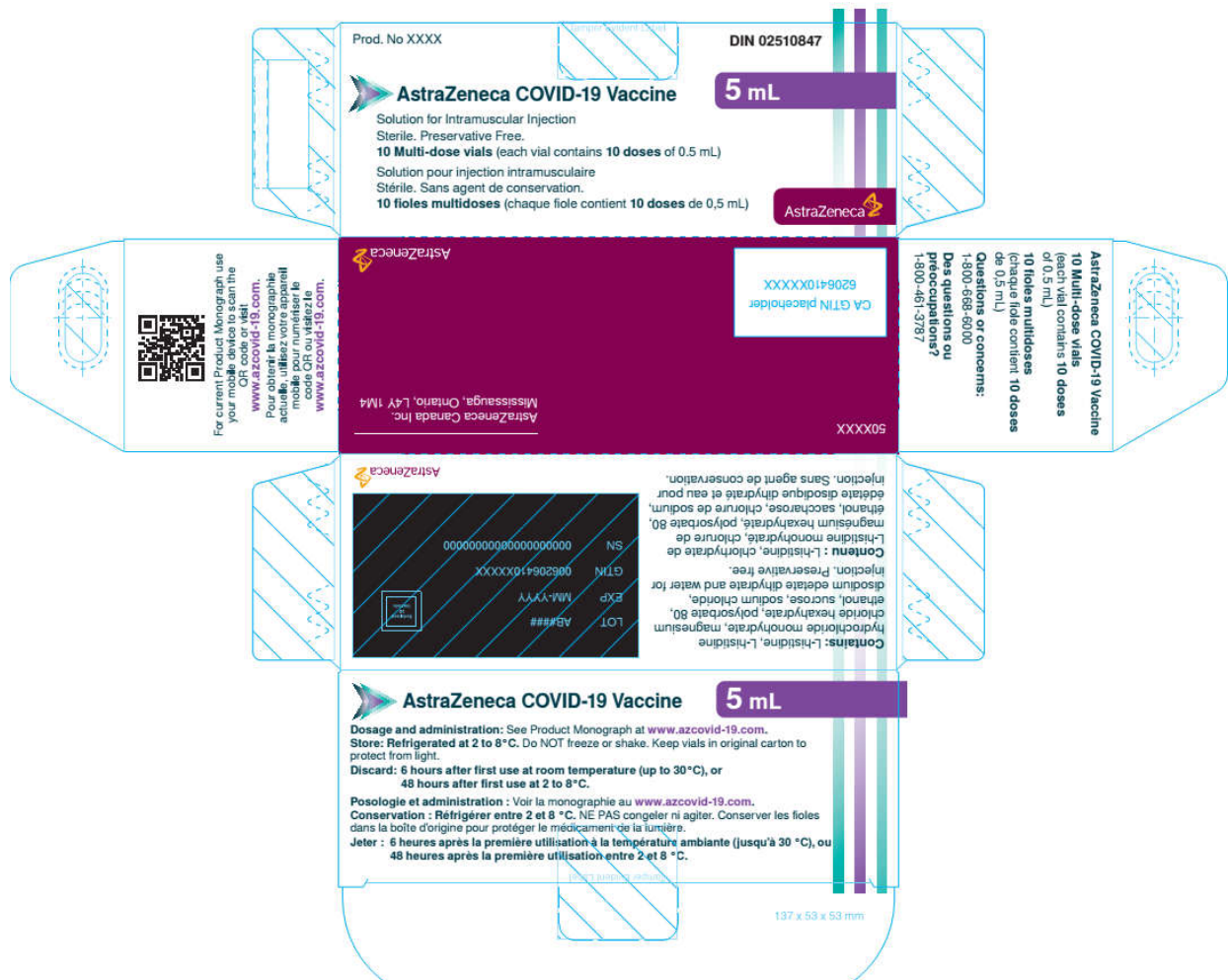
Appendix B: Vial and carton labels for AstraZeneca COVID-19 Vaccine with Health Canada approved English and French labelling (Canadian-labelled supply)

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