EMA/CHMP/244588/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Icatibant Accord

icatibant

On 20 May 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Icatibant Accord, intended for the treatment of acute attacks of hereditary angioedema. The applicant for this medicinal product is Accord Healthcare S.L.U.

Icatibant Accord will be available as a 30 mg solution for injection. The active substance of Icatibant Accord is icatibant as acetate, which belongs to the pharmacotherapeutic group of hematological agents used to treat hereditary angioedema (ATC code: B06AC02). Icatibant antagonizes the vasodilatory effect of excess bradykinin and blocks oedema formation.

Icatibant Accord is a generic of Firazyr, which has been authorised in the EU since 11 July 2008. A question and answer document on generic medicines can be found here.

The full indication is:

> Icatibant Accord is indicated for symptomatic treatment of acute attacks of hereditary angioedema in adults, adolescents and children aged 2 years and older, with C1-esterase-inhibitor deficiency.

Icatibant Accord should be prescribed by physicians experienced in the treatment of hereditary angioedema.

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 made 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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