10 November 2016
EMA/CHMP/732641/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Ruconest

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On 10 November 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Ruconest. The marketing authorisation holder for this medicinal product is Pharming Group N.V.

The CHMP recommended approval of a new pharmaceutical form (powder and solvent for solution for injection). The new pharmaceutical form will be available with a kit for administration and is intended to facilitate administration by the patient or the caregiver in the home care setting (home-treatment and self-administration).

For information, the full indication for Ruconest remains unchanged as follows:

“Ruconest is indicated for treatment of acute angioedema attacks in adults and adolescents with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.”

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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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