Rovator
Rosuvastatin

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.

PHARMACOLOGY
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.

INDICATION
• Primary hyperlipidemia and mixed dyslipidemia (adult) as an adjunct to diet.
• Heterozygous familial hypercholesterolemia (8 -17 years).
• Homozygous familial hypercholesterolemia (7 -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.
• Risk reduction of myocardial infarction, stroke and arterial revascularization procedures.

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 is 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 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.

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.

WARNING AND 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, Darolutamide, Regorafenib, certain anti-viral medicines or their combinations.
Patients should be advised to promptly report unexplained muscle pain, tenderness or weakness. Rosuvastatin can be discontinued if signs or symptoms appear.
Immune-Mediated Necrotizing Myopathy: There have been rare reports of IMNM, an autoimmune myopathy, associated with statin use. IMNM is characterized by: proximal muscle weakness and elevated serum creatine kinase, which persist despite discontinuation of statin treatment; positive anti-HMG CoA reductase antibody; muscle biopsy showing necrotizing myopathy; and improvement with immunosuppressive agents.
Liver enzyme abnormalities and monitoring: Persistent elevations in hepatic transaminases can occur. Liver enzymes should be monitored before and during treatment.

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.

USE IN PREGNANCY AND LACTATION
Use in pregnancy: It is contraindicated for use as the safety in pregnant women has not been established.
Use in lactation: It is contraindicated for use.

USE IN CHILDREN
The safety and effectiveness in prepubertal patients have not been established.

DRUG INTERACTION
Combination of Sofosbuvir/Velpatasvir/Voxilaprevir or Ledipasvir/Sofosbuvir: Combination increases Rosuvastatin exposure. Use in combination is not recommended.
Cyclosporine and Darolutamide: Combination increases Rosuvastatin exposure. Rosuvastatin dose should be limited to 5 mg once daily.
Gemfibrozil: Combination should be avoided. If used together, Rosuvastatin dose should be limited to 10 mg once daily.
Atazanavir/Ritonavir, Lopinavir/Ritonavir, Simeprevir or combination of Dasabuvir/ Ombitasvir/ Paritaprevir/ Ritonavir, Elbasvir/Grazoprevir, Sofosbuvir/Velpatasvir and Glecaprevir/Pibrentasvir: Combination increases Rosuvastatin exposure. Rosuvastatin dose should be limited to 10 mg once daily.
Regorafenib: Combination increases Rosuvastatin exposure. Rosuvastatin dose should be limited to 10 mg once daily.
Coumarin anticoagulants: Combination prolongs INR. Achieve stable INR prior to starting Rosuvastatin. Monitor INR 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.

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 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.

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NIPRO JMI Pharma

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