25 February 2016
EMA/CHMP/79845/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

IDELVION

albutrepenonacog alfa

On 25 February 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 IDELVION, intended for treatment and prophylaxis of bleeding in patients with Haemophilia B. IDELVION was designated as an orphan medicinal product on 04 February 2010. The applicant for this medicinal product is CSL Behring GmbH.

IDELVION will be available as 250 IU, 500 IU, 1000 IU and 2000 IU Powder and solvent for solution for injection. The active substance of IDELVION is albutrepenonacog alfa, an antihaemorrhagic, blood coagulation factor IX, (ATC code: B02BD04). It works as replacement therapy and temporarily increases plasma levels of factor IX, helping to prevent and control bleeding.

The benefits with IDELVION are its ability to stop the bleeding when given on demand and prevent bleeding when used as routine prophylaxis or for surgical procedures. The most common side effects are injection site reaction and headache.

The full indication is: "the treatment and prophylaxis of bleeding in patients with Haemophilia B (congenital factor IX deficiency)". Idelvion can be used in all age groups. It is proposed that IDELVION be prescribed by physicians experienced in the treatment of haemophilia B.

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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