



# Tixagevimab plus cilgavimab (Evusheld®) Patient Information

This information leaflet includes important information about the medicine called tixagevimab plus cilgavimab (Evusheld®) which can be used to protect a patient from getting COVID-19 or from getting very sick if they contract COVID-19.

NOTE: Evusheld® is not recommended as a substitute for COVID-19 vaccination in individuals for whom COVID-19 vaccination is recommended.

## What is the medication used for?

Tixagevimab plus cilgavimab (Evusheld®) has been provisionally approved in Australia for the prevention of COVID-19 in adults and adolescents (aged 12 years and older weighing more than 40 kg) when vaccination is not recommended or is unlikely to have worked well for them and are at high risk of becoming severely unwell. It is important that you have not recently been in contact with someone who has had COVID-19 before commencing treatment.

## What does this medication do?

Evusheld® belongs to a group of medicines called monoclonal antibodies. Evusheld® has been developed for the prevention of COVID-19 disease progression. It works by binding to the virus and preventing it from entering human cells and multiplying in the body. The results of a recent study indicate it probably reduces your risk of contracting symptomatic COVID-19 or being admitted to hospital or dying from COVID-19.

### What should be considered when using Evusheld®?

Because Evusheld® is a new medicine, information about how well it works and how safe it is, is currently being collected.

It is important that patients and their carers understand when and why Evusheld® may be useful.

Your health practitioner will provide more information about how well it works and how safe it is for your condition.

Evusheld® is a new medicine used in adults and adolescents for prevention of COVID-19 for certain eligible individuals who:

- are 12 years of age and older who weigh at least 40 kg
- 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
- have moderate to severely weakened immune system due to a medical condition, have received immunosuppressive medicines or treatments and may not mount an adequate immune response to COVID-19 vaccination or
- are not eligible to receive the COVID-19 vaccine due to a history of severe adverse reaction (such as severe allergic reaction) to the COVID-19 vaccine(s) or COVID-19 vaccine ingredient(s).

The use of Evusheld® is new and it is important for you to provide consent before receiving Evusheld®. You can always change your mind about treatment with Evusheld® and withdraw your consent at any time.

## How is Evusheld® given?

Evusheld® will be given as 2 separate injections. They are usually given one after the other. It is injected into the muscle of the buttocks (one in each of your buttocks) by a doctor or nurse.

- tixagevimab 150mg in 1.5mL
- cilgavimab 150mg in 1.5mL

You will be observed by the nurse or doctor for 15 minutes after receiving Evusheld® to make sure you do not have an allergic reaction.

After the initial dose, if your doctor determines that you need to receive additional doses of Evusheld® for ongoing protection, the additional doses would be administered once every 6 months.

## Are there special precautions with Evusheld® treatment?

### Use with Other Medicines

Evusheld® is a new medicine. So far, no medicine interactions have been identified for Evusheld® in any clinical trials. However, it is important that the doctors and other health practitioners (such as the pharmacist or nurse) are informed about all medications normally taken or planned. This includes over-the-counter and complementary medicines e.g. vitamins, minerals, herbal or naturopathic medicines.

The health practitioner will check for medicine interactions before Evusheld® is started and when it is stopped.

### Vaccinations

There is currently limited information about the effect Evusheld® may have on any recent vaccinations you have had, including any COVID-19 vaccination. This treatment may reduce your response to vaccines given within 14 days (before or after) treatment with Evusheld®. Make sure you tell the health practitioner about any of your recent vaccinations. Consult your health practitioner about future vaccinations and their timing, including any COVID-19 vaccinations.

### Fertility, Pregnancy and Breastfeeding

- Further studies about using Evusheld® in pregnancy and breastfeeding are underway. Consult your health practitioner (e.g. doctor or pharmacist) for information and advice.
- Currently, the effect of Evusheld® on fertility is unknown.

For further information about the use of this medicine in pregnancy, breastfeeding or family planning, please contact the King Edward Memorial Hospital Obstetric Medicines Information Service on 6458 2723.

## What are the side effects of Evusheld®?

All medicines have side effects. Sometimes they are serious, but most of the time they are not, and many side effects disappear with time or when treatment is stopped. Medical treatment may be needed with some side effects.

Some people will not experience side effects. There is also the possibility of experiencing other unknown side effects with Evusheld® when it is used. Some possible side effects that might be experienced during and after treatment with Evusheld® for COVID-19 are listed on the next page.

## What should the health practitioner know before you are prescribed Evusheld®?

Tell your healthcare provider if you:

- Have any allergies
- Have low numbers of blood platelets, 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)

Possible side effects of Evusheld®	What to do
<ul style="list-style-type: none"> <li>• Skin redness or rash (hives)</li> <li>• Diarrhoea</li> <li>• Pain, bruising of the skin, soreness, swelling, and possible bleeding or infection at the injection site.</li> </ul>	<p>Tell your doctor or nurse if these symptoms occur and they can help treat them.</p>
<p>Non-allergy reactions while you receive Evusheld® may include:</p> <ul style="list-style-type: none"> <li>○ fever or chills</li> <li>○ chest pain or pressure</li> <li>○ fast, slow, or abnormal heartbeat</li> <li>○ upset stomach</li> <li>○ headache or dizziness</li> <li>○ throat irritation or shortness of breath</li> <li>○ itchiness and rash</li> </ul>	<p>Tell your doctor or nurse immediately if these symptoms occur when receiving treatment and they can help treat them.</p>
<p>Allergic reaction symptoms may include:</p> <ul style="list-style-type: none"> <li>○ feeling short of breath, wheezing, difficulty breathing</li> <li>○ swelling of the face, lips, tongue, or other parts of the body</li> <li>○ severe skin rash, itching, hives</li> </ul>	<p>Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
<p>Serious cardiac and blood clot adverse events including the following symptoms:</p> <ul style="list-style-type: none"> <li>○ pain, pressure, or discomfort in the chest, arms, neck, back, stomach, legs or jaw, abdominal pain</li> <li>○ shortness of breath,</li> <li>○ faster than normal heartbeat,</li> <li>○ feeling tired or weak (fatigue), feeling sick (nausea),</li> <li>○ swelling in your ankles or lower legs,</li> <li>○ coughing up blood,</li> <li>○ difficulties speaking or confusion,</li> <li>○ loss of movement or weakness on one side of the body or face, severe headache.</li> </ul>	<p>Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> <p>It is not known if these events are related to Evusheld® or underlying medical conditions.</p>
<p><b>Please note:</b> This is not a complete list of all possible side effects. A link to find out more information on the side effects of Evusheld® is listed at the end of this information leaflet. Your health practitioner can provide a more complete list of side effects.</p> <p>Side effects can be reported to the health practitioner directly and/or to the Therapeutic Goods Administration at <a href="http://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>.</p>	

**If you are experiencing any side effects, including any of the ones listed above, or are feeling unwell in any way, please call the health practitioner on the phone number below for advice**

Name of health practitioner to call:	
Telephone number:	

## More information on Evusheld®?

- AstraZeneca Pty Ltd. Australian Consumer Medicines Information Evusheld®. Therapeutic Goods Administration. Published 25 February 2022.  
<https://www.tga.gov.au/sites/default/files/evusheld-cmi.pdf>
- National COVID-19 Clinical Evidence Taskforce. Australian Guidelines for the Clinical Care of people with COVID-19. Tixagevimab plus cilgavimab (Evusheld®) for pre-exposure prophylaxis  
<https://app.magicapp.org/#/guideline/L4Q5An/section/j7Amwz>

**This document can be made available in alternative formats on request for a person with disability.**

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