

**Important Safety Information on the Distribution of  
EVUSHELD (tixagevimab and cilgavimab for injection)  
with English-Only Vial and Carton Labels**



2022/04/14

**Audience**

Healthcare professionals including physicians, pharmacists, nursing staff and public health officials.

**Key messages**

- **On April 14, 2022, EVUSHELD (tixagevimab and cilgavimab for injection) was authorized by Health Canada.**
- **EVUSHELD is indicated for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents ( $\geq 12$  years of age weighing at least 40 kg), who have not had a known recent exposure to an individual infected with SARS-CoV-2 and:**
  - **Who are immune compromised and unlikely to mount an adequate immune response to COVID-19 vaccination or**
  - **For whom COVID-19 vaccination is not recommended.**
- **In order to provide rapid access to EVUSHELD, AstraZeneca will distribute product vials and cartons with global labels in English only for a limited period of time (see Appendix A).**
- **Healthcare professionals are advised that:**
  - **Important Canadian-specific information is absent from EVUSHELD vial and carton labels (see the Information for healthcare professionals section).**
  - **Canadian-specific labelling information, including the EVUSHELD Canadian Product Monograph (CPM), can be accessed at [astrazeneca.ca](https://www.astrazeneca.ca), or by scanning the QR code on the global English-only carton label to visit [www.laab.azcovid-19.com](https://www.laab.azcovid-19.com). This information is also available on the federal government's [covid-vaccine.canada.ca](https://www.covid-vaccine.canada.ca) website.**
  - **The EVUSHELD CPM, which is also available in French and English on Health Canada's [Drug Product Database](#), should be referenced for complete product information.**

## **What is the issue?**

EVUSHELD (tixagevimab and cilgavimab for injection) was authorized by Health Canada on April 14, 2022. In order to provide rapid access to EVUSHELD in the context of the global COVID-19 pandemic, AstraZeneca will distribute product vials and cartons with English-only global labels for a limited period of time. The global vial and carton labels are missing some important Canadian-specific information normally found on Health Canada approved labels (see the Information for healthcare professionals section).

## **Products affected**

EVUSHELD (150 mg/1.5 mL tixagevimab; 150 mg/1.5 mL cilgavimab) co-packaged solution for intramuscular injection.  
DIN: 02526271

## **Background information**

EVUSHELD is indicated for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents ( $\geq 12$  years of age weighing at least 40 kg), who have not had a known recent exposure to an individual infected with SARS-CoV-2 and:

- Who are immune compromised and unlikely to mount an adequate immune response to COVID-19 vaccination **or**
- For whom COVID-19 vaccination is not recommended.

Each carton of EVUSHELD contains one 1.5 mL single-dose vial (150 mg) of tixagevimab solution for injection and one 1.5 mL single-dose vial (150 mg) of cilgavimab solution for injection.

Given the public health emergency resulting from the current COVID-19 pandemic, Health Canada has authorized the importation, sale, and advertising of EVUSHELD with vial and carton labels that are in English only for the initial global distribution of the product (see Appendix A).

AstraZeneca has developed French and English vial and carton labels that Health Canada has approved (see Appendix B). AstraZeneca will provide supplies with Canadian-specific labels as soon as possible.

EVUSHELD with global vial and carton labels is the same as the Health Canada authorized EVUSHELD in all aspects (i.e., formulation, strength, route of administration) and should be used in Canada for the same indication. The CPM for EVUSHELD, which is approved by Health Canada and available in French and English, should be used for complete product information.

## **Information for healthcare professionals**

Healthcare professionals are advised that:

- The following important Canadian-specific information is absent from the global EVUSHELD vial and carton labels:

- Drug Identification Number (DIN)
  - “Pr” (prescription) symbol
  - Name and address of the Canadian DIN holder
  - Name and address of the Canadian importer and distributor
  - All corresponding text in French
- Canadian-specific labelling information, including the EVUSHELD CPM, can be accessed at [astrazeneca.ca](https://astrazeneca.ca), or by scanning the QR code on the global English-only carton label to visit [www.laab.azcovid-19.com](http://www.laab.azcovid-19.com). This information is also available on the federal government’s [covid-vaccine.canada.ca](https://covid-vaccine.canada.ca) website.
  - The EVUSHELD CPM, which is also available in French and English on Health Canada’s [Drug Product Database](#), should be referenced for complete product information.
  - For any product or general inquiries, contact AstraZeneca Canada Inc. Medical Information at 1-800-668-6000, or email [medinfo.canada@astrazeneca.com](mailto:medinfo.canada@astrazeneca.com).

