VEGAROSE TABLETS

Rosuvastatin Calcium equivalent to Rosuvastatin
5 mg, 10 mg and 20 mg | Pack size: 10 tablets

COMPOSITION

Each tablet contains Rosuvastatin Calcium equivalent to Rosuvastatin 5 mg, 10 mg or 20 mg, as indicated on the pack. Excipients: as per the approved Vegarose formulation.

THERAPEUTIC CLASS

HMG-CoA reductase inhibitor (statin); lipid-lowering agent. Primary medical segment: Cardiology; also Internal Medicine and Endocrinology.

PHARMACOLOGY

Rosuvastatin competitively inhibits HMG-CoA reductase, reducing hepatic cholesterol synthesis and increasing LDL receptor activity. It lowers LDL cholesterol, total cholesterol, non-HDL cholesterol and triglycerides, and may increase HDL cholesterol.

INDICATIONS

Adjunct to diet and lifestyle measures for primary hyperlipidaemia and mixed dyslipidaemia; selected inherited lipid disorders including familial hypercholesterolaemia; and reduction of cardiovascular risk in eligible patients. Age-specific paediatric and other indications depend on locally approved labeling.

DOSAGE AND ADMINISTRATION

Adults: Common recommended dose range is 5–40 mg once daily; Vegarose is available in 5 mg, 10 mg and 20 mg strengths. Select starting dose according to LDL-C, cardiovascular risk, ethnicity, renal function and interacting drugs. For patients of Asian ancestry, a 5 mg starting dose is recommended in US labeling. Reassess LDL-C after approximately 4 weeks and adjust if needed. Do not exceed product-specific maximum doses.

METHOD OF ADMINISTRATION

Take once daily, at any time of day, with or without food. Swallow tablet with water. Continue prescribed diet and lifestyle measures. If a dose is missed, take it when remembered unless nearly time for the next dose; do not double.

RENAL AND HEPATIC IMPAIRMENT

In severe renal impairment (creatinine clearance below 30 mL/min/1.73 m2) not receiving haemodialysis, initiate at 5 mg once daily and do not exceed 10 mg once daily under US labeling. Rosuvastatin is contraindicated in acute liver failure or decompensated cirrhosis. Evaluate other liver disorders and individualize therapy.

CONTRAINDICATIONS

Hypersensitivity to rosuvastatin or any excipient; acute liver failure or decompensated cirrhosis. Other regional product labels may list additional contraindications; consult locally approved prescribing information.

WARNINGS: MUSCLE TOXICITY

Myopathy and rhabdomyolysis can occur, sometimes with kidney injury. Risk rises with higher doses, renal impairment, older age, uncontrolled hypothyroidism and certain interacting drugs. Stop treatment and seek medical evaluation for unexplained muscle pain, tenderness or weakness, particularly with fever or dark urine.

OTHER WARNINGS AND PRECAUTIONS

Check liver enzymes before starting and thereafter when clinically indicated. Discontinue if serious liver injury is suspected. Rare immune-mediated necrotizing myopathy may persist after stopping a statin. Proteinuria or haematuria and increases in blood glucose/HbA1c have been reported. Monitor as clinically appropriate.

DRUG INTERACTIONS

Certain medicines increase rosuvastatin exposure and muscle toxicity risk, including cyclosporine, gemfibrozil, some antiviral combinations and selected oncology drugs; dose limits or avoidance may be required. Fibrates and niacin may increase myopathy risk. Monitor INR with warfarin. Separate aluminium/magnesium-containing antacids by at least 2 hours after rosuvastatin where applicable.

PREGNANCY AND LACTATION

Discontinue rosuvastatin in most patients once pregnancy is recognized; ongoing treatment is rarely justified and requires specialist assessment. Breastfeeding is not recommended during rosuvastatin treatment. Patients who become pregnant should promptly contact their clinician.

PAEDIATRIC AND ELDERLY USE

Paediatric dosing is indication- and age-specific; specialist assessment is required. In older adults, evaluate renal function, comorbidities and susceptibility to muscle adverse effects.

ADVERSE REACTIONS

Commonly reported reactions include headache, nausea, abdominal pain, constipation, dizziness, weakness and muscle pain. Serious adverse effects include myopathy/rhabdomyolysis, immune-mediated necrotizing myopathy, liver injury and severe hypersensitivity.

OVERDOSAGE

Seek medical advice immediately. No specific antidote is available; provide supportive treatment and monitor clinical status and laboratory parameters as indicated.

STORAGE

Store according to the approved Vegarose product label, protected from moisture and excessive heat. Keep out of reach of children. Do not use after the expiry date.

PRESENTATION

Vegarose Tablets 5 mg: pack of 10 tablets.
Vegarose Tablets 10 mg: pack of 10 tablets.
Vegarose Tablets 20 mg: pack of 10 tablets.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.