Authorization of Sotrovimab for Injection for Use in Relation to the COVID-19 Pandemic

22 September 2021

Audience
Healthcare professionals including infectious disease physicians, emergency room (ER) physicians, internal medicine physicians, critical care physicians, respirologists, pharmacists, hospital pharmacy departments, and chiefs of medicine in hospitals.

Key messages

- **On July 30, 2021, sotrovimab for injection, a monoclonal antibody, was authorized for use in Canada in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19.**
- **Sotrovimab is indicated for the treatment of mild to moderate coronavirus disease 2019 (COVID-19), confirmed by direct SARS-CoV-2 viral testing, in adults and adolescents (12 years of age and older weighing at least 40 kg) who are at high risk for progressing to hospitalization and/or death.**
- **At this time, GlaxoSmithKline is providing sotrovimab with European French and English labelling, in order to expedite the distribution of the product. Sotrovimab supply with Canadian-specific labelling information is anticipated in 2022.**
- **Healthcare professionals are advised that:**
  - **Important Canadian-specific information is absent from the 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, www.gsk.ca or www.sotrovimabinfo.com should be used for complete product information.**
  - **The Canadian-specific labelling information, including the Product Monograph, can be accessed at www.sotrovimabinfo.com and https://covid-vaccine.canada.ca/ or by scanning the QR code found on the outer carton or package leaflet.**
  - **The expiry date printed on the carton and vial label for**

sotrovimab with European French and English labelling should be verified because it may not reflect the shelf-life authorized by Health Canada for this product. Current Canadian expiry information should be verified at www.sotrovimabinfo.com. Sotrovimab should not be used beyond the valid Canadian expiry date provided at www.sotrovimabinfo.com.

- **GlaxoSmithKline has developed French and English vial and carton labels that Health Canada has approved (see Appendix B), and has made them available on www.sotrovimabinfo.com for reference by healthcare professionals.**
- **Paper copies of the Canadian Product Monograph, including Patient Medication Information, are available upon request from GlaxoSmithKline (1-800-387-7374).**

What is the Issue?

Sotrovimab was authorized for use in relation to the COVID-19 pandemic, in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. To provide earlier access to the product in the context of the global pandemic, GlaxoSmithKline will distribute sotrovimab with European French and English labelling in Canada.

Products Affected

Sotrovimab for injection, anti-SARS-CoV-2 spike protein monoclonal antibody, solution for infusion, 500 mg / 8 mL, single-use vial, DIN 02518341.

Background Information

Sotrovimab is indicated for the treatment of mild to moderate coronavirus disease 2019 (COVID-19), confirmed by direct SARS-CoV-2 viral testing, in adults and adolescents (12 years of age and older weighing at least 40 kg) who are at high risk for progressing to hospitalization and/or death.

Sotrovimab is NOT authorized for use in patients:

- who are hospitalized due to COVID-19, OR
- who require oxygen therapy due to COVID-19, OR
- who require an increase in baseline oxygen flow rate due to COVID-19 (in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity).

The safety and efficacy of sotrovimab for injection have not been assessed in pediatric patients (less than 18 years of age). Close monitoring in this patient population is highly recommended.

The use of sotrovimab is permitted under an interim authorization delivered in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19, pending the results of trials

to verify its clinical benefit. Patients should be advised of the nature of the authorization.

Information for Health Care Professionals
In order to manage drug supply for COVID-19 patients in the context of the global pandemic, GlaxoSmithKline will distribute sotrovimab in Canada for a limited period of time with European French and English labelling (see Appendix A). Sotrovimab supply with Canadian-specific labelling information is anticipated in 2022.

