14 September 2017
EMA/CHMP/590603/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Firazyr

icatibant

On 14 September 2017, 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 Firazyr. The marketing authorisation holder for this medicinal product is Shire Orphan Therapies GmbH.

The CHMP adopted an extension to the existing indication as follows:[2]

"Firazyr is indicated for symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults, **adolescents and children aged 2 years and older,** ~~(~~with 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
[2] New text in bold, removed text as strikethrough

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