PATIENT MEDICATION INFORMATION

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

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

*Bamlanivimab

Bamlanivimab for injection

Read this carefully before you start taking bamlanivimab. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about bamlanivimab.

What is bamlanivimab used for?

Bamlanivimab is a medicine being studied for the treatment of COVID-19. Bamlanivimab may help limit the amount of the COVID-19 causing virus in your body; this may help you get better faster. Bamlanivimab may be given if you or your child are 12 years of age or older and weigh at least 40 kg (kilograms) and are not already in the hospital. Bamlanivimab is only given to patients at high-risk of having the disease get worse. Your healthcare professional will decide if you or your child should take bamlanivimab.

How does bamlanivimab work?

COVID-19 is caused by a virus called a coronavirus. Bamlanivimab may help limit the amount of virus in your body, which may help you get better faster.

What are the ingredients in bamlanivimab?

Medicinal ingredients: bamlanivimab

Non-medicinal ingredients: L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sodium chloride, sucrose, water for injection

Bamlanivimab comes in the following dosage forms:

Bamlanivimab solution, 700 mg/20 mL (35 mg/mL)

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take bamlanivimab. Talk about any health conditions or problems you may have, including if you:

- Have any allergies
- Are pregnant or plan to become pregnant
• Are breast-feeding a child
• Have any serious illnesses
• Are taking any medications (prescription, over-the-counter, vitamins, or herbal products)
• Have reactions during or after the infusion. Symptoms of a possible allergic reaction include:
  • Changes to blood pressure or heart rate, low oxygen level in the blood, high temperature, shortness of breath, wheezing, swelling of the face, lips, tongue, or throat, rash/hives/itching, feeling sick or nauseous, sweating, shivering, muscle soreness, dizziness, headache
  Tell your doctor if you get any of these signs or symptoms.
• Have sudden, severe worsening in COVID-19 symptoms

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take bamlanivimab:
• Bamlanivimab will be given to you by a healthcare professional through a vein (intravenous or IV) for at least 1 hour.

Usual dose:
Bamlanivimab is given once. The recommended dose is 700 mg.

Overdose:
If you think you, or a person you are caring for, have taken too much bamlanivimab, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using bamlanivimab?
Possible side effects of bamlanivimab are:
• Allergic reactions. Allergic reactions can happen during and after infusion with bamlanivimab. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, and dizziness.
• Worsening symptoms after treatment: You may experience new or worsening symptoms after infusion, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these occur, contact your healthcare provider or seek immediate medical attention as some of these events have required hospitalization. It is unknown if these events are related to treatment or are due to the progression of COVID-19.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

These are not all the possible side effects of bamlanivimab. Not a lot of people have been given bamlanivimab. Serious and unexpected side effects may happen. Bamlanivimab is still being studied so
it is possible that all of the risks are not known at this time.

It is possible that bamlanivimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, bamlanivimab may reduce your body’s immune response to a vaccine for SARS-CoV-2.

Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

If you experience any side effects not listed here, tell your healthcare professional.

**Reporting Side Effects**

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

- Visiting the Web page on Adverse Reaction Reporting ([https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html)) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

**If you want more information about bamlanivimab:**

- Talk to your healthcare professional

This leaflet was prepared by Eli Lilly Canada, Inc.

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