17 March 2011
EMA/CHMP/217963/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Cinryze

C1 inhibitor, human

On 17 March 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion on the risk-benefit balance of the medicinal product Cinryze, 500 U, powder and solvent for solution for injection intended for the treatment and pre-procedure prevention of angioedema attacks in adults and adolescents with hereditary angioedema (HAE) and for the routine prevention of angioedema attacks in adults and adolescents 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. Cinryze was designated as an orphan medicinal product on 8 October 2009. The applicant for this medicinal product is ViroPharma SPRL, Brussels, Belgium. 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 Cinryze is C1 inhibitor, human, proteinase inhibitors (B02AB03), a naturally occurring protein normally present in human plasma. Cinryze increases the levels of functional C1 inhibitor in patients with deficient or decreased levels of C1 inhibitor, which lead to swelling attacks.

The benefits with Cinryze are its ability to raise the amount of C1 inhibitor in blood and to stop or prevent swelling attacks in hereditary angioedema patients. The most common side effect is rash.

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

The approved indication is: "Treatment and pre-procedure prevention of angioedema attacks in adults and adolescents with hereditary angioedema (HAE). Routine prevention of angioedema attacks in adults and adolescents 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.".

It is proposed that Cinryze is prescribed by physicians experienced in the treatment of hereditary angioedema (HAE).

[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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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 a marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Cinryze.

However, the CHMP notes that pursuant to the Commission Communication on the Community marketing authorisation procedures for medicinal products (98/C 229/03), Viropharma is to be considered as the same applicant/marketing authorisation holder as Sanquin, which holds marketing authorisations in a number of Member States for a medicinal product containing the same qualitative and quantitative composition in active substance(s) and pharmaceutical form and having overlapping indication(s) as Cinryze. These particulars may preclude the granting of a marketing authorisation for Cinryze.