# Rostatin

## Tablet

DRUG INTERNATIONAL LTD.

**Composition :**

**Rostatin-5 :** Each film coated tablet contains Rosuvastatin 5mg (as Rosuvastatin Calcium USP).

**Rostatin-10 :** Each film coated tablet contains Rosuvastatin 10mg (as Rosuvastatin Calcium USP).

**Rostatin-20 :** Each film coated tablet contains Rosuvastatin 20mg (as Rosuvastatin Calcium USP).

**Pharmacology :** Rosuvastatin calcium is a synthetic lipid-lowering agent. Rosuvastatin is an inhibitor of 3-hyroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase. This enzyme catalyzes the conversion of HMG-CoA to mevalonate, an early and rate-limiting step in cholesterol biosynthesis.

The adsolute bioavailability of Rosuvastatin is approximately 20%. Administration of Rosuvastatin with food decreases the rate of drug absorption by 20% as assessed by Cmax, but there is no effect on the extent of adsorption as assessed by AUC.

Distribution : Mean volume of distribution at steady-state of Rosuvastatin is approximately 134 liters. Rosuvastatin is 88% bound to plasma proteins, mostly albumin. The binding is reversible and independent of plasma concentrations.

Metabolism : Rosuvastatin is not extensively metabolized; approximately 10% of a radiolabeled dose is recovered as metabolite.

Excretion : Following oral administration, Rosuvastatin and its metabolites are primarily excreted in the feces (90%). The elimination half-life (t1/2) of Rosuvastatin is approximately 19 hours.

**Indications :** **Rostatin** is indicated for - Heterozygous Hypercholesterolemia (Familial and Nonfamilial), Homozygous Hypercholesterolemia (Familial), Mixed Dyslipidemia (Fredrickson Type IIa and IIb).

**Dosage and administration :** **Heterozygous Hypercholesterolemia (Familial and Nonfamilial) and Mixed Dyslipidemia (Fredrickson Type IIa and IIb):** The usual recommended starting dose of **Rostatin** is 10mg once daily. Initiation of therapy with 5mg once daily may be considered for patients requiring less aggressive LDL-C reductions or who have predisposing factors for myopathy. For patients with marked hypercholesterolemia (LDL-C>190 mg/dL) and aggressive lipid targets, a 20mg starting dose may be considered. **Homozygous Hypercholesterolemia (Familial):** The recommended starting dose of **Rostatin** is 20mg once daily in patients with Homozygous FH. The maximum recommended daily dose is 40mg.

**Dosage in Patients With Renal Insufficiency :** For patients with severe renal impairment (CLcr <30 ml/min/1.73m$^2$) not on hemodialysis, dosing of Rostatin should be started at 5mg once daily and not to exceed 10mg once daily. **Pediatric patients :** The safety and effectiveness in pediatric patients have not been established. Or, as directed by the registered physician.

**Contraindications :** **Rostatin** is contraindicated in patients with hypersensitivity to any component of this medications, active liver disease or unexplained persistent, elevations of serum transaminases.

**Side effects :** **Rostatin** is generally well tolerated. The most common side effects are constipation, myalgia, asthenia, abdominal pain and nausea.

**Pregnancy and Lactation :** **Rostatin** is contraindicated in pregnancy and while breast feeding. **Rostatin** should be administered to women of child bearing age only when such patients are highly unlikely to conceive and have been informed of the potential hazards.

**Drug Interaction:** The risk of myopathy during treatment with other drugs in this class is increased with concurrent administration of cyclosporine, fibric acid derivatives, erythromycin, azole antifungal or niacin. This increases in risk may also occur when combining these drugs with Atorvastatin.

**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.

**Storage :** Store below 30°C in a dry place.

**Packing :**

**Rostatin-5 :** Each box contains 3 X 14's tablets in blister pack.

**Rostatin-10 :** Each box contains 2 X 14's tablets in blister pack.

**Rostatin-20 :** Each box contains 1 X 14's tablets in blister pack.