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EPAR summary for the public

Ruconest

conestat alfa

This is a summary of the European public assessment report (EPAR) for Ruconest. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Ruconest.

What is Ruconest and what is it used for?

Ruconest is a medicine used to treat attacks of hereditary angioedema in adults and adolescents. Patients with angioedema have attacks of swelling that can occur anywhere in the body, such as in the face or limbs, or around the gut, causing discomfort and pain. Ruconest is used in patients with hereditary angioedema that is linked to naturally low levels of a protein called 'C1 esterase inhibitor'.

Ruconest contains the active substance conestat alfa.

How is Ruconest used?

Ruconest can only be obtained with a prescription and treatment should be started under the supervision of a doctor with experience in diagnosing and treating hereditary angioedema.

Ruconest is available as a powder (with or without solvent) that is made up into a solution for injection. It is given by slow injection into a vein lasting around five minutes. The dose depends on the patient's body weight. One injection is usually enough to treat an attack, but a second injection may be given if the patient does not improve enough after the first one. A patient should not be given more than two injections within any 24-hour period. Patients may be able to inject the medicine themselves after they have been properly trained. In this case the powder that comes with the solvent should be used.

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How does Ruconest work?

The C1 esterase inhibitor protein is required to control the 'complement' and 'contact' systems, collections of proteins in the blood that fight against infection and cause inflammation. Patients with low levels of this protein have excessive activity of these two systems, which leads to the symptoms of angioedema. The active substance in Ruconest, conestat alfa, is a copy of the C1 esterase inhibitor protein and wor ks in the same way as the natural human protein. When it is given during an angioedema attack, conestat alfa stops this excessive activity, helping to relieve the patient's symptoms.

What benefits of Ruconest have been shown in studies?

Ruconest was studied in two main studies involving a total of 70 adults and adolescents with hereditary angioedema caused by low levels of C1 esterase inhibitor protein. When an attack occurred, the patients were given Ruconest or placebo (a dummy treatment). The main measure of effectiveness was how long it took for the symptoms to start to improve. Improvement was measured by the patients rating the severity of their symptoms on a scale from 0 to 100.

Ruconest was more effective than placebo at improving the symptoms of patients having an attack of angioedema. Patients receiving Ruconest at doses of 50 units/kg and 100 units/kg started to improve after one and two hours. Patients receiving placebo started to improve after four hours in one study and after over eight hours in the other.

What is the risk associated with Ruconest?

The most common side effect with Ruconest (seen in between 1 and 10 patients in 100) is headache. For the full list of all side effects reported with Ruconest, see the package leaflet.

Ruconest must not be used in patients with known or suspected allergy to rabbits. For the full list of restrictions, see the package leaflet.

Why is Ruconest approved?

The CHMP decided that Ruconest's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

The company that markets Ruconest will ensure that healthcare professionals who are expected to prescribe Ruconest are provided with an educational pack containing information on the proper use of the medicine and warnings about the risk of allergy. The company will also provide prescribers with an alert card for their patients.

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

Other information about Ruconest

The European Commission granted a marketing authorisation valid throughout the European Union for Ruconest on 28 October 2010.

The full EPAR for Ruconest can be found on the Agency's website under EMA website/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Ruconest, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 01-2017.