### **Action taken by Health Canada**

Health Canada is permitting the use of global English-only vial and carton labels for a limited period of time. Health Canada has imposed terms and conditions requiring AstraZeneca Canada Inc. to provide 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](https://covid-vaccine.canada.ca) website.

Health Canada has worked with AstraZeneca Canada Inc. to prepare this alert for EVUSHELD. Health Canada is communicating this important safety information to healthcare professionals and Canadians via the [Recalls and Safety Alerts Database](#) on the Healthy Canadians website. 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 EVUSHELD should be reported to AstraZeneca Canada Inc. or Health Canada.

**AstraZeneca Canada Inc.**

1004 Middlegate Road, Suite 5000  
Mississauga  
Ontario L4Y 1M4

For any medical questions related to EVUSHELD, contact AstraZeneca Canada Inc. Medical Information at 1-800-668-6000 or via <https://contactazmedical.astrazeneca.com>.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax.

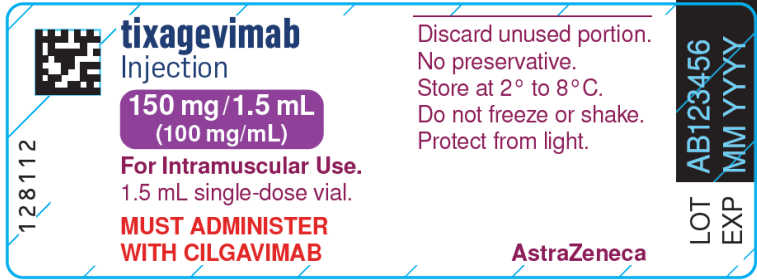
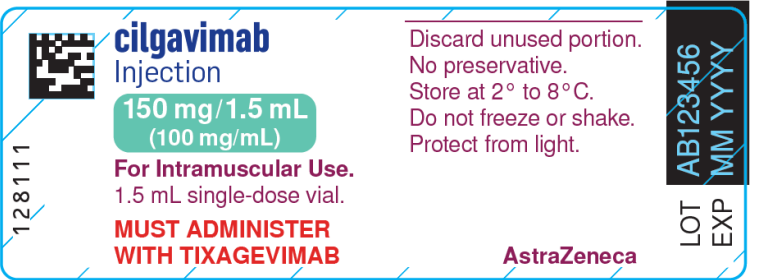
For other health product inquiries related to this communication, contact Health Canada at: Biologic and Radiopharmaceutical Drugs Directorate  
E-mail: [brdd.dgo.enquiries@hc-sc.gc.ca](mailto:brdd.dgo.enquiries@hc-sc.gc.ca)

