

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### **EVUSHELD™** tixagevimab and cilgavimab injection, intramuscular use

Read this carefully before you start taking **EVUSHELD** and each time you get a refill. 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 **EVUSHELD**.

#### **What is EVUSHELD used for?**

EVUSHELD is used:

- For the pre-exposure prophylaxis (prevention) of Coronavirus Disease 2019 (COVID-19) illness in adults and adolescents (aged 12 years and older weighing at least 40 kg) who:
  - have a weaker immune system and are unlikely to be protected by a COVID-19 vaccine
  - or when vaccination is not recommended.
- To treat adults and adolescents (aged 12 years and older weighing at least 40 kg) with confirmed mild to moderate COVID-19.

EVUSHELD is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended.

#### **How does EVUSHELD work?**

EVUSHELD contains the active substances tixagevimab and cilgavimab. Tixagevimab and cilgavimab are types of protein called 'monoclonal antibodies'. EVUSHELD work specifically against the SARS-CoV-2 virus (the virus that causes COVID-19 illness) by preventing the virus from infecting healthy cells in your body. This can help prevent you from getting COVID-19 illness or help your body to overcome the infection and reduce the risk of you developing severe illness.

#### **What are the ingredients in EVUSHELD?**

Medicinal ingredients: tixagevimab and cilgavimab

Non-medicinal ingredients: L-histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose and water.

#### **EVUSHELD comes in the following dosage forms:**

A carton containing two clear glass vials:

- 1 vial of tixagevimab (100 mg/mL) solution for injection (dark grey vial cap)
- 1 vial of cilgavimab (100 mg/mL) solution for injection (white vial cap)

Both solutions are a clear to opalescent, colourless to slightly yellow solution.

#### **Do not use EVUSHELD if:**

- if you are allergic to tixagevimab, cilgavimab or any of the other ingredients of this medicine (see What are the ingredients in EVUSHELD).

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

- have low numbers of blood platelets (which help blood clotting), a bleeding disorder or are taking an anticoagulant medicine (to prevent blood clots).
- are pregnant, think you may be pregnant or are planning to have a baby, ask your healthcare professional for advice before receiving this medicine. There is not enough information to be sure that EVUSHELD is safe for use in pregnancy. EVUSHELD will only be given if the potential benefits of use outweigh the potential risks to you and your unborn child.
- are breast-feeding, ask your healthcare professional for advice before receiving this medicine. It is unknown if EVUSHELD or the COVID-19 virus pass into human breast milk. You will need to consider the potential benefits of use for you, compared with the health benefits and risks of breast-feeding for your baby.
- have a history of severe allergic reaction to this drug.
- have had a heart attack or stroke, have other heart problems, or are at high-risk of cardiac (heart) events.

### **Serious allergic reaction**

Tell your healthcare professional or seek medical help right away if you notice any signs of serious allergic reaction during or following administration of EVUSHELD including: difficulty breathing or swallowing, swelling of the face, lips, tongue or throat, severe itching of the skin, with a red rash or raised bumps.

### **Other warnings you should know about:**

EVUSHELD should not be given to children below 12 years of age or weighing less than 40 kg.

COVID-19 is caused by different strains (variants) of the SARS-CoV-2 virus that change over time. EVUSHELD may be less effective at preventing COVID-19 caused by some strains than others. Contact your healthcare professional right away if you get symptoms of COVID-19. COVID-19 affects different people in different ways:

- the most common symptoms include fever, cough, tiredness and loss of taste or smell;
- the most serious symptoms include difficulty breathing or shortness of breath, loss of speech or mobility, or confusion and chest pain.

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

### **How to take EVUSHELD:**

EVUSHELD will be given to you by a healthcare professional as two intramuscular injections, usually one into each of your buttocks.

### **Usual dose:**

EVUSHELD consists of two medicines, tixagevimab and cilgavimab. You will receive 2 injections one after the other.

The recommended dose for pre-exposure prophylaxis (prevention) of COVID-19 is 300 milligrams (mg) given as two 1.5 mL injections:

- 150 mg of tixagevimab

- 150 mg of cilgavimab

The recommended dose for pre-exposure prophylaxis (prevention) of some variants of COVID-19 is 600 milligrams (mg), given as two 3.0 mL injections:

- 300 mg of tixagevimab
- 300 mg of cilgavimab

The recommended dose for treatment of mild to moderate COVID-19 is 600 mg, given as two 3.0 mL injections:

- 300 mg of tixagevimab
- 300 mg of cilgavimab

Your healthcare professional will decide which dose you need to receive.

**Overdose:**

If you think you, or a person you are caring for, have taken too much EVUSHELD, 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 EVUSHELD?**

These are not all the possible side effects you may have when taking EVUSHELD. If you experience any side effects not listed here, tell your healthcare professional.

Allergic reactions may be serious and occur during or following administration of monoclonal antibodies (see Serious allergic reaction above).

A higher percentage of people who received EVUSHELD compared to people who did not receive EVUSHELD reported serious cardiac adverse events in a clinical trial. It is not known if these events are related to EVUSHELD or underlying medical conditions. Contact your healthcare professional or get medical help right away if you get any symptoms of cardiac events, including pain, pressure, or discomfort in the chest, arms, neck, back, stomach or jaw, as well as shortness of breath, feeling tired or weak (fatigue), feeling sick (nausea), or swelling in your ankles or lower legs.

If you notice any side effects, please tell your healthcare professional right away:

**Common:** may affect up to 1 in 10 people

- hypersensitivity reaction (rash or hives - an itchy red rash or raised bumps)
- injection site reaction (pain, redness, itching, swelling where the injection was given)

**Uncommon:** may affect up to 1 in 100 people

- injection related reaction (examples of these include headache, chills and redness, discomfort or soreness near where the injection was given)

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, 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/adverse-reaction-reporting.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.*

### **Storage:**

The following information about storage, expiry and use and handling is intended for the healthcare professional:

- Keep out of reach and sight of children.
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C to 8°C).
- Do not freeze. Do not shake.
- Store in the original package in order to protect from light.
- Prepared syringes should be used immediately. If necessary, store the prepared syringes for no more than 4 hours either: at 2°C to 8°C, or at room temperature up to 25°C.
- Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

### **If you want more information about EVUSHELD:**

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website: [www.astrazeneca.ca](http://www.astrazeneca.ca), or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at [www.astrazeneca.ca](http://www.astrazeneca.ca).

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