ROZUCOR F

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

Abbreviated Prescribing information for Rozucor F (Rosuvastatin 5/10 mg and Fenofibrate 160 mg Tablets) [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: Rozucor F is indicated for treatment of combined hyperlipidemia in patients with normal hepatic and renal function.

DOSAGE AND ADMINISTRATION: Rozucor F can be administered as a single dose of 1 tablet daily. After initiation of therapy with Rozucor F, lipid levels should be monitored periodically and the dosage adjusted accordingly. Consideration should be given to reducing the dosage if lipid levels fall significantly below the targeted range.

CONTRAINDICATION: known hypersensitivity to any component of this product, Patients with active liver disease,which may include unexplained persistent elevations of hepatic transaminase levels and any serum transaminase elevation more than 3 times upper normal limits, Women who are pregnant or may become pregnant, Nursing mothers, Patients with myopathy, Patients taking ciclosporin, in patients with hepatic or severe renal dysfunction, including primary biliary cirrhosis, and patients with unexplained persistent liver function abnormality and in patients with preexisting gallbladder disease

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. Caution should be exercised when coumarin anticoagulants are given in conjunction with Fenofibrate. The dosage of the anticoagulants should be reduced to maintain the prothrombin time/inr at the desired level to prevent bleeding complications. Since bile acid sequestrants may bind other drugs given concurrently, patients should take Fenofibrate at least 1 hour before or 4-6 hours after a bile acid binding resin to avoid impeding its absorption.

DRUG INTERACTION: Rosuvastatin:-Cyclosporine, Gemfibrozil, Protease Inhibitors, Coumarin Anticoagulants, Niacin, Fenofibrate and Colchicine. **Fenofibrate: -** Since bile acid sequestrants may bind other drugs given concurrently, patients should take Fenofibrate at least 1 hour before or 4-6 hours after a bile acid binding resin to avoid impeding its absorption. Because cyclosporine 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.

ADVERSE REACTIONS: Rosuvastatin:-Rhabdomyolysis with myoglobinuria and acute renal failure, myopathy (including myositis), liver enzyme abnormalities, headache, myalgia, abdominal pain, asthenia and nausea. **Fenofibrate: -** Chest pain, Angina pectoris, hypertension, Dyspepsia, flatulence, nausea, increased appetite, gastroenteritis, Diabetes mellitus Anemia, leukopenia, ecchymosis, Creatinine increased, weight gain, Myositis, arthralgia, insomnia, depression, vertigo, Pharyngitis, bronchitis, Conjunctivitis, eye disorder, Urinary frequency and prostatic disorder.

MARKETED BY:

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(Additional information is available on request)