ROZUCOR EZ

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for ROZUCOR EZ 20 & 40 (Rosuvastatin Calcium & Ezetimide Tablets I.P.)

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

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Plasma cholesterol is derived from intestinal absorption and endogenous synthesis. ROZUCOR EZ contains rosuvastatin and ezetimide, two lipid-lowering compounds with complementary mechanisms of action. ROZUCOR EZ reduces elevated total cholesterol (total-C), LDL-C, apolipoprotein B (Apo B), triglycerides (TG), and non-high-density lipoprotein cholesterol (non- HDL-C), and increases high-density lipoprotein cholesterol (HDL-C) through dual inhibition of cholesterol synthesis and absorption.

INDICATIONS: It is indicated for the treatment of patients with primary hypercholesterolemia.

DOSAGE AND ADMINISTRATION: The recommended dose is one ROZUCOR EZ tablet daily. Route of administration is oral. ROZUCOR EZ can be administered at any time of the day, with or without food. The tablet should be swallowed whole with a drink of water.

CONTRAINDICATION: Hypersensitivity to the active substances or to any of the excipients listed, Pregnancy, breast-feeding and in women of childbearing potential not using appropriate contraceptive measures, Active liver disease or unexplained persistent elevations in serum transaminases and any serum transaminase elevation exceeding 3x the upper limit of normal (ULN), In patients with severe renal impairment (creatinine clearance). ROZUCOR EZ is contraindicated in patients with pre-disposing factors for myopathy/rhabdomyolysis. Such factors include: Moderate renal impairment, Hypothyroidism, Personal or family history of hereditary muscular disorders, Previous history of muscular toxicity with another HMG-CoA reductase inhibitor or fibrate, Alcohol abuse, Situations where an increase in plasma levels of rosuvastatin may occur, Severe renal impairment (CrCl<30mL/min), Asian patients, Concomitant use of fibrates.

WARNINGS & PRECAUTIONS: Skeletal muscle effects: Myalgia, myopathy and, rarely, rhabdomyolysis have been reported in rosuvastatin-treated patients with all doses and in particular with doses >20 mg. Creatine kinase measurement: Before treatment, caution should be exercised in patients with renal impairment, hypothyroidism etc. Whilist on Treatment, Therapy should be discontinued if CK levels are markedly elevated (>5xULN) or if muscular symptoms are severe and cause daily discomfort. Liver effects: Discontinued or the dose reduced if the level of serum transaminases is greater than 3 times the upper limit of normal. It is not recommended, in patients with moderate or severe hepatic impairment, Liver disease and alcohol: Caution to be followed with other HMG-CoA reductase inhibitors and in patients who consume excessive quantities of alcohol and/or have a history of liver disease. Renal effects: In particularly 40 mg, Proteinuria has been observed. Diabetes mellitus: It may produce a level of hyperglycaemia where formal diabetes care is appropriate, Interstitial lung disease: Exceptional cases of interstitial lung disease have been reported with some statins, especially with long term therapy, Severe cutaneous adverse reactions: If the patient has developed a serious reaction such as SJS or DRESS with the use of ROZUCOR EZ, treatment with ROZUCOR EZ must not be restarted in this patient at any time , Protease inhibitors: The concomitant use with certain protease inhibitors is not recommended unless the dose of rosuvastatin is adjusted, Fibrates: If cholelithiasis is suspected in a patient receiving ROZUCOR EZ and fenofibrate, gallbladder investigations are indicated and this therapy should be discontinued, Anticoagulants: If ROZUCOR EZ is added to warfarin, another coumarin anticoagulant, or fluindione, the International Normalised Ratio (INR) should be appropriately monitored, Fusidic acid: ROZUCOR EZ must not be co-administered with systemic formulations of fusidic acid or within 7 days of stopping

fusidic acid treatment.

DRUG INTERACTIONS: *Contraindicated combinations*: Sofosbuvir/velpatasvir/voxilaprevir, Ledipasvir/sofosbuvir, Ciclosporin, *Not-recommended combinations*: Fibrates and other lipid-lowering products, Protease inhibitors, Transporter protein inhibitors, Fusidic acid, *Other interactions*: Cytochrome P450 enzymes, Antacids, Colestyramine, Anticoagulants, Vitamin K antagonists, Clopidogrel, Ticagrelor, Erythromycin, Oral contraceptive/hormone replacement therapy (HRT).

ADVERSE REACTIONS: Diabetes Mellitus, Headache, Dizziness, Constipation, Nausea, Abdominal Pain, Myalgia, ALT and/or AST Increased, Asthenia, Fatigue, Decreased Appetite, Paraesthesia, Hot Flush, Cough, Dyspepsia; Gastroesophageal Reflux Disease, Pruritus, Rash, Arthralgia; Muscle Spasms, Liver Function Test Abnormal, Chest Pain, Thrombocytopenia, Hypersensitivity Reactions Including Angioedema, Pancreatitis, Increased Hepatic Transaminases, Myopathy (Including Myositis), Rhabdomyolysis, Polyneuropathy, Memory Loss, Jaundice, Hepatitis, Arthralgia, Haematuria, Gynaecomastia.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

Torrent Pharmaceuticals Limited.

IN/ROZUCOR EZ 20 MG & 40 MG/AUG-2024/01/PI

(Additional information is available on request)