ROSUVASTATIN

RUVASTIN-10

10 mg Film-Coated Tablet
Anti-hyperlipidaemic

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Formulation:
Ruvastin-10 Tablet: Each Film-coated tablet contains:
Rosuvastatin (as Calcium).....10 mg

Product Description:
A white to almost white, heart shaped and biconvex film coated tablet, having breakline on both sides.

Pharmacology:
Rosuvastatin is selective, potent and competitive inhibitor of HMG-CoA reductase effective in lowering LDL (Low-Density Lipoprotein) cholesterol and triglycerides. It produces its lipid modifying effects in two ways; firstly it increases the number if hepatic LDL receptors on the cell surface to enhance uptake and catabolism of LDL and secondly it inhibits the hepatic synthesis of VLDL (Very Low Density Lipoprotein), which reduces the total number of VLDL & LDL particles.

Indications:
Used in the treatment of hyperlipidaemia (type IIa or IIb hyperlipoproteinaemias), hypertriglyceridaemia (type IV), and primary dysbetalipoproteinaemia (type III), and may also be used as adjunct therapy in patients with homozygous familial hypercholesterolaemia who have some LDL-receptor function, and in cardiovascular risk reaction.

Dosage and Administration:
Hypercholesterolaemia, initially 5-10mg once daily increased if necessary at intervals of at least 4 weeks to 20mg once daily, increased after further 4 weeks to 40mg daily only in severe hypercholesterolaemia; elderly initially 5mg once daily; patient of asian origin, initially 5mg once daily increase if necessary to maximum, 20mg daily. Initially 5mg once daily with concominant fibrate increased if necessary to maximum, 20mg daily. Prevention of cardiovascular events, 20mg once daily.

Contraindications:
Rosuvastatin is contraindicated in patients with hypersensitivity to any component of this product. It is also contraindicated in patients with active liver disease or with unexplained elevations in transaminase.

Adverse effects:
Rosuvastatin is generally well tolerated. The common side effects are headache, myalgia, asthenia, constipation, dizziness and abdominal pain. It may rarely cause myositis, rhabdomyolysis, pancreatitis and hypersensitivity reaction.

Drug Interactions:
Erythromycin: Co-administration of Erythromycin with Rosuvastatin decreased AUC and Cmax of Rosuvastatin. Itraconazole: Itraconazole increases the AUC of Rosuvastatin. Fluconazole: Co-administration of Fluconazole with Rosuvastatin increases the AUC of Rosuvastatin. Warfarin: The pharmacokinetics of Warfarin is not significantly affected following co-administration with Rosuvastatin. Cyclosporin: Co-administration of Rosuvastatin with Cyclosporin resulted in no significant changes in Cyclosporin plasma concentration. Gemfibrozil: Concomitant use of Rosuvastatin and Gemfibrozil resulted in a two-fold increase in C max and AUC (0-t). Antacid: The simultaneous dosing of Rosuvastatin with an antacid suspension containing Aluminium and Magnesium hydroxide resulted in a decrease in Rosuvastatin plasma concentration of approximately 50%. There are no clinically significant interactions with an oral contraceptive, Digoxin, Fenofibrate, antihypertensive agents, antidiabetic agents and hormone replacement therapy.

Reporting of Suspected Adverse Reactions:
To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor and/or report to FDA: www.fda.gov.ph.
Patients are advised to seek immediate medical attention at the first sign/s of adverse reactions.

Precaution:
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.
Use in children: The safety and effectiveness in pediatric patients have not been established.

Storage Conditions:
Store at temperature not exceeding 30°C. Keep out of reach of children.

Caution:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Availability:
Ruvastin-10 Tablet: Alu-Alu blister pack x 10's (Box of 20 tablets).

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Manufactured by:
ARISTOPHARMA LTD.
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