

## Rosuvastatin USP and Ezetimibe USP

**Composition**

**Rostab® EZ 5:** Each film coated tablet contains Rosuvastatin Calcium USP equivalent to Rosuvastatin 5 mg and Ezetimibe USP 10 mg.

**Rostab® EZ 10:** Each film coated tablet contains Rosuvastatin Calcium USP equivalent to Rosuvastatin 10 mg and Ezetimibe USP 10 mg.

**Rostab® EZ 20:** Each film coated tablet contains Rosuvastatin Calcium USP equivalent to Rosuvastatin 20 mg and Ezetimibe USP 10 mg.

**Pharmacology**

**Rosuvastatin:** Rosuvastatin is an inhibitor of HMG CoA-reductase, the rate-limiting enzyme that converts 3-hydroxy3-methylglutaryl coenzyme A to mevalonate, a precursor of cholesterol. In in vivo and in vitro studies, Rosuvastatin produces its lipid-modifying effects in two ways. First, it increases the number of hepatic LDL receptors on the cell-surface to enhance uptake and catabolism of LDL. Second, Rosuvastatin inhibits hepatic synthesis of VLDL, which reduces the total number of VLDL and LDL particles.

**Ezetimibe :** The molecular target of ezetimibe is the sterol transporter, Niemann-Pick C1-Like 1 (NPC1L1), which is involved in the intestinal uptake of cholesterol and phytosterols. Ezetimibe localizes 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. This causes a reduction of hepatic cholesterol stores and an increase in clearance of cholesterol from the blood.

**Indication**

**Rostab® EZ is indicated in adults:**

As an adjunct to diet in patients with primary non-familial Hyperlipidemia to reduce low-density lipoprotein cholesterol (LDLC).

Alone or as an adjunct to other LDL-C lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

**Dosage & Administration**

**Route of Administration:** Orally.

Swallow Rostab® EZ tablet whole at any time of day, with or without food. Do not crush, dissolve, or chew tablets.

The dosage range is 5 mg/10 mg to 40 mg/10 mg once daily. The recommended dose of Rostab® EZ depends on a patient's indication for usage, LDLC, and individual risk for cardiovascular events.

**Contraindication**

**Rosuvastatin and Ezetimibe is contraindicated in patients with:**

- Acute liver failure or decompensated cirrhosis.
- Hypersensitivity to any component of Rosuvastatin and Ezetimibe.

**Warning & Precautions**

**Myopathy and Rhabdomyolysis:** Risk factors include age 65 years or greater, uncontrolled hypothyroidism, renal impairment, concomitant use with certain other drugs, and higher Rosuvastatin and Ezetimibe dosage. Discontinue Rosuvastatin and Ezetimibe if markedly elevated CK levels occur or myopathy is diagnosed or suspected. Temporarily discontinue Rosuvastatin and Ezetimibe in patients experiencing an acute or serious condition at high risk of developing renal failure secondary to rhabdomyolysis.

**Immune-Mediated Necrotizing Myopathy (IMNM):** Rare reports of IMNM, an autoimmune myopathy, have been reported with statin use.

**Hepatic Dysfunction:** Increases in serum transaminases have occurred, some persistent. Rare reports of fatal and non-fatal hepatic failure have occurred. Consider testing liver enzyme tests before initiating therapy and as clinically indicated thereafter. If serious hepatic injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs, promptly discontinue Rosuvastatin and Ezetimibe.

**Side effects**

Most common adverse reactions for Rosuvastatin (incidence >2% and greater than placebo) are headache, nausea, myalgia, arthralgia, dizziness, asthenia, constipation, and abdominal pain.

Ezetimibe (incidence >2% and greater than placebo) are upper respiratory tract infection, diarrhea, arthralgia, sinusitis, pain in extremity, fatigue, and influenza.

Ezetimibe co-administered with a statin (incidence >2% and greater than statin alone) are nasopharyngitis, myalgia, upper respiratory tract infection, arthralgia, diarrhea, back pain, influenza, pain in extremity, and fatigue.

**Use in Pregnancy and Lactation**

**Pregnancy:** Discontinue Rosuvastatin and Ezetimibe when pregnancy is recognized.

**Nursing mothers:** Breastfeeding is not recommended during treatment with Rosuvastatin and Ezetimibe.

**Use in Children & Adolescents**

The safety and effectiveness of Rosuvastatin and Ezetimibe have not been established in pediatric patients.

**Drug Interaction**

**Gemfibrozil or Cyclosporin:** Avoid concomitant use with Rosuvastatin and Ezetimibe.

**Antivirals:** Avoid concomitant use of Rosuvastatin and Ezetimibe with certain antivirals and adjust the dose of Rosuvastatin and Ezetimibe with other antivirals.

**Darolutamide:** Do not exceed Rosuvastatin and Ezetimibe 5 mg/10 mg once daily.

**Regorafenib:** Do not exceed Rosuvastatin and Ezetimibe 10 mg/10 mg once daily

**Fenofibrates, Niacin, Colchine:** Consider the risks and benefits of concomitant use with Rosuvastatin and Ezetimibe.

**Warfarin:** Obtain INR before Rosuvastatin and Ezetimibe initiation and monitor INR during Rosuvastatin and Ezetimibe dosage initiation or adjustment.

**Overdose**

No specific treatments of over dosage with Rosuvastatin and Ezetimibe are known. Hemodialysis does not significantly enhance clearance of Rosuvastatin.

**Storage**

Store below 30°C temperature & dry place, protected from light. Keep all medicines out of reach of children.

**Packaging**

**Rostab® EZ 5:** Each box contains 3x10 tablets in Alu-Alu blister pack.

**Rostab® EZ 10:** Each box contains 2x10 tablets in Alu-Alu blister pack.

**Rostab® EZ 20:** Each box contains 1x10 tablets in Alu-Alu blister pack.

\* Further information is available on request.



Manufactured by:

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