10 November 2016
EMA/699392/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Afstyla

lonoctocog alfa

On 10 November 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Afstyla, intended for the treatment and prophylaxis of bleeding in patients with haemophilia A. The applicant for this medicinal product is CSL Behring GmbH.

Afstyla will be available as a powder (250 IU, 500 IU, 1000 IU, 1500 IU, 2000 IU, 2500 IU and 3000 IU) and solvent for solution for injection or infusion. The active substance of Afstyla is lonoctocog alfa, a single-chain recombinant human factor VIII product (ATC code: B02BD02). Afstyla replaces the missing coagulation factor VIII needed for effective haemostasis.

The benefits with Afstyla are its ability to prevent and control bleeding when used on demand and used for surgical procedures as seen in clinical trials in adult and paediatric patients with haemophilia A. Afstyla has demonstrated a higher affinity for von Willebrand factor (VWF) than full-length recombinant factor VIII. VWF stabilises factor VIII and protects it from degradation. The most common side effects are hypersensitivity, dizziness, paraesthesia, rash, pyrexia.

The full indication is: "Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). AFSTYLA can be used for all age groups." It is proposed that Afstyla 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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