

Package leaflet: Information for the patient

Evusheld 150 mg / 150 mg solution for injection tixagevimab/cilgavimab

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Evusheld is and what it is used for
2. What you need to know before you are given Evusheld
3. How Evusheld is given
4. Possible side effects
5. How to store Evusheld
6. Contents of the pack and other information

1. What Evusheld is and what it is used for

Evusheld is made up of two active substances tixagevimab and cilgavimab. These are both medicines called *antiviral monoclonal antibodies*. They work specifically against SARS-CoV-2, the virus that causes COVID-19. They prevent the virus from entering human cells.

Evusheld is used to help prevent COVID-19 infection in adults who are not currently infected with COVID-19 and who have not been recently in contact with someone who has COVID-19 when they:

- are unlikely to be protected by a COVID-19 vaccine
- or when vaccination is not recommended

Evusheld is used to treat COVID-19 in adults who do not require supplemental oxygen and who are at risk of progressing to severe COVID-19.

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

2. What you need to know before you are given Evusheld

This medicine must not be given:

- if you are **allergic** to tixagevimab, cilgavimab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you are given Evusheld:

- If you have low numbers of blood platelets (which help blood clotting), any blood clotting problems or are taking a medicine to prevent blood clots (an anticoagulant).
- have had a heart attack or stroke, have other heart problems, or are at high-risk of cardiac (heart) problems or blood clots.

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 or treating COVID-19 caused by some strains than others. The doctor will take into consideration what is known about the circulating viral variants before prescribing Evusheld. However, do contact your doctor right away if you get symptoms of COVID-19 or if your COVID-19 symptoms worsen. 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 a doctor, pharmacist or nurse or get medical help immediately if you notice any signs of a 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

See also section 4.

Children and adolescents

Evusheld should not be given to children.

Other medicines and Evusheld

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines including any medicines that you buy without a prescription from your pharmacy or supermarket.

Pregnancy and breastfeeding

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

Driving and using machines

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

3. How Evusheld is given

Evusheld will be given to as two injections one after the other into a muscle (usually one injection into each of your buttocks).

The injections will be administered by a doctor or nurse in a healthcare setting. You will be observed for at least 1 hour after getting the injections.

The recommended dose for prevention of COVID-19 is 300 mg, given as two injections:

- 150 mg of tixagevimab
- 150 mg of cilgavimab

The recommended dose for prevention of some variants of COVID-19 is 600 mg, given as two injections:

- 300 mg of tixagevimab
- 300 mg of cilgavimab

The recommended dose for treatment of COVID-19 is 600 mg, given as two injections:

- 300 mg of tixagevimab
- 300 mg of cilgavimab

You should be given Evusheld within 7 days of starting to experience symptoms of COVID-19.

Your doctor will decide what dose you need and if you need to receive additional doses of Evusheld for ongoing protection.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible serious effects

Allergic reactions may occur during or following administration of monoclonal antibodies. Signs include:

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

Tell your doctor, pharmacist or nurse or get medical help immediately if you notice any signs of a serious allergic reaction.

Other side effects that may occur

Common: may affect up to 1 in 10 people

- hypersensitivity reaction (rash or an itchy red rash or raised bumps) with 300mg dose
- injection site reaction (pain, redness, itching, swelling near where the injection was given)

Uncommon: may affect up to 1 in 100 people

- hypersensitivity reaction (rash or an itchy red rash or raised bumps) with 600mg dose
- injection related reaction (examples of these include headache, chills and redness, discomfort or soreness near where the injection was given)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Coronavirus Yellow Card Reporting site at <https://coronavirus-yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Evusheld

Your doctor, pharmacist or nurse is responsible for storing this medicine and disposing of any unused product correctly. The following information is intended for healthcare professionals.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Evusheld should not be used in case of discolouration or particles being observed.

Store the unopened vials in a refrigerator (2°C to 8°C).

Do not freeze.

Do not shake.

Keep vials 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

Do not throw away any medicines via wastewater or household waste. Your healthcare professional will throw away any medicines that are no longer being used. These measures will help protect the environment.

6. Contents of the pack and other information

What Evusheld contains

The active substances are:

- tixagevimab – 150 mg in 1.5 ml of solution.
- cilgavimab – 150 mg in 1.5 ml of solution.

