ROSTAR

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

Abbreviated Prescribing information for Rostar

(Rosuvastatin Tablets I.P.) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action: 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.

INDICATIONS: 1)Treatment of hypercholesterolaemia. 2)As an adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia. 3)As an adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels. 4)Risk reduction of MI stroke and arterial revascularization procedure in patients without clinically evident CHD but with multiple risk factors.

DOSAGE AND ADMINISTRATION: As directed by the Physician. Tablets should be taken orally.

CONTRAINDICATION: In patients with hypersensitivity to Rosuvastatin 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), In patients with severe renal impairment (creatinine clearance <30 ml/min), In patients with myopathy, In patients receiving concomitant cyclosporine, during pregnancy and lactation and in women of childbearing potential not using appropriate contraceptive measures, In patients with hypersensitivity to Rosuvastatin 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), In patients with severe renal impairment (creatinine clearance <30 ml/min), In patients with myopathy, In patients receiving concomitant cyclosporine, during pregnancy and lactation and in women of childbearing potential not using appropriate contraceptive measures

WARNINGS & PRECAUTIONS: Renal Effects: Proteinuria, detected by dipstick testing and mostly tubular in origin, has been observed in patients treated with higher doses of Rosuvastatin, in particular 40 mg. Skeletal Muscle Effects: Effects on skeletal muscle e.g. myalgia, myopathy and, rarely, rhabdomyolysis have been reported in Rosuvastatin-treated patients with all doses and in particular with doses > 20 mg. Creatine Kinase Measurement: If CK levels are significantly elevated at baseline (>5xULN) a confirmatory test should be carried out within 5 – 7 days. Before Treatment: Rosuvastatin should be prescribed with caution in patients with pre-disposing factors for myopathy/rhabdomyolysis. Such factors include renal impairment, hypothyroidism, personal or family history of hereditary muscular disorders, previous history of muscular toxicity with another HMG-CoA reductase inhibitor or fibrate, alcohol abuse, age >70 years, situations where an increase in plasma levels may occur, concomitant use of fibrates. Whilst on Treatment: Patients should be asked to report inexplicable muscle pain, weakness or cramps immediately, particularly if associated with malaise or fever. CK levels should be measured in these patients, therapy should be discontinued if CK levels are markedly elevated (>5xULN) or if muscular symptoms are severe and cause daily discomfort

DRUG INTERACTIONS: Transporter protein inhibitors: It result in increased Rosuvastatin plasma concentrations and an increased risk of myopathy. Cyclosporine: During concomitant treatment with Rosuvastatin and ciclosporin, Rosuvastatin AUC values were on average 7 times higher than those observed in healthy volunteers. Gemfibrozil and other lipid-lowering product: Concomitant use of Rosuvastatin and gemfibrozil resulted in a 2-fold increase in Rosuvastatin Cmax and AUC. Oral contraceptive/hormone replacement therapy (HRT): Concomitant use of ROSTAR and an oral contraceptive resulted in an increase in ethinyl estradiol and norgestrel AUC of 26% and 34%, respectively. These increased plasma levels should be considered when selecting oral contraceptive doses. Erythromycin: Concomitant use of Rosuvastatin and erythromycin resulted in a 20% decrease in AUC and a 30% decrease in Cmax of Rosuvastatin.

ADVERSE REACTIONS:

MARKETED BY:

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(Additional information is available on request)