**Original signed by**



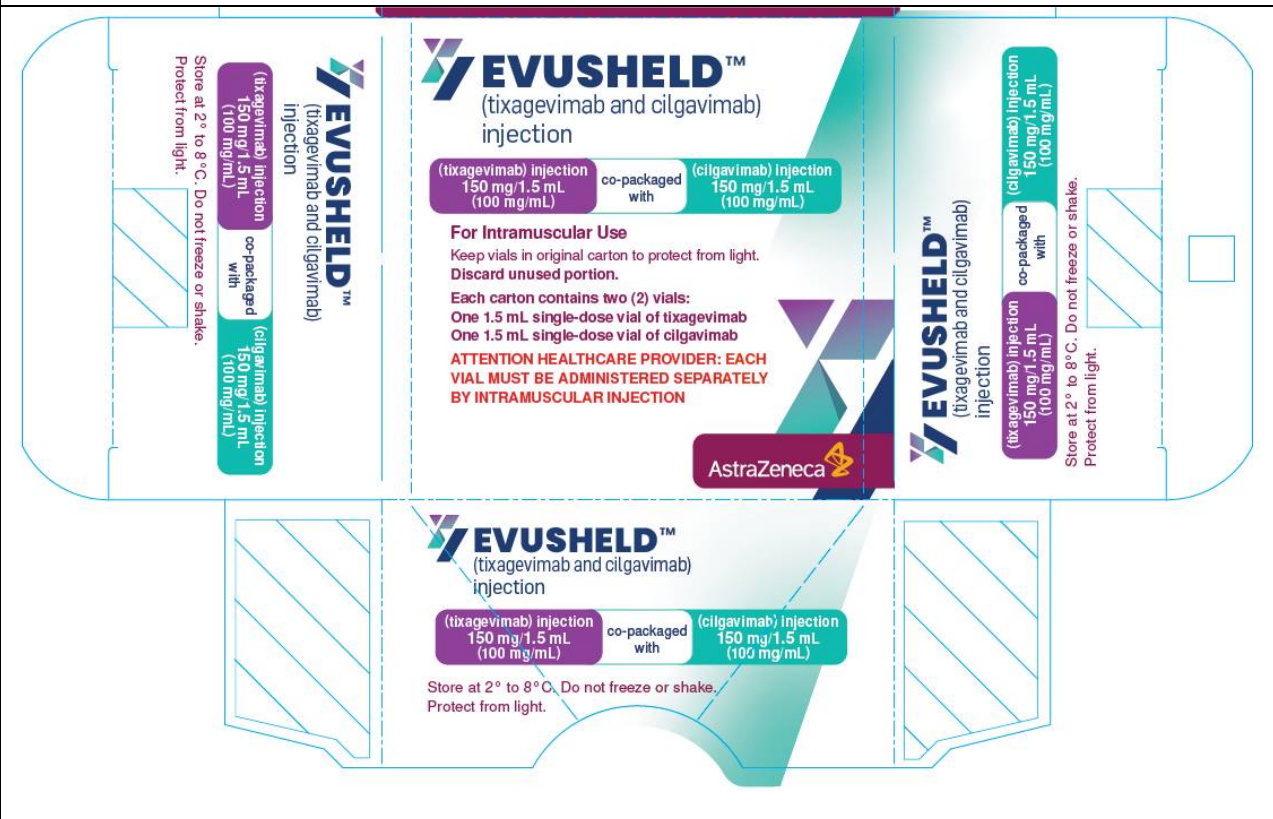
Alex Romanovschi, MD  
Vice President, Scientific Affairs  
AstraZeneca Canada Inc.

**Appendix A: Global-labelled supply – Vial and carton labels for EVUSHELD with English-only labelling**

Global-labelled supply	
<b>Vial label - tixagevimab<sup>A</sup></b>	
 <p><b>tixagevimab</b> Injection 150 mg / 1.5 mL (100 mg/mL) <b>For Intramuscular Use.</b> 1.5 mL single-dose vial. <b>MUST ADMINISTER WITH CILGAVIMAB</b> AstraZeneca</p>	<p>Discard unused portion. No preservative. Store at 2° to 8°C. Do not freeze or shake. Protect from light.</p> <p>LOT EXP</p>
<p><b>tixagevimab</b> Injection 150 mg/1.5 mL (100 mg/mL) <b>For Intramuscular Use.</b> 1.5 mL single-dose vial. <b>MUST ADMINISTER WITH CILGAVIMAB</b> Discard unused portion. No preservative. Store at 2° to 8°C. Do not freeze or shake. Protect from light. <b>AstraZeneca</b> LOT EXP</p>	
<b>Vial label - cilgavimab<sup>A</sup></b>	
 <p><b>cilgavimab</b> Injection 150 mg / 1.5 mL (100 mg/mL) <b>For Intramuscular Use.</b> 1.5 mL single-dose vial. <b>MUST ADMINISTER WITH TIXAGEVIMAB</b> AstraZeneca</p>	<p>Discard unused portion. No preservative. Store at 2° to 8°C. Do not freeze or shake. Protect from light.</p> <p>LOT EXP</p>
<p><b>cilgavimab</b> Injection 150 mg/1.5 mL (100 mg/mL) <b>For Intramuscular Use.</b> 1.5 mL single-dose vial. <b>MUST ADMINISTER WITH TIXAGEVIMAB</b> Discard unused portion. No preservative. Store at 2° to 8°C. Do not freeze or shake. Protect from light. <b>AstraZeneca</b> LOT EXP</p>	

**Global-labelled supply**

**Carton label (front)<sup>A</sup>**



**EVUSHELD™**

(tixagevimab and cilgavimab) injection

**(tixagevimab) injection 150 mg/1.5 mL (100 mg/mL) co-packaged with (cilgavimab) injection 150 mg/1.5 mL (100 mg/mL)**

**For Intramuscular Use**

Keep vials in original carton to protect from light.