The other ingredients are histidine, histidine hydrochloride monohydrate, sucrose, polysorbate 80 (E433) and water for injections.

What Evusheld looks like and contents of the pack

Evusheld contains two clear glass vials of solution for injection:

- Tixagevimab solution for injection (dark grey vial cap) is a clear to opalescent, colourless to slightly yellow solution.
- Cilgavimab solution for injection (white vial cap) is a clear to opalescent, colourless to slightly yellow solution.

Each carton of Evusheld contains 2 vials, 1 vial each of tixagevimab and cilgavimab.

Marketing Authorisation Holder

AstraZeneca UK Limited,
600 Capability Green,
Luton,
LU1 3LU,
UK.

Manufacturer

AstraZeneca AB
Gärtnavägen,
Södertälje, 151 85,
Sweden

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Other sources of information

Scan the QR code with a mobile device to view this information.

www.evusheldpi.com

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000

Please be ready to give the following information:

Product name	Reference number
Evusheld solution for injection	17901/0360

This is a service provided by the Royal National Institute of the Blind.

The following information is intended for healthcare professionals only. Please refer to the Summary of Product Characteristics for further information.

Instructions for healthcare professionals**Evusheld 150 mg / 150 mg solution for injection**

Tixagevimab and cilgavimab must be administered as separate sequential intramuscular injections

Administration instructions

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Evusheld (tixagevimab and cilgavimab) should be administered by a qualified healthcare professional using aseptic technique.

Tixagevimab and cilgavimab must be given as separate sequential intramuscular injections at different injection sites in two different muscles, preferably in the gluteal muscles. The order in which the two products are administered does not matter.

Each carton contains two vials:

- tixagevimab 150 mg solution for injection (dark grey vial cap)
- cilgavimab 150 mg solution for injection (white vial cap)

Visually inspect the vials for particulate matter and discolouration. Both tixagevimab and cilgavimab are clear to opalescent, colourless to slightly yellow solutions. Discard the vials if the solution is cloudy, discoloured or visible particles are observed.

Do not shake the vials.

Do not mix Evusheld with any medicinal product.

Remove the flip-off top of the vial cap and clean the stopper with 70 % ethanol or equivalent. Insert the needle into the vial and withdraw into a syringe an appropriate volume of tixagevimab and cilgavimab (see Table 1).

Table 1: Recommended dose(s) of Evusheld (tixagevimab and cilgavimab)

Indication	Evusheld dose tixagevimab and cilgavimab	Antibody dose	Number of vials needed[†]	Volume to withdraw from vial(s)
Pre-exposure Prophylaxis of COVID-19	300 mg (1 EVUSHELD carton)	tixagevimab 150 mg	1 vial	1.5 mL
		cilgavimab 150 mg	1 vial	1.5 mL
	600 mg [‡] (2 EVUSHELD cartons)	tixagevimab 300 mg	2 vials	3.0 mL
		cilgavimab 300 mg	2 vials	3.0 mL
Treatment of COVID- 19	600 mg (2 EVUSHELD cartons)	tixagevimab 300 mg	2 vials	3.0 mL
		cilgavimab 300 mg	2 vials	3.0 mL

[†] Each vial contains an overfill to allow the withdrawal of 150 mg (1.5 mL).

[‡] A higher dose of 600 mg of Evusheld, as 300 mg of tixagevimab and 300 mg of cilgavimab, may be more appropriate for some SARS-CoV-2 variants (for example, Omicron BA.1, Omicron BA.1.1).

The solutions for injection do not contain a preservative and therefore, the prepared syringes should be administered immediately.

If immediate administration is not possible, and the prepared tixagevimab and cilgavimab syringes need to be stored, the total time from vial puncture to administration should not exceed 4 hours, either in a refrigerator (2°C to 8°C) or at room temperature (up to 25°C).

Any unused product or waste material should be disposed of in accordance with local requirements.

Overdose

There is no specific treatment for overdose with Evusheld.

In clinical trials, doses up to 600 mg intramuscular injections (300 mg each of tixagevimab and cilgavimab) and 3000 mg intravenously (1500 mg each of tixagevimab and cilgavimab) have been administered without dose-limiting toxicity.

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