

ROZUPLATT

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.
Abbreviated Prescribing information for ROZUPLATT (Rosuvastatin Calcium I.P. and Clopidogrel hard gelatin capsules)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Rosuvastatin is a selective and competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl coenzyme A to mevalonate, a precursor for cholesterol. The primary site of action of rosuvastatin is the liver, the target organ for cholesterol lowering. Rosuvastatin 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.

Clopidogrel is a prodrug, one of whose metabolites is an inhibitor of platelet aggregation. Clopidogrel must be metabolised by CYP450 enzymes to produce the active metabolite that inhibits platelet aggregation. The active metabolite of clopidogrel selectively inhibits the binding of adenosine diphosphate (ADP) to its platelet P2Y₁₂ receptor and the subsequent ADP-mediated activation of the glycoprotein GPIIb/IIIa complex, thereby inhibiting platelet aggregation. Due to the irreversible binding, platelets exposed are affected for the remainder of their lifespan (approximately 7-10 days) and recovery of normal platelet function occurs at a rate consistent with platelet turnover. Platelet aggregation induced by agonists other than ADP is also inhibited by blocking the amplification of platelet activation by released ADP.

DOSAGE AND ADMINISTRATION:

Dosage should be taken as directed by your Physician.

CONTRAINDICATION:

1. Known hypersensitivity to Rosuvastatin or Clopidogrel or to any of the excipients.
2. In patients with pre-disposing factors for myopathy/rhabdomyolysis such as alcohol abuse, Hypothyroidism, moderate renal impairment, pathological bleeding etc.
3. In patients with active liver disease, severe renal impairment, myopathy, receiving concomitant ciclosporin and during pregnancy and lactation.

WARNINGS & PRECAUTIONS: ROZUPLATT has effects on skeletal muscle and can cause myalgia, myopathy and, rarely, rhabdomyolysis and bleeding related issues, immediately stop taking medicine and seek doctor advise.

DRUG INTERACTION: It can interact with Ciclosporin, Protease inhibitors, Gemfibrozil and other lipid-lowering products, Ezetimibe, Antacid, Erythromycin, Cytochrome P450 enzymes, Vitamin K antagonists, Oral contraceptive/hormone replacement therapy (HRT), Digoxin, Fusidic Acid, Oral anticoagulants, Glycoprotein IIb/IIIa inhibitors, Acetylsalicylic acid, Heparin, Thrombolytics, NSAIDs, SSRIs Proton Pump Inhibitors (PPI) etc.

ADVERSE REACTIONS: Rash, itching or other skin reactions, vomiting, nausea, constipation, excessive gas in stomach or intestines, extreme tiredness/ feeling weak, headache, stomach pain, constipation, feeling sick, muscle pain, dizziness, increase in the amount of protein in the urine, diabetes and bleeding.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.
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IN/ ROZUPLATT 10 mg, 75 mg/Aug-20/01/AbPI

(Additional information is available on request)