ROZUCOR F

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

Abbreviated Prescribing information for ROZUCOR F [Rosuvastatin and Fenofibrate Tablets I.P.]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: ***Rosuvastatin*** **-** Rosuvastatin increases the number of hepatic LDL receptors on the cell-surface, enhancing uptake and catabolism of LDL and it inhibits the hepatic synthesis of VLDL, thereby reducing the total number of VLDL and LDL particles The primary site of action of rosuvastatin is the liver, the target organ for cholesterol lowering**.** ***Fenofibrate*** **-** Through activation of PPARα, fenofibrate increases the lipolysis and elimination of atherogenic triglyceride rich particles from plasma by activating lipoprotein lipase and reducing production of Apo protein CIII. Activation of PPARα also induces an increase in the synthesis of Apo proteins AI and AII. The above stated effects of fenofibrate on lipoproteins lead to a reduction in very low- and low-density fractions (VLDL and LDL) containing Apo protein B and an increase in the high-density lipoprotein fraction (HDL) containing Apo protein AI and AII.

INDICATIONS: It is indicated for the treatment of combined hyperlipidemia in patients with normal hepatic and renal function.

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 individualised according to the goal of therapy and patient response, using current consensus guidelines. Tablet should be swallowed whole during a meal.

CONTRAINDICATION: • In patients with hypersensitivity to rosuvastatin, fenofibrate or to any of the excipients. • In patients with active liver disease including unexplained, persistent elevations of serum transaminases and any serum transaminase elevation exceeding 3 times the upper limit of normal (ULN). Hepatic insufficiency (including biliary cirrhosis and unexplained persistent liver function abnormality. • Known gallbladder disease • Severe renal insufficiency (estimated glomerular filtration rate < 30 mL/min/1.73 m^2). In patients with severe renal impairment (creatinine clearance < 60 ml/min) • Hypothyroidism • Personal or family history of hereditary muscular disorders • Previous history of muscular toxicity with another HMG-CoA reductase inhibitor or fibrate • Alcohol abuse • Situations where an increase in plasma levels may occur • Asian patients • Concomitant use of fibrates.

WARNINGS & PRECAUTIONS: ***Rosuvastatin*** **-** An assessment of renal function should be considered during routine follow-up of patients treated with a dose of 40 mg. If CK levels are significantly elevated at baseline (>5xULN) a confirmatory test should be carried out within 5 – 7 days. If the repeat test confirms a baseline CK >5xULN, treatment should not be started. Rosuvastatin should be used with caution in patients who consume excessive quantities of alcohol and/or have a history of liver disease. The concomitant use with certain protease inhibitors is not recommended unless the dose of Rosuvastatin is adjusted. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. If it is suspected a patient has developed interstitial lung disease, statin therapy should be discontinued. Patients at risk (fasting glucose 5.6 to 6.9 mmol/l, BMI >30 kg/m^2, raised triglycerides, hypertension) should be monitored both clinically and biochemically. It should be prescribed with caution in patients with pre-disposing factors for myopathy/rhabdomyolysis such as Renal impairment, Hypothyroidism, Age >70 years and increase in plasma levels. ***Fenofibrate*** **-** Secondary cause of hypercholesterolemia should be adequately treated before Fenofibrate therapy is considered. Pancreatitis has been reported in patients taking fenofibrate. muscle toxicity, including rare cases of rhabdomyolysis, with or without renal failure,

has been reported with administration of fibrates and other lipid-lowering agents. Fenofibrate 160 mg is contraindicated in severe renal impairment. Fenofibrate 160 mg should be used with caution in patients with mild to moderate renal insufficiency. Dose should be adjusted in patients whose estimated glomerular filtration rate is 30 to 59 mL/min/1.73 m^2.

DRUG INTERACTIONS: ***Rosuvastatin*** **-** The initiation of treatment or dosage up-titration of Rosuvastatin in patients treated concomitantly with vitamin K antagonists (e.g. warfarin or another coumarin anticoagulant) may result in an increase in International Normalised Ratio (INR). The risk of myopathy, including rhabdomyolysis may be increased by the concomitant administration of systemic fusidic acid with statins. ***Fenofibrate*** **-** Fenofibrate enhances oral anticoagulant effect and may increase risk of bleeding. Some severe cases of reversible renal function impairment have been reported during concomitant administration of fenofibrate and cyclosporin. Some cases of reversible paradoxical reduction of HDL-cholesterol have been reported during concomitant administration of fenofibrate and glitazones.

ADVERSE REACTIONS: Thrombocytopenia, haemoglobin decreased, white blood cell count decreased, hypersensitivity reactions including angioedema, diabetes mellitus, depression, headache, dizziness, polyneuropathy, memory loss, peripheral neuropathy, sleep disturbances (including insomnia and nightmares), thromboembolism (pulmonary embolism, deep vein thrombosis), cough, dyspnoea, interstitial lung disease, constipation, gastrointestinal signs and symptoms (abdominal pain, nausea, vomiting, diarrhoea, flatulence), transaminases increased, hepatitis, jaundice, complications of cholelithiasis a (e.g. cholecystitis, cholangitis, biliary colic), cutaneous hypersensitivity (e.g. rash, pruritus, urticaria), alopecia, photosensitivity reactions, stevens-johnson syndrome, severe cutaneous reactions (e.g. erythema multiform, toxic epidermal necrolysis), muscle disorder (e.g. myalgia, myositis, muscular spasms and weakness) myopathy (including myositis), rhabdomyolysis, lupus-like syndrome, muscle rupture, arthralgia, tendon disorders, sometimes complicated by rupture immune-mediated necrotising myopathy, haematuria, sexual dysfunction, gynaecomastia, asthenia, oedema, acute renal failure, pancreatitis and fatigue

MARKETED BY:

Torrent Pharmaceuticals Limited.

IN/ROZUCOR F 5, 10, 20, 160mg/JAN-20/04/ABPI

(Additional information is available on request)