

# Fact Sheet for Patients, Parents And Caregivers Emergency Use Authorization (EUA) of EVUSHELD™ (tixagevimab co-packaged with cilgavimab) for Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider believes it is necessary to provide you with EVUSHELD (tixagevimab co-packaged with cilgavimab) for pre-exposure prophylaxis for prevention of coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus.

This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking EVUSHELD, which you have received or may receive.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to make EVUSHELD available during the COVID-19 pandemic (for more details about an EUA please see “**What is an Emergency Use Authorization?**” at the end of this document). EVUSHELD is not an FDA-approved medicine in the United States.

Read this Fact Sheet for information about EVUSHELD. Talk to your healthcare provider if you have any questions. It is your choice to receive or not receive EVUSHELD.

## **What is COVID-19?**

COVID-19 is caused by a virus called a coronavirus. You can get COVID-19 through close contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. Older people and people of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19.

## **What is EVUSHELD (tixagevimab co-packaged with cilgavimab)?**

EVUSHELD is an investigational medicine used in adults and adolescents (12 years of age and older who weigh at least 88 pounds [40 kg]) for pre-exposure prophylaxis for prevention of COVID-19 in persons who are:

- not currently infected with SARS-CoV-2 and who have not had recent known close contact with someone who is infected with SARS-CoV-2 **and**
  - Who have moderate to severe immune compromise due to a medical condition or have received immunosuppressive medicines or treatments **and** may not mount an adequate immune response to COVID-19 vaccination **or**

- For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) or COVID-19 vaccine ingredient(s).

EVUSHELD is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using EVUSHELD for pre-exposure prophylaxis for prevention of COVID-19. EVUSHELD is not authorized for post-exposure prophylaxis for prevention of COVID-19.

The FDA has authorized the emergency use of EVUSHELD for pre-exposure prophylaxis for prevention of COVID-19 under an Emergency Use Authorization (EUA).

### **What should I tell my healthcare provider before I receive EVUSHELD?**

#### **Tell your healthcare provider if you:**

- Have any allergies, including if you have had a severe allergic reaction to a COVID-19 vaccine
- Have low numbers of blood platelets (which help blood clotting), a bleeding disorder, or are taking anticoagulants (to prevent blood clots)
- Have had a heart attack or stroke, have other heart problems, or are at high-risk of cardiac (heart) events
- Are pregnant or plan to become pregnant
- Are breastfeeding a child
- Have any serious illness
- Are taking any medications (prescription, over-the-counter, vitamins, or herbal products)

### **How will I receive EVUSHELD?**

- EVUSHELD consists of two investigational medicines, tixagevimab and cilgavimab.
- You will receive 1 dose of EVUSHELD, consisting of 2 separate injections (tixagevimab and cilgavimab).
- EVUSHELD will be given to you by your healthcare provider as 2 intramuscular injections, given one after the other.

Viruses can change over time (mutate) and develop into a slightly different form of the virus, called a variant. Based on what we know about current SARS-CoV-2 variants, you will need to receive additional doses of EVUSHELD **every 6 months** if ongoing protection is needed. Talk to your healthcare provider for more information.

### **Who should generally not take EVUSHELD?**

Do not take EVUSHELD if you have had a severe allergic reaction to EVUSHELD.

### **What are the important possible side effects of EVUSHELD?**

Possible side effects of EVUSHELD are:

- **Allergic reactions.** Allergic reactions can happen during and after injection of EVUSHELD and can sometimes be serious or life-threatening. You may have an increased risk of allergic reaction with EVUSHELD if you have had a severe allergic reaction to a COVID-19 vaccine. EVUSHELD contains polysorbate 80, an ingredient in some COVID-19 vaccines. Also, polysorbate 80 is similar to polyethylene glycol (PEG), an ingredient in other COVID-19 vaccines. Your healthcare provider may consult with a healthcare provider who specializes in allergy and immunology before giving you EVUSHELD if you have had a serious allergic reaction to a COVID-19 vaccine.

