EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2010
EMA/CHMP/380794/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Ruconest

conestat alfa

On 24 June 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ruconest, 2100 U, powder for solution for injection intended for the treatment of hereditary angioedema. Ruconest was designated as an orphan medicinal product on 11 May 2001. The applicant for this medicinal product is Pharming Group N.V.

They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Ruconest, conestat alfa (ATC Code not yet assigned), is a recombinant human component 1 (C1) esterase inhibitor. C1-inhibitor controls the activation of certain proteins in the complement, coagulation, fibrinolytic and contact systems that are involved in inflammation. Patients with hereditary angioedema (HAE) caused by C1 inhibitor deficiency experience recurrent attacks of angioedema. Replacement therapy with Ruconest relieves the symptoms and reduces the duration of these attacks. The most common side effect from taking Ruconest is headache.

A pharmacovigilance plan for Ruconest will be implemented as part of the marketing authorisation.

The approved indication is: “Ruconest is indicated for treatment of acute angioedema attacks in adults with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.” It is proposed that Ruconest is initiated under the guidance and supervision of a physician experienced in the diagnosis and treatment of hereditary angioedema. Ruconest should be administered by a health care professional.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Ruconest and therefore recommends the granting of the marketing authorisation.