ROZUCOR F LS

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

Abbreviated Prescribing information for Rozucor F (Rosuvastatin 10 mg and Fenofibrate 67 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. Fenofibrate is a lipid-regulating agent for oral administration.

INDICATION: For the treatment of combined hyperlipidemia in patients with normal hepatic and renal function.

DOSAGE AND ADMINISTRATION: It is given orally once daily with or without food.

CONTRAINDICATION: Patients with a known hypersensitivity to any component of this product. Hypersensitivity reactions including 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. Fenofibrate is contraindicated in patients with severe renal impairment, including those receiving dialysis, patients with active liver disease, including those with primary biliary cirrhosis and unexplained persistent liver function abnormalities patients with preexisting gallbladder disease, patients who have a known hypersensitivity to fenofibrate or fenofibric acid.

WARNINGS & PRECAUTIONS: Skeletal Muscle Effects Cases of myopathy and rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with HMG-CoA reductase inhibitors, including Rosuvastatin. It is recommended that liver enzyme tests be performed before the initiation of 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. **Fenofibrate-**It can increase serum transaminases, Elevations in serum creatinine have been reported in patients on fenofibrate, Fenofibrate, like clofibrate and gemfibrozil, may increase cholesterol excretion into the bile, leading to cholelithiasis., Pancreatitis has been reported in patients taking fenofibrate, gemfibrozil, and clofibrate. Hematologic changes, hypersensitivity reactions, and venothromboembolic disease is seen with fibrates.

DRUG INTERACTION: Rosuvastatin:-Cyclosporine, Gemfibrozil, Protease Inhibitors, Coumarin Anticoagulants, Niacin, Fenofibrate and Colchicine. **Fenofibrate: -** potentiation of coumarin-type anticoagulant effects has been observed with prolongation of the PT/INR. Caution should be exercised when coumarin anticoagulants are given in conjunction with fenofibrate. immunosuppressants such as cyclosporine, tacrolimus, bile-acid binding resins and colchicine.

ADVERSE REACTIONS: Rosuvastatin:-Rhabdomyolysis with myoglobinuria and acute renal failure, myopathy (including myositis), liver enzyme abnormalities, headache, myalgia, abdominal pain, asthenia and nausea. **Fenofibrate: -** Abdominal Pain, back Pain, headache, abnormal liver function tests, nausea, constipation, increased AST, increased ALT, increased creatine phosphokinase, pancreatitis, muscle spasms, respiratory disorder and rhinitis.

MARKETED BY:

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(Additional information is available on request)