### **Evusheld**

**Tixagevimab and Cilgavimab** (COVID-19 long-acting antibody combination)

Patient guide

### Not all individuals respond to COVID-19 vaccines equally and are protected:

#### What is Evusheld?

Is a medicine used in adults and adolescents (12 years of age and older who weigh at least 40 kg) for pre-exposure prophylaxis for prevention of COVID-19.



Despite being vaccinated, if you have a weak immune system, it could make you more susceptible to getting COVID-19 and being more likely to pass it on to your contacts at home.<sup>2</sup>



Because compromised patients' response to COVID-19 vaccines is lower than the general population, you are more likely to get a severe infection that requires hospital treatment, more often than healthy people.<sup>1,2</sup>

<sup>1.</sup> Center of disease control and prevention. People with Certain Medical Conditions. Available at: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Last accessed 20.2.2022 2. Dooling K. Evidence to recommendation framework: an additional dose of mRNA COVID-19 vaccine following a primary series in immunocompromised people. Published August 13, 2021. Accessed December 16, 2021. https://bit.ly/2Uqqy3H

# The response to COVID-19 vaccines may be lower if the individual has immunodeficiency:

#### An individual's response to COVID-19 vaccine may be lower if they:



Take immunosuppressive medications.<sup>2</sup>



If they have HIV infection.<sup>2</sup>



Undergo organ transplant operations or donor organ recipients.<sup>2</sup>



Suffer from moderate or severe primary immunodeficiency.<sup>2</sup>



Receive active treatment for solid tumors or have malignant blood tumors.<sup>2</sup>



Suffer from chronic kidney disease or are on dialysis.<sup>2</sup>

<sup>1.</sup> Galmiche S, Luong Nguyen LB, Tartour E, et al. Immunological and clinical efficacy of COVID-19 vaccines in immunocompromised populations: a systematic review. Clin Microbiol Infect. 2022;28{2}:1-1.

<sup>2.</sup> Dooling K . Evidence to recommendation framework: an additional dose of mRNA COVID-19 vaccine following a primary series in immunocompromised people. Published August 13, 2021. Accessed December 16, 2021. https://bit.ly/2Uqqy3H



While vaccines remain the best strategy for preventing COVID-19, long-acting monoclonal antibodies as Tixagevimab/Cilgavimab, can reduce the risk of contracting COVID-19 in some immunocompromised people.<sup>12</sup>



Tixagevimab/Cilgavimab can be a preventive measure for an additional layer of protection against COVID-19 in patients with compromised immunity.<sup>1,2</sup>

Ask your physician how Tixagevimab/Cilgavimab (long-acting antibodies) could be a measure for an additional layer if:



You have a history of **severe adverse reactions** to the COVID-19 vaccine and/or its components, therefore, it is not recommended that you receive the currently available COVID-19 vaccine.<sup>3</sup>





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You have immunodeficiency due to a medical condition or taking medications or receiving immunosuppressive treatments and may not show an adequate immune response to the COVID-19 vaccine.<sup>3</sup>

<sup>1.</sup> Taylor, P.C., Adams, A.C., Hufford, M.M. et al. Neutralizing monoclonal antibodies for treatment of COVID-19. Nat Rev Immunol 21, 382–393 (2021). https://doi.org/10.1038/s41577-021-00542-x

<sup>2.</sup> Fact sheet for healthcare providers. Emergency Use Authorization (EUA) of EVUSHELD™ (tixagevimab co-packaged with cilgavimab). 2021.

<sup>3.</sup> U.S. Food and drug administration. Coronavirus (COVID-19) Update: FDA Authorizes New Long-Acting Monoclonal Antibodies for Pre-exposure Prevention of COVID-19 in Certain Individuals. Available at: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-new-long-acting-monoclonal-antibodies-pre-exposure#:~:text=Tixagevimab%20and%20cilgavimab%20are%20long,and%20entry%20into%20human%20cells.

# How Tixagevimab/Cilgavimab long acting monoclonal antibody is administered?



You will receive a single dose consisting of 2 sequential IM injections of **Tixagevimab and Cilgavimab.**<sup>1</sup>



Given by your healthcare provider as two Intramuscular injections at different injection sites.<sup>1</sup> (preferably in the gluteal muscles)



After the initial dose, if your healthcare provider determines that you need to receive additional doses of Tixagevimab/Cilgavimab for continued protection, additional doses will be given once every 6 months based on the COVID-19 circulation.1



Wait at **At least 2 weeks** if you've had the COVID-19 vaccine.<sup>1</sup>

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

### What should I expect after receiving Tixagevimab/Cilgavimab long acting antibody?



### Tixagevimab/Cilgavimab is safe to use.



You may feel some side effects of having any medication given by intramuscular injection, which may include<sup>1</sup>:



Pain and bruising of the skin.



Rigidity, swelling, possible bleeding, or infection at the injection site.

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

# What should I tell my healthcare provider before I receive Tixagevimab/Cilgavimab long acting antibody?



If you have any allergies.1



If you have a low number of blood platelets (which help blood clots), a bleeding disorder, or you are taking anticoagulants (to prevent blood clots).<sup>1</sup>



If you have had a heart attack or stroke, have other heart problems, or are at risk of developing heart disease.1



If you are **pregnant** or planning to become pregnant.<sup>1</sup>



If you are breastfeeding.1



Taking any medications
(prescription,
over-the-counter,
vitamins, or herbal
products).1

<sup>1.</sup> Fact Sheet for Patients, Parents And Caregivers Emergency Use Authorization (EUA) of EVUSHELD™ (tixagevimab co-packaged with cilgavimab) for Coronavirus Disease 2019 (COVID-19).

What are the important possible side effects of Evusheld?

Allergic reactions: Allergic reactions can happen during and after injection of Tixagevimab/Cilgavimab. 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 or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, dizziness and sweating. These reactions may be severe or life threatening.

Cardiac (heart) events: In people with risk factors for cardiac events (including a history of heart attack) who received experienced serious cardiac events more than people who did not receive Tixagevimab/Cilgavimab.

For Medical information please send an email to medinfo-ksa@astrazeneca.com
For AE reporting send email to ksa.ae@astrazeneca.com

Date of Preparation: August 2022 In case of any Adverse Events please contact with The National Pharmacovigilance Centre (NPC) Saudi Food and Drug Authority (SFDA)

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