



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Elocta

efmoroctocog alfa

On 24 September 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Elocta, intended for the treatment and prophylaxis of bleeding in haemophilia A (congenital factor VIII deficiency). Elocta was designated as an orphan medicinal product on 20 September 2010. The applicant for this medicinal product is Biogen Idec Ltd.

Elocta will be available as powder and solvent for solution for injection (250 IU, 500 IU, 750 IU, 1000 IU, 1500 IU, 2000 IU and 3000 IU). The active substance of Elocta is efmoroctocog alfa, an anti-haemorrhagic (ATC code: B02). It works as a replacement therapy to increase temporarily the plasma levels of factor VIII, so that the patient is less prone to bleeding and when used on demand or for surgical procedures, to control the bleeding.

The benefits with Elocta are its ability to provide adequate prophylaxis in terms of annualised bleeding rate, to control bleeding on demand and to provide haemostatic efficacy for surgical procedures as seen in clinical trials in adult and paediatric patients. Hypersensitivity reactions have been reported rarely.

The full indication is: "Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). Elocta can be used for all age groups." It is proposed that Elocta be prescribed by physicians experienced in the treatment of haemophilia A.

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

