ROZUCOR F 20

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

Abbreviated Prescribing information for Rozucor F20 (Rosuvastatin 20 mg and Fenofibrate 160 mg Tablet) [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:** Rozucor F 20 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-CoA 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 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: It is recommended that liver enzyme tests should be performed before starting statin therapy 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 & fenofibrate 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, like clofibrate and gemfibrozil, may increase cholesterol excretion into the bile, leading to cholelithiasisExceptional cases of interstitial lung disease have been reported with some statins, Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **DRUG INTERACTION: Rosuvastatin:**-Cyclosporine, Gemfibrozil, Protease Inhibitors, Coumarin Anticoagulants, Niacin, Fenofibrate and Colchicine. **Fenofibrate:** *In vitro* studies using human liver microsomes indicate that fenofibrate and fenofibric acid are not inhibitors of cytochrome (CYP) P450 isoforms CYP3A4, CYP2D6, CYP2E1, or CYP1A2. They are weak inhibitors of CYP2C8, CYP2C19 and CYP2A6, and mild-to-moderate inhibitors of CYP2C9 at therapeutic concentrations. Caution should be exercised when coumarin anticoagulants are given in conjunction with Fenofibrate. The dosage of the anticoagulants should be reduced to maintain the PT/INR at the desired level to prevent bleeding complications. Immunosuppressants such as cyclosporine and tacrolimus can produce nephrotoxicity with decreases in creatinine clearance and rises in serum creatinine, and because renal excretion is the primary elimination route of fibrate drugs including Fenofibrate, there is a risk that an interaction will lead to deterioration of renal function. Since bile acid binding resins may bind other drugs given concurrently, patients should take Fenofibrate at least 1 hour before or 4 to 6 hours after a bile acid binding resin to avoid impeding its absorption. Cases of myopathy, including rhabdomyolysis, have been reported with fenofibrates co-administered with colchicine, and caution should be exercised when prescribing fenofibrate with 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)