**Discard unused portion.**

**Each carton contains two (2) vials:**

**One 1.5 mL single-dose vial of tixagevimab**

**One 1.5 mL single-dose vial of cilgavimab**

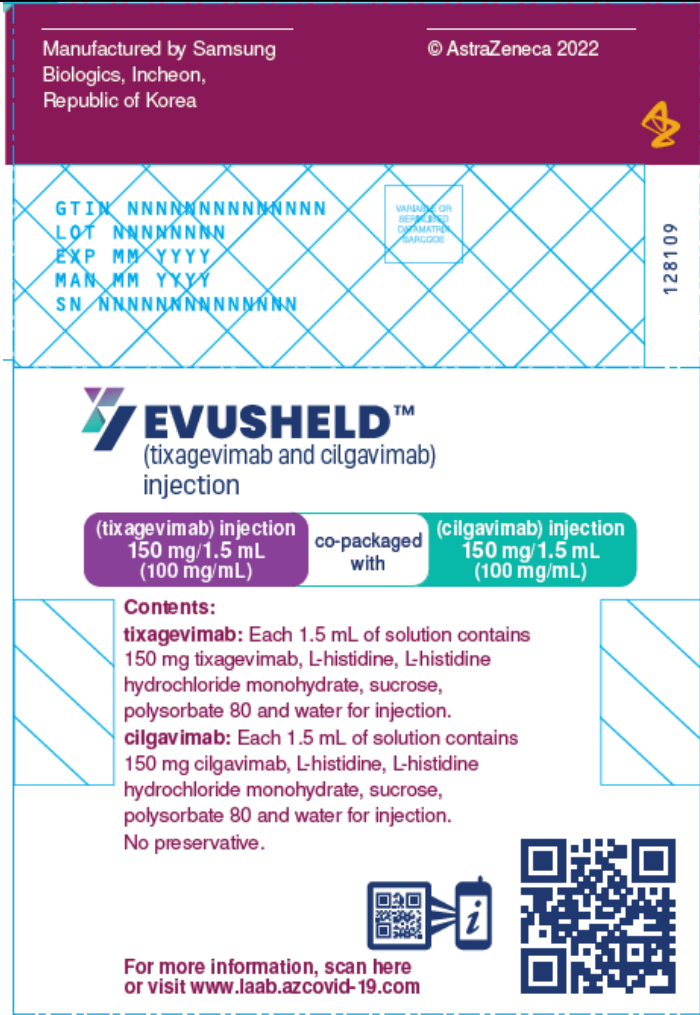
ATTENTION HEALTHCARE PROVIDER: EACH VIAL MUST BE ADMINISTERED SEPARATELY BY INTRAMUSCULAR INJECTION

Store at 2° to 8° C. Do not freeze or shake.

Protect from light.

**Global-labelled supply**

**Carton label (back)<sup>A</sup>**



Manufactured by Samsung Biologics, Incheon, Republic of Korea  
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**EVUSHELD™**  
(tixagevimab and cilgavimab) injection  
**(tixagevimab) injection**  
**150 mg/1.5 mL (100 mg/mL)** co-packaged with **(cilgavimab) injection 150 mg/1.5 mL (100 mg/mL)**

**Contents:**  
**tixagevimab:** Each 1.5 mL of solution contains 150 mg tixagevimab, L-histidine, L-histidine hydrochloride monohydrate, sucrose, polysorbate 80 and water for injection.  
**cilgavimab:** Each 1.5 mL of solution contains 150 mg cilgavimab, L-histidine, L-histidine hydrochloride monohydrate, sucrose, polysorbate 80 and water for injection.  
No preservative.

**For more information, scan here or visit [www.laab.azcovid-19.com](http://www.laab.azcovid-19.com)**  
[QR Code image]

<sup>A</sup> Package label layout and technical information may contain minor differences compared to images shown. Some package labels may contain a listed manufacturing date in addition to expiry date.

<sup>B</sup> Some package labels may refer to "L-histidine hydrochloride monohydrate" as "L-histidine hydrochloride".

