



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

NovoEight turoctocog alfa

On 19 September 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product NovoEight 250, 500, 100, 1500, 2000, or 3000 IU, powder and solvent for solution for injection, intended for the treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). The applicant for this medicinal product is Novonordisk. 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 NovoEight is turoctocog alfa, human recombinant factor VIII that enables the temporary substitution of the endogenous coagulation factor VIII in haemophilia A patients. The benefits with NovoEight are its ability to prevent and treat the bleeds in previously treated patients with severe haemophilia A. The most common side effects are increase in hepatic enzymes and injection site reaction.

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

The approved indication is: "Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency)". It is proposed that NovoEight be prescribed by physicians experienced in the treatment of Haemophilia A. It is proposed that treatment should be initiated under the supervision of a doctor 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.

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

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.

