ROSTAR F

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

Abbreviated Prescribing information for ROSTAR 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 is a selective and competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A to mevalonate, a precursor for cholesterol. The primary site of action of rosuvastatin is the liver, the target organ for cholesterol lowering. 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. **Fenofibrate:** Fenofibrate is a fibric acid derivative whose lipid modifying effects reported in humans are mediated via activation of Peroxisome Proliferator Activated Receptor type alpha (PPARα). 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.

DOSAGE AND ADMINISTRATION: One tablet once daily or as directed by physician.

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 m2). In patients with severe renal impairment (creatinine clearance <30 ml/min). Chronic or acute pancreatitis with the exception of acute pancreatitis due to severe hypertriglyceridemia. Known photoallergy or phototoxic reaction during treatment with fibrates or ketoprofen. In patients with myopathy. In patients receiving concomitant ciclosporin. During pregnancy and lactation and in women of childbearing potential not using appropriate contraceptive measures. The 40 mg dose is contraindicated in patients with predisposing factors for myopathy/rhabdomyolysis. Moderate 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:* Renal Effects, Skeletal Muscle Effects, Creatine Kinase Measurement, Liver Effects, Protease Inhibitors, Lactose Intolerance, Interstitial Lung Disease, Diabetes Mellitus. *Fenofibrate:* Secondary causes of hyperlipidemia, Liver function, Pancreatitis, Muscle toxicity, Renal function.

DRUG INTERACTION: *Rosuvastatin:* Effect of co-administered medicinal products on Rosuvastatin: Ciclosporin, Protease inhibitors, Gemfibrozil, Ezetimibe, Antacid, Erythromycin, Cytochrome P450 enzymes Effect of rosuvastatin on co-administered medicinal products: Vitamin K antagonists, Oral contraceptive/hormone replacement therapy, Digoxin, Fusidic Acid. *Fenofibrate:* Oral anticoagulants, Cyclosporin, Glitziness.

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, Nausea, Abdominal pain, Gastrointestinal signs and symptoms (abdominal pain, nausea, vomiting, diarrhoea, flatulence), Cholelithiasis, Increased hepatic transaminases, Jaundice, Hepatitis, Alopecia, Photosensitivity reactions, Stevens-Johnson syndrome Severe cutaneous reactions (e.g. erythema multiform, Stevens-Johnson syndrome, toxic epidermal necrolysis), Myalgia, Muscle disorder (e.g. myalgia, myositis, muscular spasms and weakness), Arthralgia, Tendon disorders, sometimes complicated by rupture Immune-mediated necrotising myopathyRhabdomyolysis, Rhabdomyolysis, Sexual dysfunction, Gynaecomastia, Haematuria, Oedema, Fatigue, Asthenia.

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IN/ ROSTAR F 10,160mg/Dec-20/02/ABPI
(Additional information is available on request)