15 December 2016
EMA/CHMP/590711/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Cinryze

c1-esterase inhibitor, human

On 15 December 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 Cinryze. The marketing authorisation holder for this medicinal product is Shire Services BVBA.

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

> "Treatment and pre-procedure prevention of angioedema attacks in adults ~~and~~, adolescents ~~12 to 17~~and **children (2** years old **and above)** with hereditary angioedema (HAE).
>
> Routine prevention of angioedema attacks in adults ~~and~~, adolescents ~~12 to 17~~and children **(6** years old **and above)** with severe and recurrent attacks of hereditary angioedema (HAE), who are intolerant to or insufficiently protected by oral prevention treatments, or patients who are inadequately managed with repeated acute treatment."

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 shown in bold; removed text as strikethrough

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