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Evusheld (*tixagevimab / cilgavimab*)

An overview of Evusheld and why it is authorised in the EU

What is Evusheld and what is it used for?

Evusheld is a medicine used to prevent COVID-19 in adults and adolescents (from 12 years of age weighing at least 40 kilograms). It is also used to treat COVID-19 in adults and adolescents who do not require supplemental oxygen and who are at increased risk of the disease becoming severe.

Evusheld contains two active substances, tixagevimab and cilgavimab.

How is Evusheld used?

Evusheld is given as two injections (one of tixagevimab and one of cilgavimab) given one after the other at different sites, preferably in the gluteal muscles (buttocks). For the prevention of COVID-19, tixagevimab and cilgavimab are given at a dose of 150 mg each. For treatment, the two injections are given at a dose of 300 mg each, as soon as possible after a positive test for SARS CoV-2 and within 7 days of the start of symptoms of COVID-19.

The medicine can only be obtained with a prescription and should be given under conditions that allow patients to be adequately monitored and managed in case they develop severe allergic reactions, including anaphylaxis.

For more information about using Evusheld, see the package leaflet or contact your doctor or pharmacist.

How does Evusheld work?

Evusheld contains tixagevimab and cilgavimab, two monoclonal antibodies. A monoclonal antibody is a type of protein that has been designed to recognise and attach to a specific structure. Tixagevimab and cilgavimab have been designed to attach to the spike protein of SARS-CoV-2 (the virus that causes COVID-19) at two different sites. When the antibodies in Evusheld attach to the spike protein, the virus cannot enter the cells to multiply.

What benefits of Evusheld have been shown in studies?

Prevention of COVID-19

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

One main study involving over 5,000 people showed that Evusheld reduced the risk of COVID-19 infection by 77%, with duration of protection from the virus estimated to be at least six months. In the study, adults who had never had COVID-19 and had not received a COVID-19 vaccine or other preventative treatment received Evusheld or placebo (a dummy injection). Of the people given Evusheld, 0.2% (8 out of 3,441) had lab-confirmed breakthrough COVID-19, compared with 1% (17 out of 1,731) of the people who received placebo.

The study data were collected before the emergence of the Omicron variant. Laboratory studies show that the Omicron BA.1 variant may be less sensitive to tixagevimab and cilgavimab at 150 mg doses than the Omicron BA.2 variant.

Treatment of COVID-19

A main study involving around 900 adults with COVID-19 who did not need oxygen and who were at increased risk of their illness becoming severe showed that Evusheld led to fewer cases of severe COVID-19 or death than placebo. Of the patients who were not hospitalised at the time of treatment, 4.4% (18 out of 407) treated with Evusheld developed severe COVID-19 or died within 29 days of treatment, compared with 8.9% (37 out of 415) of those receiving placebo.

No clinical data were collected on the latest variants of concern, including Omicron sub-variants.

What are the risks associated with Evusheld?

The most common side effects with Evusheld (which may affect up to 1 in 10 people) are hypersensitivity (allergic reactions) and reactions at the site of injection.

For the full list of side effects and restrictions of Evusheld, see the package leaflet.

Why is Evusheld authorised in the EU?

Evusheld was shown to reduce the risk of developing COVID-19 in the first six months after being given as preventive treatment. As a treatment for patients with COVID-19 who were at increased risk of their disease becoming severe, the medicine was shown to reduce the risk of severe disease or death. The safety profile of Evusheld is favourable and side effects are generally mild.

The European Medicines Agency therefore decided that Evusheld's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Evusheld?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Evusheld have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Evusheld are continuously monitored. Suspected side effects reported with Evusheld are carefully evaluated and any necessary action taken to protect patients.

Other information about Evusheld

Evusheld received a marketing authorisation valid throughout the EU on 25 March 2022.

Further information on Evusheld can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/evusheld

This overview was last updated in 10-2022.