15 December 2016
EMA/CHMP/816889/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vihuma

simoctocog alfa

On 15 December 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 Vihuma, intended for the treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency). The applicant for this medicinal product is Octapharma AB.

Vihuma will be available as a powder (250 IU, 500 IU, 1000 IU and 2000 IU) and solvent for solution for injection. The active substance of Vihuma is simoctocog alfa, a recombinant blood coagulation factor VIII (ATC code: B02BD02) that replaces the missing factor VIII, thereby giving temporary control of the bleeding disorder.

Vihuma has been shown to be effective at preventing and treating bleeding in 3 pivotal trials. No side effects were commonly reported in the safety database of 135 previously treated patients. The immunogenicity of the medicine was evaluated in clinical trials in 135 previously treated patients with severe haemophilia A (74 adult and 61 paediatric patients). None of the patients developed inhibitors.

Vihuma has been submitted as an informed consent application. In an informed consent application, reference is made to an authorised medicine and the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Vihuma is Nuwiq.

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