Rovator
Rosuvastatin

Rovator (Rosuvastatin) is a selective and competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methyl glutaryl 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 inhibits hepatic synthesis of VLDL, which reduces the total number of VLDL and LDL particles.

COMPOSITION

Rovator 5 tablet: Each film coated tablet contains Rosuvastatin Calcium BP equivalent to Rosuvastatin 5 mg.
Rovator 10 tablet: Each film coated tablet contains Rosuvastatin Calcium BP equivalent to Rosuvastatin 10 mg.

INDICATION

- Primary hyperlipidemia and mixed dyslipidemia (adult) as an adjunct to diet.
- Heterozygous familial hypercholesterolemia (8 -17 years).
- Hypertriglyceridemia (adult) as an adjunct to diet.
- Primary dysbetalipoproteinemia (adult ,Type III hyperlipoproteinemia) as an adjunct to diet.
- Homozygous familial hypercholesterolemia (adult).
- Slowing the progression of atherosclerosis.

DOSAGE AND ADMINISTRATION

General Dosing:
General dose in adults is 5-40 mg once daily. The usual starting dose is 10- 20 mg once daily. The usual starting dose for homozygous familial hypercholesterolemia (adult) is 20 mg once daily. The maximum dose of 40 mg .
When initiating therapy or switching from another HMG-CoA reductase inhibitor, the appropriate starting dose should first be utilized, and then dose can be titrated accordingly.
After initiation or upon titration, lipid levels should be analyzed within 2-4 weeks and the dosage will be adjusted accordingly.
Rovator can be administered as at any time of day, with or without food.
Dosing in Asian Patients:
In Asian patients, consider initiation therapy with 5 mg once daily.
Pediatric Dosing:
In heterozygous familial hypercholesterolemia:
Children (8-10 years): 5-10 mg once Daily
Children (11-17 years): 5-20 mg once Daily
In homozygous familial hypercholesterolemia (7-17 years), the recommended dose is 20 mg once daily.

SIDE EFFECT

Rosuvastatin is generally well tolerated. The most frequent adverse events thought to be related to Rosuvastatin were headache, myalgia, constipation, asthenia, abdominal pain and nausea.

CONTRAINDICATION

Rosuvastatin is contraindicated if-

- Known hypersensitivity to product components
- Liver disease, which may include unexplained persistent elevations in hepatic transaminase levels
- Pregnant women and women who may become pregnant
- Nursing mothers

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

DRUG INTERACTION

Cyclosporine: Combination increases Rosuvastatin exposure. Rosuvastatin dose should be limited to 5 mg once daily.
Gemfibrosil: Combination should be avoided. If used together, Rosuvastatin dose should be limited to 10 mg once daily.
Lopinavir/Ritonavir or atazanavir/ritonavir: Combination increases Rosuvastatin exposure. Rosuvastatin dose should be to 10 mg once daily.
Coumarin anticoagulants: Combination prolongs international normalized ratio (INR). Stable INR should be achieved prior to starting Rosuvastatin. INR should be monitored frequently until stable upon initiation or alteration of Rosuvastatin therapy.
Concomitant lipid-lowering therapies: Use with Fibrates and Niacin products may increase the risk of skeletal muscle effects.

USE IN SPECIAL GROUPS

Use in pregnancy: The safety in pregnant women has not been established.
Use in lactation: It is not known whether Rosuvastatin is excreted in human milk or not.
Use in children: The safety and effectiveness in pediatric patients have not been established.

STORAGE CONDITION

Keep below 30^{O} C temperature, protected from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Rovator 5 tablet: Each box contains 30 tablets in alu-alu blister pack.
Rovator 10 tablet: Each box contains 20 tablets in alu-alu blister pack.

NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Comilla, Bangladesh.