EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 March 2017
EMA/CHMP/193129/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Refixia

nonacog beta pegol

On 23 March 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Refixia, intended for the treatment and prophylaxis of bleeding in patients 12 years and above with haemophilia B (congenital factor IX deficiency). Refixia was designated as an orphan medicinal product on 15 May 2009. The applicant for this medicinal product is Novo Nordisk A/S.

Refixia will be available as a powder and solvent for solution for injection (500 IU, 1000 IU and 2000 IU). The active substance of Refixia is nonacog beta pegol, a recombinant coagulation factor IX (ATC code: B02BD) which works in the body in the same way as human factor IX. It replaces the missing factor IX, thereby helping the blood to clot and giving temporary control of bleeding.

The benefits of Refixia are its ability to prevent and treat bleeding in patients with haemophilia B. The most common side effects are nausea, pruritus, fatigue and injection site reactions. Some patients taking factor IX medicines may develop inhibitors (antibodies) against factor IX, causing the medicine to stop working and resulting in a loss of bleeding control. Factor IX medicines can also potentially cause problems due to the formation of blood clots in the blood vessels. In addition, it is known that hypersensitivity reactions can occur with factor IX products.

The full indication is: "treatment and prophylaxis of bleeding in patients 12 years and above with haemophilia B (congenital factor IX deficiency)". It is proposed that Refixia be prescribed by physicians experienced in the treatment of haemophilia B.

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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