

EVRENZO™ (roxadustat) 20, 50, 70, 100 and 150 mg film-coated tablets

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Pharmacotherapeutic group: Anti-anaemic preparations, other anti-anaemic preparations (B03XA05).

Therapeutic indications: Treatment of adult patients with symptomatic anaemia associated with chronic kidney disease (CKD).

***Posology and method of administration:** The dose should be individualised to achieve and maintain target Hb levels of 10 to 12 g/dL. Must be taken orally three times per week and not on consecutive days. See the Summary of Product Characteristics (SmPC), section 4.2, for further details.

Contraindications: Hypersensitivity to the active substance, peanut, soya or to any of the excipients; Third trimester of pregnancy; Breast-feeding.

***Special warnings and precautions for use:** Includes risk for serious (including fatal) cardiovascular and thrombotic vascular events (TVEs), seizures and serious infections, including sepsis. Secondary hypothyroidism has also been reported. Should be used with caution in patients with a history of seizures (convulsions or fits), epilepsy or medical conditions associated with a predisposition to seizure activity such as central nervous system infections, as well as in patients with pre-existing risk factors for TVE. Caution is warranted when administered to patients with moderate hepatic impairment (Child-Pugh class B) and is not recommended for use in patients with severe hepatic impairment (Child-Pugh class C). Should not be initiated in women planning on becoming pregnant or during pregnancy. Misuse may lead to an excessive increase in packed cell volume. This may be associated with life-threatening complications of the cardiovascular system.

***Undesirable effects:** The most frequent ($\geq 10\%$) adverse reactions (ADRs) in clinical studies were hypertension, vascular access thrombosis, diarrhoea, peripheral oedema, hyperkalaemia and nausea. The most frequent ($\geq 1\%$) serious ADRs were sepsis, hyperkalaemia, hypertension and deep vein thrombosis. Dermatitis exfoliative generalised, part of severe cutaneous adverse reactions (SCARs), has been reported during postmarketing surveillance (frequency not known).

Marketing authorisation holder: Astellas Pharma Europe B.V., The Netherlands.

Country specific information

Sweden: Status of the product: Rx (incl. "särskilt läkemedel"). **Reimbursement:** Yes. **Local representative:** Astellas Pharma AB, Tel: +46 (0)40 650 15 00. For more information, pack size and price see www.fass.se.

Based on authorised summary of product characteristics dated 02 June 2023.

***The section has been rewritten and/or abbreviated compared to the authorised SmPC. The SmPC can be ordered free of charge from the local representative.**