



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 June 2021  
EMA/CHMP/341057/2021  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Evrenzo roxadustat

On 24 June 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Evrenzo, intended for the treatment of anaemia symptoms in patients with chronic kidney disease.

The applicant for this medicinal product is Astellas Pharma Europe B.V.

Evrenzo will be available as 20 mg, 50 mg, 70 mg, 100 mg and 150 mg film-coated tablets. The active substance of Evrenzo is roxadustat, an orally administered antianaemic preparation (ATC code: B03XA05). Roxadustat is a first-in-class inhibitor of hypoxia-inducible factor (HIF) prolyl hydroxylase that corrects anaemia by activating a response that occurs naturally when oxygen levels in the blood are low, promoting erythropoiesis and increasing the blood's oxygen-carrying capacity.

The benefits of Evrenzo are its ability to correct haemoglobin levels and reduce the need for rescue therapy in both non-dialysis-dependent (NDD) and dialysis-dependent (DD) patients. The effects of Evrenzo on haemoglobin levels and the need for rescue therapy are comparable to those seen with erythropoiesis-stimulating agents.

The most common side effects are hypertension, vascular access thrombosis, diarrhoea, peripheral oedema, hyperkalaemia and nausea.

The full indication is:

Evrenzo is indicated for treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).

Evrenzo 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.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

