26 April 2019
EMA/CHMP/170114/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Esperoct

turoctocog alfa pegol

On 26 April 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Esperoct, intended for the treatment and prophylaxis of bleeding in patients 12 years and above with haemophilia A (congenital factor VIII deficiency). Esperoct was designated as an orphan medicinal product on 26 April 2012. The applicant for this medicinal product is Novo Nordisk A/S.

Esperoct will be available as a powder and solvent for solution for injection (500, 1000, 1500, 2000 and 3000 International Unit (IU)). The active substance of Esperoct is turoctocog alfa pegol, a recombinant human factor VIII which replaces the missing coagulation factor VIII needed for effective haemostasis (ATC code: B02BD02).

The benefits of Esperoct are its ability to prevent and control bleeding when used prophylactically or on-demand and during surgical procedures in adult and adolescent patients with haemophilia A. The most common side effects are rash, erythema, pruritus, injection site reactions.

The full indication is: "treatment and prophylaxis of bleeding in patients 12 years and above with haemophilia A (congenital factor VIII deficiency)". It is proposed that Esperoct 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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