25 January 2018
EMA/CHMP/785115/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Hemlibra

emicizumab

On 25 January 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Hemlibra, intended to prevent bleeding episodes in patients with haemophilia A who have factor VIII inhibitors. Hemlibra was reviewed under EMA's accelerated assessment programme. The applicant for this medicinal product is Roche Registration Limited.

Hemlibra will be available as a solution for injection (30 mg/1 ml, 60 mg/0.4 ml, 105 mg/0.7 ml and 150 mg/1 ml). The active substance of Hemlibra is emicizumab (ATC code: B02BX), a bispecific monoclonal antibody that mimics the action of factor VIII, preventing bleeding in patients with haemophilia A who have decreased or no circulating levels of factor VIII.

The benefits with Hemlibra are its ability to reduce bleeds in routine prophylaxis with a weekly injection. The most common side effects are headache, injection site reaction, pyrexia, thrombotic microangiopathy, diarrhoea, arthralgia, and myalgia.

The full indication is: "Hemlibra is indicated for routine prophylaxis of bleeding episodes in patients with haemophilia A with factor VIII inhibitors. Hemlibra can be used in all age groups." It is proposed that Hemlibra should be initiated under the supervision of a physician experienced in the treatment of haemophilia and/or bleeding disorders.

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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