**Appendix B: Canadian-labelled supply – Health Canada approved English and French vial and carton labels for EVUSHELD**

Canadian-labelled supply	
<b>Vial label – tixagevimab</b>	
	<p><b>tixagevimab™</b>      <b>DIN 02526271</b></p> <p>Injection</p> <p>150 mg / 1.5 mL (100 mg / mL)</p> <p><b>For Intramuscular Use.</b></p> <p><b>MUST ADMINISTER WITH CILGAVIMAB</b></p> <p>Read Product Monograph before use at <a href="http://www.astrazeneca.ca">www.astrazeneca.ca</a></p> <p><b>Store: 2 to 8°C.</b> Preservative Free.</p> <p>Sterile. Single-use only. Discard unused portion.</p> <p>AstraZeneca</p> <p>LOT EXP</p>
<p><b>Pr</b>tixagevimab™      <b>DIN 02526271</b></p> <p>Injection</p> <p>150 mg / 1.5 mL (100 mg / mL)</p> <p><b>For Intramuscular Use.</b></p> <p><b>MUST ADMINISTER WITH CILGAVIMAB</b></p> <p>Read Product Monograph before use at <a href="http://www.astrazeneca.ca">www.astrazeneca.ca</a></p> <p><b>Store: 2 to 8°C.</b> Preservative Free.</p> <p>Sterile. Single-use only. Discard unused portion.</p> <p>AstraZeneca</p> <p>LOT EXP</p>	
<b>Vial label – cilgavimab</b>	
	<p><b>cilgavimab™</b>      <b>DIN 02526271</b></p> <p>Injection</p> <p>150 mg / 1.5 mL (100 mg / mL)</p> <p><b>For Intramuscular Use.</b></p> <p><b>MUST ADMINISTER WITH TIXAGEVIMAB</b></p> <p>Read Product Monograph before use at <a href="http://www.astrazeneca.ca">www.astrazeneca.ca</a></p> <p><b>Store: 2 to 8°C.</b> Preservative Free.</p> <p>Sterile. Single-use only. Discard unused portion.</p> <p>AstraZeneca</p> <p>LOT EXP</p>
<p><b>Pr</b>cilgavimab™      <b>DIN 02526271</b></p> <p>Injection</p> <p>150 mg / 1.5 mL (100 mg / mL)</p> <p><b>For Intramuscular Use.</b></p> <p><b>MUST ADMINISTER WITH TIXAGEVIMAB</b></p> <p>Read Product Monograph before use at <a href="http://www.astrazeneca.ca">www.astrazeneca.ca</a></p> <p><b>Store: 2 to 8°C.</b> Preservative Free.</p> <p>Sterile. Single-use only. Discard unused portion.</p> <p>AstraZeneca</p> <p>LOT EXP</p>	



**Canadian-labelled supply**  
**Carton label (front)**



Prod. No XXXX **DIN 02526271**  
**Pr EVUSHELD<sup>TM/MC</sup>**

tixagevimab and cilgavimab injection

**1 vial tixagevimab 150 mg / 1.5 mL (100 mg / mL)** co-packaged with  
**1 vial cilgavimab 150 mg / 1.5 mL (100 mg / mL)**

**For Intramuscular Use**

Sterile. Single-use only. Discard unused portion.

**ATTENTION HEALTHCARE PROVIDER: EACH VIAL MUST BE ADMINISTERED SEPARATELY BY INTRAMUSCULAR INJECTION**

For current Product Monograph use your mobile device to scan the QR code or visit [www.astrazeneca.ca](http://www.astrazeneca.ca).

**Canadian-labelled supply**

**Carton label (back)**

**Concerns / Questions / Préoccupations : 1-800-668-6000**  
AstraZeneca Canada Inc. Mississauga, Ontario, L4Y 1M4

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**Contains:** L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose and water for injection. Preservative free.

**Dosage and Administration:** See Product Monograph at [www.astrazeneca.ca](http://www.astrazeneca.ca).

**Store:** Refrigerated at 2 to 8 °C. Do NOT freeze or shake. Keep vials in original carton to protect from light.

**Contenu :** L-histidine, chlorhydrate de L-histidine monohydraté, polysorbate 80, saccharose et eau pour injection. Sans agent de conservation.

**Posologie et administration :** Voir la monographie au [www.astrazeneca.ca](http://www.astrazeneca.ca).

**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.



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**Concerns / Questions:** 1-800-668-6000

AstraZeneca Canada Inc.  
Mississauga, Ontario, L4Y 1M4

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GTIN  
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