MERIDIAN THERAPEUTICS

Velorastat

PRODUCT INFORMATION · International

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 anaemia associated with chronic kidney disease in adults receiving maintenance dialysis.

Approval status and approved conditions of use vary between territories. This information is intended only for territories in which Velorastat has been granted a marketing authorisation, and should be read together with the locally approved product information.

2. DOSAGE AND ADMINISTRATION

The recommended starting dose is 70 mg administered orally three times weekly, adjusted at intervals of not less than four weeks according to haemoglobin response.

Locally approved dosing recommendations take precedence where these differ from the information presented here. Prescribers should consult the product information approved in their territory before prescribing.

3. IMPORTANT SAFETY INFORMATION

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

Thrombotic vascular events, including vascular access thrombosis and pulmonary embolism, have been reported. Haemoglobin should be monitored regularly and the dose adjusted so that the haemoglobin concentration is maintained within the locally approved range.

The most frequently reported undesirable effects were peripheral oedema, nausea and hypertension.

The safety information presented here is abbreviated and may not reflect the labelling approved in your territory. The locally approved product information should be consulted in all cases.

4. REPORTING OF SUSPECTED ADVERSE REACTIONS

To report a suspected adverse reaction, contact Meridian Therapeutics Drug Safety on +44 20 7946 0318 or safety.intl@meridiantx.example. Suspected adverse reactions should also be reported in accordance with local requirements.

5. APPROVAL RECORD

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