23 February 2023
EMA/CHMP/64870/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vafseo

vadadustat

On 23 February 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Vafseo, intended for the treatment of symptomatic anaemia in adults with chronic kidney disease who are on chronic dialysis.

The applicant for this medicinal product is Akebia Europe Limited.

Vafseo will be available as 150 mg, 300 mg and 450 mg film-coated tablets. The active substance of Vafseo is vadadustat, an orally administered antianaemic preparation (ATC code: B03XA08). Vadadustat inhibits hypoxia-inducible factor (HIF) prolyl hydroxylase, thereby stimulating endogenous erythropoietin production, increasing iron mobilisation and haemoglobin and red blood cell production

The benefit of Vafseo is its ability to correct haemoglobin levels in dialysis-dependent patients, with effects comparable to those seen with erythropoiesis-stimulating agents. The most common side effects are hypertension, diarrhoea, and thromboembolic events.

The full indication is:

> Vafseo is indicated for the treatment of symptomatic anaemia associated with chronic kidney disease (CKD) in adults on chronic maintenance dialysis.

Vafseo should be prescribed by physicians experienced in the treatment of anaemia.

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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