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Ekterly (*sebetralstat*)

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

What is Ekterly and what is it used for?

Ekterly is a medicine used to treat symptoms of hereditary angioedema (swelling) attacks in people aged 12 years and older. People with hereditary angioedema have attacks of rapid swelling that can occur anywhere in the body such as the face, throat, arms, legs or around the gut. These attacks can be life threatening.

Hereditary angioedema is rare, and Ekterly was designated an 'orphan medicine' (a medicine used in rare diseases) on 21 June 2022. Further information on the orphan designation can be found on the EMA website.

Ekterly contains the active substance sebetralstat.

How is Ekterly used?

Ekterly can only be obtained with a prescription and treatment should be prescribed by a doctor experienced in treating people with hereditary angioedema.

The medicine is available as tablets to be taken by mouth. One tablet should be taken at the first signs of an attack. A second tablet may be taken at least 3 hours after the first tablet if the symptoms do not improve, get worse or come back. No more than two tablets should be taken over 24 hours.

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

How does Ekterly work?

The active substance in Ekterly, sebetralstat, works by blocking the activity of a protein called kallikrein. In people with hereditary angioedema, kallikrein is overactive and leads to increased levels of another protein called bradykinin. Bradykinin causes blood vessels to widen and become leaky, allowing fluid to build up in the surrounding tissues, which causes angioedema attacks. By blocking kallikrein, Ekterly reduces the amount of bradykinin made during an attack, which prevents it from getting worse.

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What benefits of Ekterly have been shown in studies?

A main study showed that Ekterly can lead to faster improvement of symptoms during hereditary angioedema attacks compared with placebo (a dummy treatment).

The main study involved 110 people aged 12 years and older with hereditary angioedema. Participants were instructed to take one tablet of Ekterly or placebo at the first signs of an attack. They could take a second tablet after at least 3 hours if symptoms had not improved enough or had worsened or come back. The main measure of effectiveness was the time it took for symptoms to start improving after taking the treatment, as determined using the patient global impression of change (PGI-C) scale. The PGI-C scale is a questionnaire that asks patients to rate how much their symptoms have improved or worsened after treatment.

On average, symptoms started improving 1.6 hours after taking the treatment in people given Ekterly, compared with 6.7 hours for those given placebo.

What are the risks associated with Ekterly?

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

The most common side effects with Ekterly (which may affect up to 1 in 10 people) include headache.

Why is Ekterly authorised in the EU?

A main study showed that Ekterly is more effective than placebo at relieving symptoms of hereditary angioedema attacks.

At the time of authorisation, Ekterly was the first medicine for hereditary angioedema attacks that could be taken by mouth. This provides a more comfortable option for patients than receiving medicines by injection. Furthermore, a tablet can be taken sooner after a patient begin to develop symptoms of an attack, which could reduce the severity and duration of the attack.

The safety of Ekterly was evaluated in a small number of patients. Episodes of headache with Ekterly were mild to moderate in intensity and went away on their own. Overall, side effects were mild to moderate and considered acceptable. However, there are some uncertainties about the potential for Ekterly to cause QT prolongation (abnormal electrical activity of the heart that affects its rhythm). A warning has therefore been included in the product information for the medicine to highlight this potential risk in people with pre-existing QT prolongation or known risk factors.

The European Medicines Agency therefore decided that Ekterly'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 Ekterly?

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

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

Other information about Ekterly

Ekterly received a marketing authorisation valid throughout the EU on 17 September 2025.

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

This overview was last updated in 08-2025.