

RosflinkTM-10

(Rosuvastatin 10 mg tablet)

Composition:

Each Film coated tablet contains:

Rosuvastatin Calcium..... I.P.
Eq. to Rosuvastatin..... 10mg
Excipients..... q.s.
Colour: Titanium Dioxide I.P.

Pharmacology:

Rosuvastatin is a fully synthetic competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A to mevalonate, a precursor of cholesterol. Triglycerides (TG) and cholesterol in the liver are incorporated, with apolipoprotein B, into very low density lipoprotein (VLDL) and released into the plasma for delivery to peripheral tissues. VLDL particles are TG-rich. Cholesterol-rich low density lipoprotein (LDL) is formed from VLDL and is cleared primarily through the high affinity LDL receptor in the liver. Rosuvastatin produces its lipid-modifying effects in two ways; it increases the number of hepatic LDL receptors on the cell-surface, enhancing uptake and catabolism of LDL and it inhibits the hepatic synthesis of VLDL, thereby reducing the total number of VLDL and LDL particles.

Indications:

Hypercholesterolemia, Dyslipidemia.

Side Effects:

- Constipation
- Stomach pain
- Dizziness

Warnings and precautions: In pregnancy Rosuvastatin should not be used. Cholesterol compounds are essential elements for the development of a fetus. Cholesterol-lowering drugs can harm the fetus. If you become pregnant, discontinue use immediately and tell your doctor.

Contraindication:

Pregnancy (pregnancy category X) There are reports of congenital anomalies.
Breastfeeding. Active liver disease. Unexplained persistent elevations of serum transaminases.

Adverse effects:

Rosuvastatin is generally well tolerated. The adverse events seen with rosuvastatin are generally mild and transient. In controlled clinical trials less than 4% of rosuvastatin treated patients were withdrawn due to adverse events. This withdrawal rate was comparable to that reported in patients receiving placebo.

Interactions with other medicines

- Warfarin and Other Coumarin Anticoagulants
- Cyclosporine
- Digoxin
- Fenofibrate
- Gemfibrozil
- Antacids
- Cytochrome P₄₅₀ enzymes
- Oral contraceptives

Dosage:

As directed by the physician.

Route of administration: Oral.

Type of tablet: Film coated tablet

Storage: Store protected from light & moisture, at a temperature not exceeding 25°C. Keep all medicines out of reach of children.

SCHEDULE H PRESCRIPTION DRUG-CAUTION Not to be sold by retail without Prescription of a Registered Medical Practitioner.

Presentation: Rosflink-10 film coated tablet is available as 10x 10 Tablets.

Marketed By:



EPIONE PHARMACEUTICALS PVT.LTD.

804, Suyog Center, Gultekdi, Pune-411037 (MH), India.

