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Andembry (*garadacimab*)

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

What is Andembry and what is it used for?

Andembry is used for routine prevention of recurrent attacks of hereditary angioedema (HAE) in adults and adolescents aged 12 years and older.

Patients with hereditary angioedema have rapid swelling under the skin in areas such as the face, throat, gut, arms and legs. Attacks of HAE can be life threatening when the swelling around the throat presses against the airway.

Andembry contains the active substance garadacimab.

How is Andembry used?

The medicine can only be obtained with a prescription and should be started under the supervision of a healthcare professional experienced in the management of patients with HAE.

Andembry is given as an injection under the skin of the upper outer arms, abdomen (belly) or thighs, with two injections on the first day followed by monthly injections thereafter.

HAE is mainly caused by low levels or poor functioning of a protein known as C1 esterase inhibitor (type I and type II HAE). In rare cases, HAE can occur with normal C1 esterase inhibitor levels and function. If these patients do not respond to treatment and if they have not had a reduction in attacks after 3 months of treatment, doctors should consider stopping treatment.

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

How does Andembry work?

Patients with hereditary angioedema have high levels of a substance called 'bradykinin', which causes blood vessels to widen and leak fluid into the surrounding tissue, leading to the swelling and inflammation seen in angioedema. In patients with type I and type II HAE, high levels of bradykinin are caused by low levels or poor functioning of a protein known as C1 esterase inhibitor.

The active substance in Andembry, garadacimab, is a monoclonal antibody, a type of protein that has been designed to recognise and attach to FXIIa, which is a protein that triggers the production of

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bradykinin. By blocking FXIIa, Andembry prevents the production of bradykinin, which helps to prevent the swelling and related symptoms of angioedema.

What benefits of Andembry have been shown in studies?

Andembry was found to be more effective than placebo (a dummy treatment) in one main study involving 65 adults and adolescents aged 12 years or older with HAE with low levels or poorly functioning C1 esterase inhibitor. Patients taking Andembry for 6 months had an average of 0.27 attacks per month, compared with 2.0 attacks per month in patients taking placebo.

What are the risks associated with Andembry?

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

The most common side effects with Andembry (which may affect up to 1 in 10 people) include injection site reactions including erythema (redness), bruising, pruritis (itching) and urticaria (itchy rash) at the injection site, headache and abdominal pain.

Why is Andembry authorised in the EU?

Although there are treatments for HAE, there is still an unmet medical need. Andembry is effective in preventing recurrent attacks of HAE in adults and adolescents aged 12 years and older. However, the medicine may not be effective in patients with HAE with normal C1 esterase inhibitor. Although based on limited data, the safety profile is considered acceptable.

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

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

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

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

Other information about Andembry

Andembry received a marketing authorisation valid throughout the EU on 10 February 2025.

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

This overview was last updated in 12-2024.