MERIDIAN THERAPEUTICS

Velorastat

FULL PRESCRIBING INFORMATION · United States

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 (velorastat) tablets are indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months.

Limitations of Use: VELORASTAT has not been shown to improve quality of life, fatigue, or patient well-being. VELORASTAT is not indicated for use as a substitute for red blood cell transfusion in patients requiring immediate correction of anemia.

2. DOSAGE AND ADMINISTRATION

The recommended starting dose is 70 mg administered orally three times weekly.

Doses should be individualized and titrated in increments of no more than 20 mg, at intervals of no less than four weeks, to achieve and maintain a hemoglobin concentration of 10 to 11 g/dL. Do not administer more frequently than three times weekly.

Tablets should be swallowed whole and may be taken with or without food. Dose reduction should be considered in patients receiving concomitant strong inhibitors of hepatic transport.

3. IMPORTANT SAFETY INFORMATION

WARNING: INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, AND THROMBOEMBOLIC EVENTS.

VELORASTAT is contraindicated in patients with known hypersensitivity to velorastat or to any of its excipients.

Serious adverse reactions reported in clinical studies included vascular access thrombosis, deep vein thrombosis, and pulmonary embolism. The risk may be increased in patients whose hemoglobin concentration exceeds the recommended range. Hemoglobin should be monitored every two weeks during initiation and following any dose adjustment.

The most commonly reported adverse reactions, occurring in at least 10% of patients, were peripheral edema, nausea, and hypertension.

This is not a complete summary of the safety information for VELORASTAT. Please consult the full Prescribing Information.

4. REPORTING OF SUSPECTED ADVERSE REACTIONS

To report a suspected adverse reaction, contact Meridian Therapeutics Drug Safety on 1-800-555-0142 or safety.us@meridiantx.example. You are also encouraged to report suspected adverse reactions to your national regulatory authority.

5. APPROVAL RECORD

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