SPMC

ROSUVASTATIN TABLETS IP 10 mg

PRESENTATION:
Rosuvastatin tablets IP 10 mg,
Pack sizes -1000'S tablets bulk & 200'S tablets Blister (10x20)

Pink, circular, Double convex film coated tablets of 7.0 mm diameter. Each tablet contains Rosuvastatin calcium 10 mg.

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 AND DOSE:

Primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia), mixed dyslipidaemia (type IIb), or homozygous familial hypercholesterolaemia in patients who have not responded adequately to diet and other appropriate measures

Adult 18–69 years: Initially 5–10 mg once daily, then increased if necessary up to 20 mg once daily, dose to be increased gradually at intervals of at least 4 weeks

Adult (patients of Asian origin): Initially 5 mg once daily, then increased if necessary up to 20 mg once daily, dose to be increased gradually at intervals of at least 4 weeks.

Adult 70 years and over: Initially 5 mg once daily, then increased if necessary up to 20 mg once daily, dose to be increased gradually at intervals of at least 4 weeks

Primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia), mixed dyslipidaemia (type IIb), or homozygous familial hypercholesterolaemia in patients who have not responded adequately to diet and other appropriatemeasures and who have risk factors for myopathy or rhabdomyolysis

Adult: Initially 5 mg once daily, then increased if necessary up to 20 mg once daily, dose to be increased gradually at intervals of at least 4 weeks

Severe primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia), mixed dyslipidaemia (type IIb), or homozygous familial hypercholesterolaemia in patients with high cardiovascular risk who have not responded adequately to diet and other appropriate measures (specialist use only)

Adult 18–69 years: Initially 5–10 mg once daily, then increased if necessary up to 40 mg once daily, dose to be increased gradually at intervals of at least 4 weeks

Adult (patients of Asian origin): Initially 5 mg once daily, then increased if necessary up to 20 mg once daily, dose to be increased gradually at intervals of at least 4 weeks.

Adult 70 years and over: Initially 5 mg once daily, then increased if necessary up to 40 mg once daily, dose to be increased gradually at intervals of at least 4 weeks

Severe primary hypercholesterolaemia (type IIa including heterozygous familial hypercholesterolaemia), mixed dyslipidaemia (type IIb), or homozygous familial hypercholesterolaemia in patients with high cardiovascular risk who have not responded adequately to diet and other appropriate measures, and who have risk factors for myopathy or rhabdomyolysis (specialist use only)

Adult: Initially 5 mg once daily, then increased if necessary up to 20 mg once daily, dose to be increased gradually at intervals of at least 4 weeks

Prevention of cardiovascular events in patients at high risk of a first cardiovascular event

Adult 18–69 years: 20 mg once daily

Adult (patients of Asian origin): Initially 5 mg once daily, then increased if tolerated to 20 mg once daily, dose to be increased gradually at intervals of at least 4 weeks.

Adult 70 years and over: Initially 5 mg once daily, then increased if tolerated to 20 mg once daily, dose to be increased gradually at intervals of at least 4 weeks

Prevention of cardiovascular events in patients at high risk of a first cardiovascular event and with risk factors for myopathy or rhabdomyolysis

Adult: Initially 5 mg once daily, then increased if tolerated to 20 mg once daily, dose to be increased gradually at intervals of at least 4 weeks

SIDE EFFECTS:

Rare or very rare Arthralgia . gynaecomastia . haematuria polyneuropathy

Frequency not known Cough . dyspnoea . oedema . proteinuria . Stevens-Johnson syndrome . tendon disorders.

Significant: Myopathy, myalgia, diabetes mellitus, haematuria, proteinuria, interstitial lung disease, liver enzyme abnormalities, increased creatine phosphokinase levels.

Blood and lymphatic system disorders: Rarely, thrombocytopenia.

Gastrointestinal disorders: Abdominal pain, constipation, nausea.

General disorders and administration site conditions: Asthenia.

Hepatobiliary disorders: Rarely, pancreatitis, hepatitis, jaundice.

Immune system disorders: Hypersensitivity (e.g. angioedema).

Musculoskeletal and connective tissue disorders: Rarely, arthralgia, muscle rupture, Lupus-like syndrome.

Nervous system disorders: Dizziness, headache, peripheral neuropathy.

Psychiatric disorders: Depression, sleep disorders (e.g. insomnia, nightmares).

Reproductive system and breast disorders: Rarely, gynaecomastia.

Skin and subcutaneous tissue disorders: Pruritus, rash, urticaria.

Potentially Fatal: Rarely, rhabdomyolysis with acute renal failure secondary to myoglobinuria, hepatic failure.

MONITORING REQUIREMENTS:

consider routine monitoring of renal function when using 40 mg daily dose.

PATIENT AND CARER ADVICE:

Patient counselling is advised for rosuvastatin tablets (muscle effects).

RENAL IMPAIRMENT:

Avoid if eGFR less than 30 mL/minute/1.73m2.
Dose adjustments Initially 5mg once daily (do not exceed 20 mg daily) if eGFR 30–60 mL/minute/1.73m2.

HEPATIC IMPAIRMENT:

Active liver disease: Contraindicated..

SPECIAL PRECAUTIONS:

Patient with hypothyroidism; history of hereditary muscular disorders or muscular toxicity with another HMG-CoA reductase inhibitor or fibrates; excessive alcohol consumption, history of liver disease, severe respiratory failure. Patients of Asian ancestry, those with predisposing factors to myopathy or those taking concomitant ciclosporin, gemfibrozil, atazanavir/ritonavir, lopinavir/ritonavir, or simeprevir. Patient, with SLCO1B1 and ABCG2 polymorphism. Moderate renal impairment (CrCl 30-60 mL/min). Children and elderly

CONTRAINDICATION:

Active liver disease, including unexplained, persistent elevations of serum transaminases; myopathy. Severe renal impairment (CrCl <30 mL/min). Pregnancy and lactation.

PREGNANCY & LACTATION:

Rosuvastatin is contraindicated in pregnancy and lactation. Women of child bearing potential should use appropriate contraceptive measures. Since cholesterol and other products of cholesterol biosynthesis are essential for the development of the foetus, the potential risk from inhibition of HMG-CoA reductase outweighs the advantage of treatment during pregnancy. Animal studies provide limited evidence of reproductive toxicity . If a patient becomes pregnant during use of this product, treatment should be discontinued immediately. Rosuvastatin is excreted in the milk of rats. There are no data with respect to excretion in milk in humans

DRUG INTERACTIONS:

Increased exposure with certain protease inhibitors (e.g. ritonavir-boosted regimens, simeprevir), gemfibrozil, ezetimibe, ciclosporin, colchicine. Decreased plasma concentration with Al- and Mg-containing antacids, erythromycin. May increase INR when given with vit K antagonists (e.g. warfarin). May increase the plasma concentration of oral contraceptives. May increase risk of myopathy with concurrent use of strong CYP3A4 inhibitors (e.g. clarithromycin, Iitraconazole), fenofibrate, nicotinic acid.

OVERDOSAGE:

There is no specific treatment in the event of overdose. In the event of overdose, the patient should be treated symptomatically and supportive measures instituted as required. Liver function and CK levels should be monitored. Haemodialysis is unlikely to be of benefit

STORAGE:

Keep tightly closed in a cool & dry place in a original container at a temperature not exceeding 30 ^{0}C.

Keep all the medicines away from the reach of children

Manufactured by:
State Pharmaceuticals Manufacturing Corporation
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