Your healthcare provider will monitor you for allergic reactions during and for at least 1 hour after you receive EVUSHELD. **Tell your healthcare provider right away if you get any of the following signs and symptoms of an allergic reaction during or after you receive EVUSHELD:**

- trouble breathing or shortness of breath
  - chills
  - tiredness or weakness
  - fast heart rate
  - chest pain or discomfort
  - nausea and vomiting
  - swelling of your face, lips, mouth and tongue
  - hives
  - wheezing
  - itching
  - skin flushing
  - sweating
  - muscle aches
  - you feel lightheaded or faint
  - throat tightness
- **Cardiac (heart) events:** Serious cardiac adverse events have happened, but were not common, in people who received EVUSHELD and also in people who did not receive EVUSHELD in the clinical trial studying pre-exposure prophylaxis for prevention of COVID-19. In people with risk factors for cardiac events (including a history of heart attack), more people who received EVUSHELD experienced serious cardiac events than people who did not receive EVUSHELD. It is not known if these events are related to EVUSHELD or underlying medical conditions. Contact your healthcare provider 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.

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

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

It is possible that EVUSHELD may reduce your body's immune response to a COVID-19 vaccine. If you have received a COVID-19 vaccine, you should wait to receive EVUSHELD until at least 2 weeks after COVID-19 vaccination.

### **What other important information do I need to know when receiving EVUSHELD?**

**Risk of COVID-19 caused by certain SARS-CoV-2 variants:** Viruses can change over time (mutate) and develop into a slightly different form of the virus, called a variant. EVUSHELD may not be effective at preventing COVID-19 caused by certain SARS-CoV-2 variants. If you are exposed to these variants, your chance of developing COVID-19 is higher than from other variants. **Tell your healthcare provider right away, and test for COVID-19, if you develop any symptoms of COVID-19, including:**

- fever or chills
- cough
- shortness of breath or difficulty breathing
- feeling tired (fatigue)
- muscle or body aches
- headache
- sore throat
- new loss of taste or smell
- congestion or runny nose
- nausea or vomiting
- diarrhea

If you develop COVID-19, your healthcare provider may recommend one of the available COVID-19 treatments.

For more information about the symptoms of COVID-19, go to <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms>.

### **What other prevention choices are there?**

Vaccines to prevent COVID-19 are approved or available under Emergency Use Authorization. Use of EVUSHELD does not replace vaccination against COVID-19. For more information about other medicines authorized for treatment or prevention of COVID-19 go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization> for more information.

It is your choice to receive or not receive EVUSHELD. Should you decide not to receive EVUSHELD, it will not change your standard medical care.

EVUSHELD is not authorized for post-exposure prophylaxis of COVID-19.

### **What if I am pregnant or breastfeeding?**

If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.


### **How do I report side effects with EVUSHELD?**

Contact your healthcare provider if you have any side effects that bother you or do not go away. Report side effects to FDA MedWatch at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088 or call AstraZeneca at 1-800-236-9933.

### Additional Information

If you have questions, visit the website or call the telephone number provided below.

To access the most recent EVUSHELD Fact Sheets, please scan the QR code provided below.

Website	Telephone number
<p data-bbox="316 512 675 546"><a href="http://www.evusheld.com">http://www.evusheld.com</a></p> 	<p data-bbox="986 512 1214 546">1-800-236-9933</p>

### How can I learn more about COVID-19?

- Ask your healthcare provider.
- Visit <https://www.cdc.gov/COVID19>
- Contact your local or state public health department.

### What is an Emergency Use Authorization?

The United States FDA has made EVUSHELD (tixagevimab co-packaged with cilgavimab) available under an emergency access mechanism called an Emergency Use Authorization EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

EVUSHELD for pre-exposure prophylaxis for prevention of coronavirus disease 2019 (COVID-19) caused by the SARS-CoV-2 virus has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA has determined, among other things, that based on the total amount of scientific evidence available including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives.

All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic. The EUA for EVUSHELD is in effect for the duration of the COVID-19 declaration justifying emergency use of EVUSHELD, unless terminated or revoked (after which EVUSHELD may no longer be used under the EUA).

### What are the ingredients in EVUSHELD?

Each EVUSHELD co-packaged carton contains 2 vials.

**Active ingredient:** Each of the vials contains either: tixagevimab or cilgavimab

**Inactive ingredients:** Each vial contains L- histidine, L- histidine hydrochloride monohydrate, polysorbate 80, sucrose, water.



**Distributed by:** AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850

**Manufactured for:** AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850

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