



EUROPEAN MEDICINES AGENCY  
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## EPAR summary for the public

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# Ruconest

## conestat alfa

This document 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?

Ruconest is a powder that is made up into a solution for injection. It contains the active substance conestat alfa.

### What is Ruconest used for?

Ruconest is used to treat attacks of hereditary angioedema in adults (aged 18 years or over). 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'.

The medicine can only be obtained with a prescription.

### How is Ruconest used?

Treatment with Ruconest should be started under the supervision of a doctor with experience in diagnosing and treating hereditary angioedema. The medicine should only be given by a healthcare professional. Patients who have not received Ruconest before should be tested to see if they have antibodies against rabbit dander (shed skin and hair) in their blood – they should only be given Ruconest if their tests are negative.

Ruconest 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.

## **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 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 works 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.

Conestat alfa is produced by 'recombinant DNA technology': it is extracted from the milk of rabbits that have been given genes that make them able to produce the human protein in their milk.

## **How has Ruconest been studied?**

The effects of Ruconest were first tested in experimental models before being studied in humans.

Ruconest was studied in two main studies involving a total of 73 patients with hereditary angioedema caused by low levels of C1 esterase inhibitor protein. Most of the patients were adults. When an attack occurred, the patients were given one of two doses of Ruconest (50 or 100 units/kg) or placebo (a dummy treatment). Patients receiving the lower dose of Ruconest had the option of receiving a second dose up to four hours after the first. 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.

## **What benefit has Ruconest shown during the studies?**

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 have improvements after one and two hours, respectively. Patients receiving placebo started to have improvements after four hours in one study and after over eight hours in the other.

Most patients were successfully treated with the 50-unit/kg dose, with only around 10% of the patients needing a second dose. This dose had a similar success rate to the higher dose of Ruconest.

## **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 should not be used in people who may be hypersensitive (allergic) to conestat alfa or any of the other ingredients. It must not be used in patients with known or suspected allergy to rabbits.

## **Why has Ruconest been 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 use of Ruconest?**

The company that makes Ruconest will ensure that healthcare professionals in all Member States 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.

## **Other information about Ruconest:**

The European Commission granted a marketing authorisation valid throughout the European Union for Ruconest to Pharming Group N.V. on 28 October 2010. The marketing authorisation is valid for five years, after which it can be renewed.

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 07-2010.