ROSUVASTATIN
calcium

ROVASTIN

℞

10 mg Film-Coated Tablet

ANTIHYPERLIPIDAEMIC

FORMULATION:
Each film-coated tablet contains:
Rosuvastatin (as calcium).....10 mg

DESCRIPTION:
Rosuvastatin 10 mg film-coated tablet is an old rose, round, biconvex and plain on both sides.

PHARMACOKINETICS:
Peak plasma concentrations of rosuvastatin were reached 5 hours following oral dosing. The absolute bioavailability of rosuvastatin is approximately 20%. Rosuvastatin is 90% bound to plasma proteins, mostly albumin. This binding is reversible and independent of plasma concentrations. Mean volume of distribution at steady-state of rosuvastatin is approximately 134 liters.

Rosuvastatin is not extensively metabolized; approximately 10% of radiolabeled dose is recovered as metabolite. The major metabolite is *N*-desmethyl rosuvastatin, which is formed principally by cytochrome P450 isoenzyme CYP2C9. Overall, greater than 90% of active plasma HMG-CoA reductase inhibitory activity is accounted for rosuvastatin in the parent compound. Following oral administration, rosuvastatin and its metabolites are primarily excreted in feces (90%). The elimination half-life of rosuvastatin is approximately 19 hours.

INDICATIONS:
For the management of hyperlipidaemias, including primary hypercholesterolaemia (Type IIa), mixed dyslipidaemia (Type IIb), and hypertriglyceridaemia (Type IV). It may also be used in the patients with homozygous familial hypercholesterolaemia.

DOSAGE AND ADMINISTRATION:
Rosuvastatin is given by mouth in an initial dose of 5 mg to 10 mg in the evening; an initial dose of 20 mg may be used in the patients with ischaemic heart disease. The dose may be adjusted at interval of not less than 4 weeks up to maximum of 80 mg once daily in three divided doses of 20 mg, 20 mg and an evening dose of 40 mg. A maximum of 10 mg daily is recommended in those taking cyclosporine, fibric acid derivatives or nicotinic acid, and the risk of myopathy must be considered. Or as prescribed by the physician.

CONTRAINDICATIONS:
Rosuvastatin is contraindicated in patients with a known hypersensitivity to any component of this product. Rosuvastatin is also contraindicated in patients with active liver disease or with unexplained persistent elevations of serum transaminases.

It is also contraindicated during pregnancy and in nursing mothers. If patient becomes pregnant while taking this drug, therapy should be discontinued immediately and the patient should be apprised of the potential hazard to the fetus.

WARNING AND PRECAUTIONS:
Rosuvastatin should be used with caution in patients who have a history of liver disease and/or consume substantial quantities of alcohol. Unexplained persistent transaminase elevations or active liver disease are contraindications to the use of rosuvastatin. It should be prescribed with caution in patients with predisposing factors for myopathy such as renal impairment, advanced age and inadequately treated hypothyroidism.

Rosuvastatin being an HMG-CoA reductase inhibitor, effects on skeletal muscle are uncomplicated myalgia and myopathy. Patients should be advised to promptly report unexplained muscle pain, tenderness or weakness, particularly if accompanied by malaise or fever. Rosuvastatin therapy should be discontinued if markedly elevated CK levels occur or myopathy is diagnosed or suspected.

The risk of myopathy during treatment with rosuvastatin may be increased with concurrent administration of other lipid lowering therapies, cyclosporine, or lopinavir/ ritonavir.

Rosuvastatin therapy should also be temporarily withheld in any patient with an acute, serious condition suggestive of myopathy or predisposing to the development of renal failure secondary to rhabdomyolysis (e.g., sepsis, hypotension, dehydration, major surgery, trauma, severe metabolic endocrine, and electrolyte disorders, or uncontrolled seizures).

Combination therapy of rosuvastatin and gemfibrozil should generally be avoided.

DRUG INTERACTIONS:
The potential drug-drug interactions with rosuvastatin is minimal since there is a minimal metabolism via CYP isoenzyme system. Co-administration of cyclosporine or gemfibrozil, which both increased concentrations of rosuvastatin, thereby requiring a decrease in rosuvastatin dose when administered.

ADVERSE EFFECTS:
Rosuvastatin's adverse effects are generally mild and transient. However, the incidence of adverse drug reactions tend to increase with increasing dose. The common adverse effects of therapy are gastrointestinal disturbances, headache, skin rashes, dizziness, blurred vision, insomnia and dysgeusia.

OVERDOSE AND TREATMENT:
There is no specific treatment for overdosage. In the event of overdose, the patient should be treated symptomatically and supportive measures instituted as required. Liver function and creatine kinase levels should be monitored. Hemodialysis is unlikely to be of benefit.

STORAGE RECOMMENDATIONS:
Store at temperatures not exceeding 30°C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

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

For suspected adverse drug reaction, report to the FDA: **www.fda.gov.ph**
Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

AVAILABILITY:
10 mg Film-Coated Tablet - Alu/Alu Blister Pack x 10's (Box of 100's)
DRP-6743-02

DATE OF FIRST AUTHORIZATION:
May 10, 2019

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August 2021

Manufactured by:
HIZON LABORATORIES, INC.
Assumption Road, Sumulong Highway,
Antipolo City

Distributed by:
GX INTERNATIONAL, INC.
RMG Corporate Center, Lot 60 Block 11,
Buencamino St., Cupang, Muntinlupa City

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