



European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 24 April 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
FIRAZYR

International Nonproprietary Name (INN): *icatibant acetate*

On 24 April 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Firazyr 30 mg solution for injection pre-filled syringe intended for treatment of hereditary angioedema (HAE) in adults (with C1-esterase-inhibitor deficiency). Firazyr was designated as an orphan medicinal product on 17 February 2003. The applicant for this medicinal product is Jerini AG.

The active substance of Firazyr is icatibant acetate, a selective competitive antagonist at the bradykinin type 2 (B2) receptor (ATC Code not assigned yet). It is a synthetic decapeptide with a structure similar to bradykinin, but with 5 nonproteinogenic amino acids. In HAE increased bradykinin concentrations are the key mediator in the development of the clinical symptoms.

The benefits with Firazyr are its effect (in terms of time to onset of symptoms relief) in the treatment of acute HAE attacks with or without laryngeal symptoms. The most common side effects are reactions at the site of administration such as erythema, swelling, warm sensation, burning, itching and/or cutaneous pain.

A pharmacovigilance plan for Firazyr, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: “symptomatic treatment of acute attacks of hereditary angioedema (HAE) in adults (with C1-esterase-inhibitor deficiency)”.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for *Firazyr* and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.