ROZUCOR 5/10/20/40

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only

Abbreviated Prescribing information for Rozucor (Rosuvastatin Tablets 5/10/20/40 mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Rosuvastatin is a 3-hydroxy-3-methyl glutaryl coenzyme A (HMGCoA) reductase inhibitor indicated for the treatment of hyperlipidemia.

INDICATION: Treatment of hypercholesterolemia, as an adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia, as an adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels.

DOSAGE AND ADMINISTRATION: Before treatment initiation the patient should be placed on a standard cholesterol-lowering diet that should continue during treatment. The dose should be individualized according to the goal of therapy and patient response, using current consensus guidelines. Rosuvastatin may be given at any time of day, with or without food.

CONTRAINDICATION: Contraindicated in patients with a known hypersensitivity to any component of this product. Hypersensitivity reactions includes rash, pruritus, urticaria, and angioedema have been reported with Rosuvastatin, Patients with active liver disease, which may include unexplained persistent elevations of hepatic transaminase levels. Rosuvastatin may cause fetal harm when administered to pregnant women, nursing mothers, because another drug in this class passes into breast milk, and because HMG-Co reductase inhibitors have the potential to cause serious adverse reactions in nursing infants, women who require Rosuvastatin treatment should be advised not to nurse their infants.

WARNINGS & PRECAUTIONS: Cases of myopathy and rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with HMG-CoA reductase inhibitors, including Rosuvastatin, caution should be exercised when anticoagulants are given in conjunction with rosuvastatin because of its potentiation of the effect of coumarin-type anticoagulants in prolonging the prothrombin time/INR, In the Rosuvastatin clinical trial program, dipstick-positive proteinuria and microscopic hematuria were observed among Rosuvastatin treated patients. Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors, including Rosuvastatin.

DRUG INTERACTION: Cyclosporine, Gemfibrozil, Protease Inhibitors, Coumarin Anticoagulants, Niacin, Fenofibrate and Colchicine.

ADVERSE REACTIONS: Rhabdomyolysis with myoglobinuria and acute renal failure, myopathy (including myositis), liver enzyme abnormalities, headache, myalgia, abdominal pain, asthenia and nausea.

MARKETED BY:

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(Additional information is available on request)