Rosuva® *EZ*

Rosuvastatin (as Rosuvastatin Calcium USP) & Ezetimibe USP

COMPOSITION: Rosuva® *EZ* 5/10: Each Film coated tablet contains Rosuvastatin 5 mg (as Rosuvastatin Calcium USP) and Ezetimibe USP 10 mg.
Rosuva® *EZ* 10/10: Each Film coated tablet contains Rosuvastatin 10 mg (as Rosuvastatin Calcium USP) and Ezetimibe USP 10 mg.
Rosuva® *EZ* 20/10: Each Film coated tablet contains Rosuvastatin 20 mg (as Rosuvastatin Calcium USP) and Ezetimibe USP 10 mg.

PHARMACOLOGY: Rosuvastatin: Rosuvastatin lowers plasma cholesterol and lipoprotein levels by inhibiting HMG-CoA reductase and cholesterol synthesis in the liver and by increasing the number of hepatic LDL receptors on the cell-surface to enhance uptake and catabolism of LDL; Rosuvastatin reduces LDL production and the number of LDL particles. Ezetimibe: Ezetimibe reduces blood cholesterol by inhibiting the absorption of cholesterol by the small intestine. The molecular target of ezetimibe has been shown to be the sterol transporter, which is involved in the intestinal uptake of cholesterol and phytosterols.

INDICATIONS: Rosuvastatin, an HMG CoA-reductase inhibitor (statin), and Ezetimibe, a dietary cholesterol absorption inhibitor, combination is indicated in adults:
- As an adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C)
- Alone or as an adjuct to other LDL-C lowering therapies in patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C

DOSAGE AND ADMINISTRATION: The dosage range of **Rosuva®** *EZ* is 5/10 mg to 40/10 mg orally once a day. The recommended dosage depends on the indication for usage, LDL-C, and individual risk for cardiovascular events. Patients with severe renal impairment (not on hemodialysis): initiate at 5 mg/10mg once daily; do not exceed 10 mg/10 mg once daily. Patients should swallow **Rosuva®** *EZ* tablet whole. Tablets should not be crushed, dissolved, or chewed. Administer **Rosuva®** *EZ* at least 2 hours before or 4 hours after administration of a bile acid sequestrant. Administer **Rosuva®** *EZ* at least 2 hours before administration of an aluminium and magnesium hydroxide combination antacid.

CONTRAINDICATIONS: Rosuva® EZ is contraindicated in patients with:
- Active liver disease or decompensated cirrhosis
- Hypersensitivity to any component of **Rosuva®** *EZ*

SIDE EFFECTS: Common side effects are headache, nausea, myalgia, arthralgia, dizziness, asthenia, constipation, abdominal pain, respiratory tract infection, diarrhea, sinusitis, pain in extremity, fatigue, influenza and back pain.
WARNING & PRECAUTION: Myopathy and rhabdomyolysis: Risk factors include age 65 years or greater, uncontrolled hypothyroidism, renal impairment, concomitant use with certain other drugs and higher **Rosuva®** ***EZ*** dosage. Discontinue **Rosuva®** ***EZ*** if markedly elevated creatine kinase (CK) levels occur or myopathy is diagnosed or suspected. Temporarily discontinue **Rosuva®** ***EZ*** in patients experiencing an acute or serious condition at high risk of developing renal failure secondary to rhabdomyolysis. 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.

DRUG INTERACTIONS: The concomitant use of Rosuvastatin & Ezetimibe combination with Cyclosporine or Gemfibrozil is not recommended. Rosuvastatin & Ezetimibe combination dosage modifications are recommended for patients taking certain antiviral medications, Darolutamide, and Regorafenib. Niacin, Fibrates and Colchicine may also increase the risk of myopathy and rhabdomyolysis.

USE IN SPECIAL POPULATION: Pregnancy: This preparation is contraindicated in women who are or may become pregnant. Lactation: Breastfeeding is not recommended. Pediatric Use: Safety and effectiveness have not been established in pediatric patients. Geriatric Use: No dosage adjustment is necessary. Patients with Hepatic Impairment: Contraindicated in patients with acute liver failure or decompensated cirrhosis. If serious hepatic injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs, promptly discontinue the medicine. Patients with Renal Impairment: In patients with severe renal impairment (CLcr less than 30 mL/min/1.73 m^2) not on hemodialysis, the recommended starting dosage is 5 mg/10 mg once daily and should not exceed 10 mg/10 mg once daily. There are no dosage adjustment recommendations for patients with mild and moderate renal impairment.

STORAGE: Store below 30°C. Protect from light and moisture. Keep all medicine out of the reach of children.

HOW SUPPLIED: Rosuva® *EZ* 5/10: Each box contains 30 tablets in Alu-Alu blister pack.
Rosuva® *EZ* 10/10: Each box contains 30 tablets in Alu-Alu blister pack.
Rosuva® *EZ* 20/10: Each box contains 20 tablets in Alu-Alu blister pack.

Manufactured by

SQUARE
PHARMACEUTICALS PLC.
BANGLADESH