Healthcare professionals are advised that:

- The following important Canadian-specific information is absent from the European vial and carton labels:
  - Drug Identification Number (DIN)
  - Prescription product "Pr" symbol
  - Drug product name (sotrovimab for injection)
  - Name and address of the Canadian DIN holder (manufacturer)
  - Name and address of the Canadian importer and distributor
  - The statement that this authorization was issued based on limited clinical testing in humans and/or limited quality information
  - Canadian package insert not enclosed
- The Canadian Product Monograph, which is available in French and English on Health Canada's Drug Product Database, www.gsk.ca or www.sotrovimabinfo.com should be used for complete product information.
- The Canadian-specific labelling information, including the Product Monograph, can be accessed at www.sotrovimabinfo.com and https://covid-vaccine.canada.ca/or by scanning the QR code found on the outer carton or package leaflet.
- The expiry date printed on the carton and vial label for sotrovimab with European French and English labelling should be verified because it may not reflect the shelf-life authorized by Health Canada for this product. Current Canadian expiry information should be verified at www.sotrovimabinfo.com. Sotrovimab should not be used beyond the valid Canadian expiry date provided at www.sotrovimabinfo.com.
- GlaxoSmithKline has developed French and English vial and carton labels that Health Canada has approved (see Appendix B), and has made them available on www.sotrovimabinfo.com for reference by healthcare professionals.
- Paper copies of the Canadian Product Monograph, including Patient Medication Information, are available upon request from GlaxoSmithKline (1-800-387-7374).

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. Sotrovimab was authorized for use by Health Canada under the Interim Order and has been added to the List of authorized drugs, vaccines and expanded indications for COVID-19.

Health Canada has worked with GlaxoSmithKline Inc. to prepare this alert for sotrovimab. 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 update 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 sotrovimab should be reported to GlaxoSmithKline Inc. or Health Canada.

GlaxoSmithKline Inc.
7333 Mississauga Road
Mississauga, Ontario
L5N 6L4
Tel: 1-800-387-7374

To correct your mailing address or fax number, contact GlaxoSmithKline Inc.

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) 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: hc.brdd.dgo.enquiries.sc@canada.ca

Original signed by

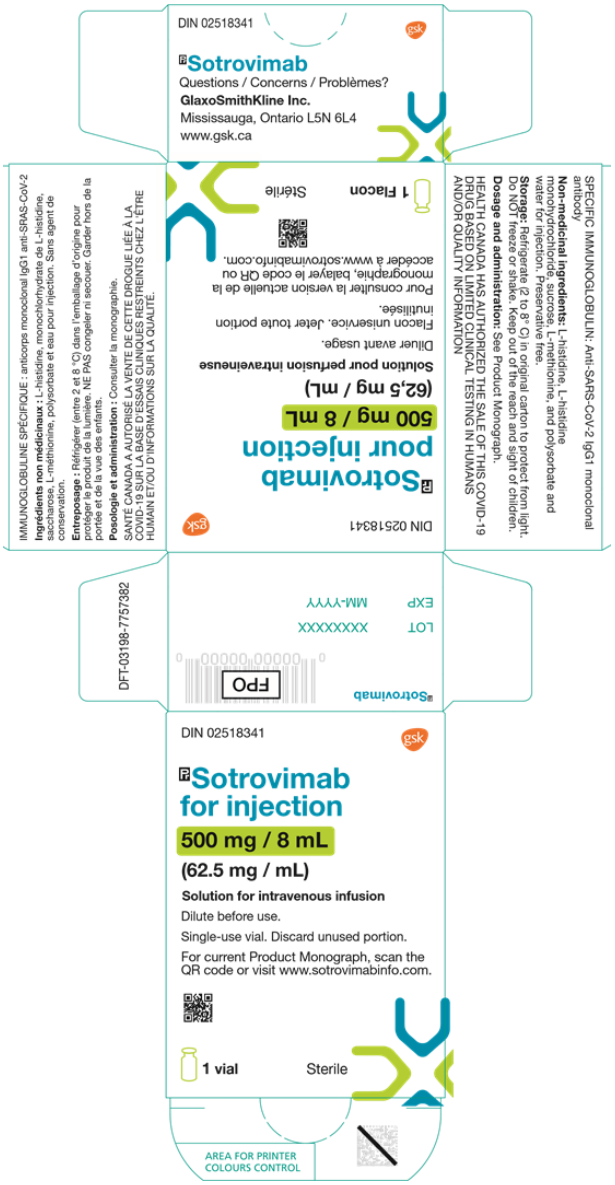
Marni Freeman
Country Medical Director, Canada
GlaxoSmithKline Inc.

