Important Safety Information -
Authorization of Bamlanivimab with English-only Labels for Use in Relation to the COVID-19 Pandemic

2020/12/15

Audience

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

Key messages

- **On November 20, 2020, bamlanivimab 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.**
- **Bamlanivimab is indicated for the treatment of adults and pediatric patients 12 years of age or older with mild to moderate COVID-19, who weigh at least 40 kg and who are at high risk of progressing to severe COVID-19 illness and/or hospitalization.**
- **Eli Lilly will provide one standard package worldwide with English-only labelling in order to expedite the global distribution of bamlanivimab.**
- **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, at www.bamlanivimabHCPinfo.com or www.lilly.ca, should be used for complete product information.**
    - **The Canadian-specific labelling information including the Product Monograph, can be accessed at www.bamlanivimabHCPinfo.com or by scanning the QR code found on the Package Insert that accompanies the product; the Package Insert only contains the QR code and does not contain printed text of the drug-specific information.**
    - **The vial and carton labels include the statement: "For Use Under Emergency Use Authorization (EUA)". This information relates to the US approval, which formed the basis of the global label and package, and should be disregarded as this is not relevant to the Canadian authorization.**

What is the issue?
Bamlanivimab 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, Lilly will distribute one standard package worldwide with English-only labelling.

Products affected
Bamlanivimab for injection, Anti-SARS-CoV-2 spike protein monoclonal antibody, solution for infusion, 700 mg/20 mL (35 mg/mL), Single-dose vial, DIN 02508176

Background information
Bamlanivimab is indicated for the treatment of adults and pediatric patients 12 years of age or older with mild to moderate coronavirus disease 2019 (COVID-19), who weigh at least 40 kg and who are at high risk of progressing to severe COVID-19 illness and/or hospitalization.

Bamlanivimab should NOT be used in patients hospitalized with severe COVID-19 respiratory disease as benefit of treatment has not been observed in this setting. Bamlanivimab, a monoclonal antibody, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

Health Canada has authorized the sale of this COVID-19 drug based on limited clinical testing in humans and limited quality information. The authorization is supported by a numerical reduction in hospitalization or emergency room visits in high risk patients treated with bamlanivimab compared to high risk patients treated with placebo. Clinical study for the authorization of bamlanivimab included subjects aged 18 years and older. Careful monitoring should be implemented for adolescents aged 12-17 years who may receive this therapy.

The use of bamlanivimab 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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html), pending the results of trials to verify its clinical benefit. Patients should be advised of the nature of the authorization.

Information for healthcare professionals
In order to provide rapid access to bamlanivimab for COVID-19 patients, Eli Lilly Canada Inc. will distribute product labelled in English only.

Healthcare professionals are advised that:

- The Canadian Product Monograph, which is available in French and English on Health Canada's Drug Product Database (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html), at www.bamlanivimabHCPinfo.com or www.lilly.ca should be used for complete product information.
- Important Canadian-specific information is absent from the vial and carton labels and includes:
    - Drug Identification Number (DIN)
    - "Pr" symbol
    - name and address of the Canadian importer and distributor
    - net contents of the carton (1 vial per carton)
    - all corresponding text in French
    - the statement that this authorization was issued based on limited clinical testing in humans and/or limited quality information.
- The Canadian-specific labelling information including the Product Monograph, can be accessed at www.bamlanivimabHCPinfo.com or by scanning the QR code found on the Package Insert that accompanies the product; the Package Insert only contains the QR code and does not contain printed text of the drug-specific information.
- The vial and carton labels include the statement: "For Use Under Emergency Use Authorization (EUA)". This information relates to the US approval, which formed the basis of the global label and package, and should be disregarded as this is not relevant to the Canadian authorization
- For any questions, contact Eli Lilly Canada Inc. directly at 1-888-545-5972.

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

Health Canada has worked with Eli Lilly Canada Inc. to prepare this alert for bamlanivimab. 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 side effects in patients receiving bamlanivimab should be reported to Eli Lilly Canada Inc., or to Health Canada.

Eli Lilly Canada Inc.
P.O. Box 73, Exchange Tower
130 King Street West, Suite 900
Toronto, Ontario M5X 1B1
1-888-545-5972

To correct your mailing address or fax number, contact Eli Lilly Canada 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

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Appendix A – Vial and carton labels for Bamlanivimab, Bamlanivimab for injection