

EVUSHELD™

tixagevimab 150 mg and cilgavimab 150 mg, solution for injection

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Evusheld**. It does not contain all the information that is known about **Evusheld**.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Evusheld** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet, you may need to read it again.

What Evusheld is used for

Evusheld contains the active ingredients tixagevimab and cilgavimab.

Tixagevimab and cilgavimab are types of protein called 'monoclonal antibodies'.

Tixagevimab and cilgavimab (**Evusheld**) work specifically against the SARS-CoV-2 virus preventing it from entering your cells. This can help prevent you from getting COVID-19 illness.

COVID-19 is an illness which can affect your lungs, airways and other organs. COVID-19 illnesses can be very mild (sometimes with no symptoms), however in some cases symptoms can be severe and can result in hospitalisation or even death.

Evusheld is used to help prevent adults and adolescents (aged 12 years and older weighing at least 40 kg), who have not been recently in contact with someone who has COVID-19, from getting COVID-19 illness when they:

- have an illness or take medicines making them unlikely to respond to or be protected by vaccination against COVID-19
- or are not recommended to have a vaccine due to a history of severe allergies to a COVID-19 vaccine or its components.

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

This medicine is only available with a doctor's prescription.

Before you use Evusheld

When you must not use it

Do not use Evusheld if: you are allergic to tixagevimab, cilgavimab or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any allergies
- have any low numbers of blood platelets (which help blood clotting)
- have had a heart attack or stroke, have other heart problems, or are at high-risk of cardiac (heart) events
- have a bleeding disorder or are taking a blood thinning medicine (to prevent blood clots)
- are taking, have recently taken or might take any medicines for any other condition.

If you have received a COVID-19 vaccine, tell your doctor or nurse, prior to using **Evusheld**. It is possible that **Evusheld** may reduce your body's immune response to a COVID-19 vaccine.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your healthcare provider for advice before receiving this medicine.

Tell your doctor if you are pregnant, or if you might be pregnant. There is not enough information to be sure that this medicine is safe for use in pregnancy. **Evusheld** will only be given if the potential benefits of treatment outweighs the potential risks to the mother and the unborn child.

Talk to your doctor if you are breastfeeding. It is not yet known whether **Evusheld** passes into human milk or what the effects might be on the baby or milk production. Your doctor will help you decide whether to keep breastfeeding or to start treatment with this medicine.

Children and adolescents

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

Taking other medicines

If you are getting a COVID-19 vaccine, tell your doctor, nurse or pharmacist that you have used or are using **Evusheld**.

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Evusheld.

How is Evusheld given

How much is given

Evusheld consists of two medicines, tixagevimab and cilgavimab. You will receive 2 injections one after the other. The recommended dose is 300 mg given as two 1.5 mL injections:

- 150 mg of tixagevimab
- 150 mg of cilgavimab

How you will be given Evusheld

Evusheld will be given to you in a healthcare facility under the supervision of a healthcare professional who is experienced in the use of this type of treatment. They will watch you closely while you are being given this medicine. This is in case you get any side effects.

Evusheld will be given as two intramuscular injections into separate muscles, usually one into each of your buttocks. Your doctor or nurse will decide how long you will be monitored after you are given the medicine, in case you have any side effects.

What should I know while I am being given Evusheld

Things you should do

Tell any other doctors you see that you have had this medicine to prevent COVID-19.

If you are getting a COVID-19 vaccine, tell the doctor, nurse or pharmacist you have had this medicine.

Call your doctor straight away if you notice any signs of serious allergic reaction, such as:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

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. If you are taking **Evusheld** to help prevent you from getting COVID-19, and you get symptoms of COVID-19 please contact your doctor right away. 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.

Driving or using machines

It is unlikely that **Evusheld** will affect your ability to drive or use machines.

Overdose

As **Evusheld** is given under the close supervision of a healthcare provider it is unlikely that you will be given too much.

If you are concerned that you have been given too much **Evusheld**, tell your healthcare provider immediately, phone the the National Poisons Centre (Ph: 0800 POISON or 0800 764 766) or go to the Emergency Department at your nearest hospital

You should do this even if there are no signs of discomfort or poisoning.

Side effects

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Allergic reactions may be serious and have occurred during or following administration of **Evusheld** (see Before you use **Evusheld** section, and serious side effects table below).

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Skin: <ul style="list-style-type: none"> • Pain, bruising of the skin, soreness or swelling at the injection site. 	Speak to your doctor if you have any of these side effects and they worry you.

Serious side effects

Serious side effects	What to do
Serious allergic reactions, some of the symptoms may include: <ul style="list-style-type: none"> • Difficulty breathing or swallowing • Swelling of the face, lips, tongue or throat • Severe itching of the skin, with a red rash or raised bumps. Cardiac (heart) and blood clot events: <ul style="list-style-type: none"> • Pain, pressure, or discomfort in the chest, arms, neck, back, stomach, legs or jaw, abdominal pain, shortness of breath, faster than normal heart beat, feeling tired or weak (fatigue), feeling sick (nausea), swelling in your ankles or lower legs, coughing up blood, difficulties speaking or confusion, loss of movement or weakness on one side of the body or face, severe headache. 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Evusheld**.

Looking after Evusheld

Storage

Evusheld will be given to you in a healthcare facility and the healthcare professionals caring for you will be responsible for storing this medicine.

Unopened vials should be stored in a refrigerator (at 2°C to 8°C), in the original carton to protect from light.

Do not freeze. Do not shake. 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.

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

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Unused medicine or waste material will be discarded by your healthcare professional.

Product description**What Evusheld looks like**

Each carton of **Evusheld** contains:

- one single use clear glass vial of tixagevimab solution for injection (dark grey vial cap)
- one single use clear glass vial of cilgavimab solution for injection (white vial cap).

Each of the single use vials contains a clear to opalescent, colourless to slightly yellow solution.

Ingredients

Active ingredient (main ingredient)	tixagevimab and cilgavimab
Other ingredients (inactive ingredients)	histidine, histidine hydrochloride monohydrate, sucrose, polysorbate 80 and water for injection

Marketed by:

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Date of preparation

This leaflet was prepared on 20 March 2023

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