Appendix A: European French/English Carton and Vial Labels

European French/English carton	**Sotrovimab 500 mg** concentrate for solution for infusion solution à diluer pour perfusion **sotrovimab** For intravenous use Pour administration intraveineuse 1 vial 1 flacon Each vial contains 500 mg sotrovimab in 8mL (62.5 mg/mL). Also contains: histidine, histidine monohydrochloride, sucrose, polysorbate 80, methionine. **Keep out of the sight and reach of children.** Store in a refrigerator. Do not freeze. Store in the original carton in order to protect from light. Chaque flacon de 8 mL contient 500 mg de sotrovimab (62,5 mg/mL). Contient également: histidine, monochlorhydrate d'histidine, saccharose, polysorbate 80, méthionine. **Tenir hors de la vue et de la portée des enfants**. À conserver au réfrigérateur. Ne pas congeler. À conserver dans l'emballage d'origine, à l'abri de la lumière. GlaxoSmithKline (Ireland) Limited 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland/Irlande Lot EXP **Sotrovimab 500 mg** concentrate for solution for infusion solution à diluer pour perfusion **sotrovimab** Read the product information before use. Scan the code with a mobile device to get this information in different languages or visit www.sotrovimabinfo.com Lire les informations concernant le produit avant utilisation. Scanner le code avec un appareil mobile afin d'obtenir ces informations dans différentes langues ou visiter www.sotrovimabinfo.com [QR code] **PRESS HERE TO OPEN** **APPUYER ICI POUR OUVRIR** **Sotrovimab 500 mg** concentrate for solution for infusion solution à diluer pour perfusion **sotrovimab**
European French/English vial label	**Sotrovimab 500 mg** concentrate for solution for infusion solution à diluer pour perfusion **sotrovimab** IV Use 500 mg/vial Voie IV 500 mg/flacon Lot EXP

Appendix B: Canadian Reference Carton and Vial labels, *with printed ENGLISH text*

Canadian Reference Carton



DIN 02518341

PrSotrovimab for injection
500 mg / 8 mL
(62.5 mg / mL)
Solution for intravenous infusion

Dilute before use.
Single-use vial. Discard unused portion.

For current Product Monograph, scan the QR code or visit www.sotrovimabinfo.com.

[QR code]

1 Vial Sterile

SPECIFIC IMMUNOGLOBULIN: Anti-SARS-CoV-2 IgG1 monoclonal antibody

Non-medicinal ingredients: L-histidine, L-histidine monohydrochloride, sucrose, L-methionine, and polysorbate and water for injection. Preservative free.

Storage: Refrigerate (2 to 8° C) in original carton to protect from light. Do NOT freeze or shake. Keep out of the reach and sight of children.

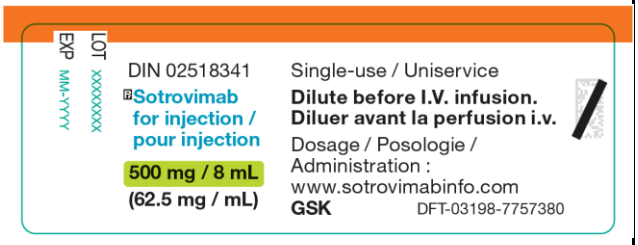
Dosage and administration:
See Product Monograph.

HEALTH CANADA HAS AUTHORIZED THE SALE OF THIS COVID-19 DRUG BASED ON LIMITED CLINICAL TESTING IN HUMANS AND/OR QUALITY INFORMATION

Questions / Concerns / Problèmes?
GlaxoSmithKline Inc.
Mississauga, Ontario L5N 6L4
www.gsk.ca

LOT XXXXXXXX
EXP MM-YYYY

Canadian reference vial label



DIN 02518341
PrSotrovimab for injection
500 mg / 8 mL
(62.5 mg / mL)

Single-use
Dilute before I.V. infusion.
Dosage / Administration:
www.sotrovimabinfo.com
GSK

LOT XXXXXXXX
EXP MM-YYYY