19 May 2022
EMA/CHMP/262927/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Cevenfacta

eptacog beta (activated)

On 19 May 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cevenfacta, intended for the treatment of bleeding episodes. The applicant for this medicinal product is Laboratoire français du Fractionnement et des Biotechnologies (LFB).

Cevenfacta will be available as a powder and solvent for solution for injection. The active substance of Cevenfacta is eptacog beta (activated), a blood coagulation factor (ATC code: B02BD08). Eptacog beta is almost identical to, and functions like, coagulation factor VII. It activates factor X, which starts the clotting process and thereby provides control of the bleeding. Because factor VII acts directly on factor X, independently from factors VIII and IX, Cevenfacta can be used to restore haemostasis in their absence or in the presence of inhibitors.

The benefit of Cevenfacta is its ability to effectively control bleeding episodes, as observed in a phase 3, multicentre, open-label trial. The most common side effects are dizziness, headache, infusion site discomfort and haematoma, increased body temperature, post-procedural haematoma and infusion-related reactions.

The full indication is:

> CEVENFACTA is indicated in adults and adolescents (12 years of age and older) for the treatment of bleeding episodes and for the prevention of bleeding in those undergoing surgery or invasive procedures in the following patient groups:
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> - in patients with congenital haemophilia with high-responding inhibitors to coagulation factors VIII or IX (i.e. ≥5 Bethesda Units (BU));
> - in patients with congenital haemophilia with low titre inhibitors (BU <5), but expected to have a high anamnestic response to factor VIII or factor IX administration or expected to be refractory to increased dosing of FVIII or FIX.

Cevenfacta should be prescribed by physicians experienced in the treatment of haemophilia and/or

[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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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.