Rostab®

Tablet

Rosuvastatin

COMPOSITION

Rostab® 5 : Each film-coated tablet contains Rosuvastatin Calcium USP equivalent to Rosuvastatin 5 mg.
Rostab® 10 : Each film-coated tablet contains Rosuvastatin Calcium USP equivalent to Rosuvastatin 10 mg.
Rostab® 20 : Each film-coated tablet contains Rosuvastatin Calcium USP equivalent to Rosuvastatin 20 mg.

PHARMACOLOGY

Rostab® (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 of cholesterol. Rosuvastatin produces its lipid-modifying effects in two ways. First, it increases the number of hepatic LDL receptors on the cell surface to enhance uptake and catabolism of LDL. Second, Rosuvastatin inhibit hepatic synthesis of VLDL, which reduces the total number of VLDL and LDL particles.

PHARMACOKINETICS

Absorption : Peak plasma concentrations of Rosuvastatin were reached 3 to 5 hours following oral dosing. Both peak concentration (Cmax) and area under the plasma concentration time curve (AUC) increase in approximate proportion to Rosuvastatin dose.
Distribution : Mean volume of distribution at steady-state of Rosuvastatin is approximately 134 liters. Rosuvastatin is 88% bound to plasma proteins, mostly albumin.
Metabolism : Rosuvastatin is not extensively metabolized. The major metabolite of Rosuvastatin is N-desmethyl Rosuvastatin which have approximately one-sixth to one-half the HMG-CoA reductase inhibitory activity of Rosuvastatin. Overall, greater than 90% of active plasma HMG-CoA reductase inhibitory activity is accounted for by Rosuvastatin.
Elimination : Following oral administration, Rosuvastatin and its metabolites are primarily excreted in the faeces (90%).The elimination half-life ($t_{1/2}$) of Rosuvastatin is approximately 19 hours.

INDICATIONS

- Hyperlipidemia and Mixed Dyslipidemia
- Heterozygous Familial Hypercholesterolemia
- Homozygous Familial Hypercholesterolemia
- To slow of the Progression of Atherosclerosis
- Primary Prevention of Cardiovascular Disease

DOSAGE AND ADMINISTRATION

Route of Administration : Oral
Dosage:
The dose range for Rosuvastatin is 5 to 40 mg orally once daily. The usual starting dose is 10-20 mg. Rosuvastatin can be administered as a single dose at any time of day, with or without food. The 40 mg dose of Rosuvastatin should be used only for those patients who have not achieved their LDL-C goal utilizing the 20 mg dose.
Homozygous Familial Hypercholesterolemia :
The recommended starting dose of Rosuvastatin is 20 mg once daily.
Patients with renal insufficiency :
No modification of dosage is necessary for patients with mild to moderate renal insufficiency .For patients with severe renal impairment (CL_{cr}<30 ml/min/1.73 m2) the dosing of Rosuvastatin should be started at 5 mg once daily and not to exceed 10 mg once daily.
OR AS DIRECTED BY THE PHYSICIAN.

CONTRAINDICATIONS

Rosuvastatin is contraindicated in patients with a known hypersensitivity to any component of this product. Rosuvastatin is contraindicated in patients with active liver disease or with unexplained persistent elevation of serum transaminase.

WARNING & PRECAUTION

Skeletal muscle effects (e.g., myopathy and rhabdomyolysis): Risks increase with use of 40 mg dose, advanced age (>65 year), hypothyroidism, renal impairment, and combination use with cyclosporine, lopinavir/ritonavir, atazanavir/ritonavir, or certain other lipid-lowering drugs. Patients should be advised to promptly report unexplained muscle pain, tenderness, or weakness. Rosuvastatin can be discontinued if signs or symptoms appear.
Liver enzyme abnormalities and monitoring: Persistent elevations in hepatic transaminases can occur. Liver enzymes should be monitored before and during treatment.

SIDE EFFECTS

Common side effects : Rosuvastatin is generally well tolerated. The most frequent adverse events thought to be related to Rosuvastatin were myalgia, constipation, asthenia, abdominal pain, and nausea.
Rare side effects : Arthralgia, Gynaecomastia, Haematuria & Polyneuropathy.

USE IN PREGNANCY AND LACTATION

Rosuvastatin should be administered to women of childbearing age only when such patients are highly unlikely to conceive. If the patient becomes pregnant while taking this drug, therapy should be discontinued immediately. It is not known whether
Rosuvastatin is excreted in human milk.

USE IN CHILDREN & ADOLESCENT

The safety and effectiveness in pediatric patients have not been established.

DRUG INTERACTIONS

With medicine :
Erythromycin: Co-administration of Erythromycin with Rosuvastatin decreased AUC and Cmax of Rosuvastatin by 20% and 31%, respectively.
Itraconazole: Itraconazole resulted in a 39% and 28% increase in AUC of Rosuvastatin after 10 mg and 80 mg dosing, respectively.
Fluconazole: Coadministration of Fluconazole with Rosuvastatin resulted in a 14% increase in AUC of Rosuvastatin.
Warfarin: Co-administration of Warfarin (25 mg) with Rosuvastatin (40 mg) did not change Warfarin plasma concentrations but increased the International Normalized Ratio (INR).
Gemfibrozil: Coadministration of Gemfibrozil (600 mg twice daily for 7 days) with Rosuvastatin (80 mg) resulted in a 90% and 120% increase for AUC and Cmax of Rosuvastatin, respectively.
Antacid: Co-administration of an antacid (aluminum and magnesium hydroxide combination) with Rosuvastatin (40 mg) resulted in a decrease in plasma concentrations of Rosuvastatin by 54%.
Oral contraceptives: Co-administration of oral contraceptives (Ethinyl Estradiol and Norgestrel) with Rosuvastatin resulted in an increase in plasma concentrations of Ethinyl Estradiol and Norgestrel by 26% and 34%, respectively.

Overdose

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. Hemodialysis does not significantly enhance clearance of Rosuvastatin.

Storage

Store below 30^0 C temperature & dry place, protected from light.
Keep all medicines out of the reach of children.

Packing

Rostab® 5 : Each box contains 5 x 10 tablets in Alu-Alu blister strip.
Rostab® 10 : Each box contains 3 x 10 tablets in Alu-Alu blister strip.
Rostab® 20 : Each box contains 2 x 10 tablets in Alu-Alu blister strip.

***Further information is available on request**

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Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness