17 December 2015
EMA/CHMP/774757/2015
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Iblias

## octocog alfa

On 17 December 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 Iblias, intended for the treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). The applicant for this medicinal product is Bayer Pharma AG.

Iblias will be available as 250 IU, 500 IU, 1000 IU, 2000 IU and 3000 IU Powder and solvent for solution for injection. The active substance of Iblias is octocog alfa (blood coagulation factor VIII), an antihaemorrhagic (ATC code: B02BD02). It works as replacement therapy and temporarily increases plasma levels of factor VIII, helping to prevent and control bleeding.

The benefits with Iblias are its ability to prevent bleeding in terms of annualised bleeding rate and to control bleeding when used on demand for surgical procedures as seen in clinical trials in adult and paediatric patients. The most common side effects are: lymphadenopathy, palpitation, sinus tachycardia, abdominal pain, abdominal discomfort, dyspepsia, pyrexia, chest discomfort, injection site reactions, headache, dizziness, insomnia, pruritus, rash, allergic dermatitis. Hypersensitivity reactions have been reported rarely.

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

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