MERIDIAN THERAPEUTICS

Velorastat

SUMMARY OF PRODUCT CHARACTERISTICS · European Union

This document is fictional and is provided for demonstration purposes only.
It is not real prescribing information and must not be used to inform clinical decisions.

1. INDICATION

Velorastat is indicated for the treatment of symptomatic anaemia associated with chronic kidney disease in adults, both in patients receiving dialysis and in patients not receiving dialysis.

Treatment should be initiated by physicians experienced in the management of anaemia associated with chronic kidney disease.

2. DOSAGE AND ADMINISTRATION

The recommended starting dose in patients not previously treated is 50 mg three times weekly in patients not receiving dialysis, and 70 mg three times weekly in patients receiving dialysis.

The dose should be titrated at intervals of not less than four weeks in order to maintain a haemoglobin concentration within the range of 10 to 12 g/dl. The maximum dose should not exceed 200 mg three times weekly.

Velorastat is taken orally and may be administered with or without food.

3. IMPORTANT SAFETY INFORMATION

Velorastat is contraindicated during pregnancy and breast-feeding, and in patients with hypersensitivity to the active substance or to any of the excipients listed in the Summary of Product Characteristics.

Cases of thrombotic vascular events, including vascular access thrombosis and pulmonary embolism, have been reported. The risk may be increased in patients in whom the haemoglobin concentration exceeds the recommended range. Haemoglobin should be monitored every two weeks until stable, and monthly thereafter.

Caution is advised in patients with a history of seizures. The most frequently reported undesirable effects were peripheral oedema, nausea, hypertension and hyperkalaemia.

This material does not constitute the full prescribing information. Refer to the Summary of Product Characteristics for the complete list of undesirable effects and for conditions of use.

4. REPORTING OF SUSPECTED ADVERSE REACTIONS

Reporting suspected adverse reactions after authorisation is important. Please report any suspected adverse reactions to Meridian Therapeutics Drug Safety on +44 20 7946 0318 or safety.eu@meridiantx.example, and via your national spontaneous reporting system.

5. APPROVAL RECORD

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