EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 October 2014
EMA/CHMP/631607/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rixubis

nonacog gamma

On 23 October 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rixubis, 250 IU, 500 IU, 1000 IU, 2000 IU, 3000 IU, powder and solvent for solution for injection intended for treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency). The applicant for this medicinal product is Baxter Innovations GmbH. 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 Rixubis is nonacog gamma, an antihaemorrhagic, blood coagulation factor IX (ATC code: B02BD04) which when activated, in combination with activated factor VIII, activates factor X to convert prothrombin into thrombin; thrombin then converts fibrinogen into fibrin and a clot is formed.
The benefits with Rixubis are its ability to achieve haemostatic efficacy for the prevention and treatment of bleeds in patients with Haemophilia B as well as efficacy during surgery. The most common side effects are dysgeusia, pain in extremity, anti Furin antibodies and postoperative anaemia.

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

The approved indication is: "Treatment and prophylaxis of bleeding in patients with haemophilia B (congenital factor IX deficiency). RIXUBIS is indicated in patients of all age groups".

It is proposed that Rixubis be prescribed by physicians experienced in the treatment of haemophilia.

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