

ROZUCOR EZ

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.
Abbreviated Prescribing information for ROZUCOR EZ (Rosuvastatin Calcium and Ezetimibe) tablet

[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.

Ezetimibe is in a new class of lipid-lowering compounds that selectively inhibit the intestinal absorption of cholesterol. Ezetimibe is orally active, and has a mechanism of action that differs from other classes of cholesterol-reducing compounds (e.g. statins, bile acid sequestrants [resins], fibric acid derivatives). The molecular target of ezetimibe is the sterol transporter, Niemann- Pick C1-Like 1 (NPC1L1), which is responsible for the intestinal uptake of cholesterol.

Ezetimibe localises at the brush border of the small intestine and inhibits the absorption of cholesterol, leading to a decrease in the delivery of intestinal cholesterol to the liver; statins reduce cholesterol synthesis in the liver and together these distinct mechanisms provide complementary cholesterol reduction.

DOSAGE AND ADMINISTRATION:

Dosage should be taken as directed by your Physician.

CONTRAINDICATION:

1. Known hypersensitivity to Rosuvastatin or Ezetimibe 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: ROZUCOR EZ has effects on skeletal muscle and can cause myalgia, myopathy and, rarely, rhabdomyolysis. Stop taking ROZUCOR EZ and talk to your doctor immediately to seek advice. Inform your doctor of any pre-existing liver problem, kidney problem and medicine prior to initiation of ROZUCOR EZ.

DRUG INTERACTION: It can interact with Antacids, Cholestyramine, Cyclosporin, Fenofibrate, Gemfibrozil, Anticoagulants, Cytochrome P450 enzymes, Oral contraceptives, Fusidic acid etc.

ADVERSE REACTIONS: Headache, Nausea, Stomach pain/Abdominal pain, Constipation, Diarrhoea, Flatulence, Feeling sick, Muscle pain, Feeling tired/ unusual tiredness or weakness/ tenderness, Dizziness, Elevations in some laboratory blood tests of liver (transaminases) or muscle (CK) function.

MARKETED BY:

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IN/ROZUCOR EZ/10, 10 mg/AUG-20/01/AbPI
(Additional information is available on request)