ROZUCOR B / BEMPESTA R

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

Abbreviated Prescribing information for ROZUCOR B / BEMPESTA R

(Rosuvastatin and Bempedoic Acid Tablets) [Please refer the complete prescribing information for details].

PHARMACOLOGICAL PROPERTIES:

Mechanism of Action:

Bempedoic acid

Bempedoic acid is an adenosine triphosphate-citrate lyase (ACL) inhibitor that lowers low-density lipoprotein cholesterol (LDL-C) by inhibition of cholesterol synthesis in the liver. ACL is an enzyme upstream of 3-hydroxy-3-methyl-glutaryl-coenzyme A (HMG-CoA) reductase in the cholesterol biosynthesis pathway. Bempedoic acid and its active metabolite, ESP15228, require coenzyme A (CoA) activation by very long-chain acyl-CoA synthetase 1 (ACSVL1) to ETC-1002-CoA and ESP15228-CoA, respectively. ACSVL1 is expressed primarily in the liver. Inhibition of ACL by ETC-1002-CoA results in decreased cholesterol synthesis in the liver and lowers LDL-C in blood via upregulation of low-density lipoprotein receptors.

Rosuvastatin

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 of cholesterol. In vivo studies in animals, and in vitro studies in cultured animal and human cells have shown rosuvastatin to have a high uptake into, and selectivity for, action in the liver, the target organ for cholesterol lowering. 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.

INDICATIONS: For the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

DOSAGE AND ADMINISTRATION: As directed by the Physician. Tablets should be taken orally.

CONTRAINDICATION: In patients with hypersensitivity to bempedoic acid or rosuvastatin or to any of the excipients, with simvastatin>40 mg, with active liver disease including unexplained, persistent elevations of serum transaminases and any serum transaminase elevation exceeding 3 times the upper limit of normal (ULN), with severe renal impairment (creatinine clearance <30 ml/min), with myopathy, receiving concomitant combination of sofosbuvir/velpatasvir/voxilaprevir, receiving concomitant ciclosporin, during pregnancy and lactation and in women of childbearing potential not using appropriate contraceptive measures, moderate renal impairment (creatinine clearance < 60 ml/min), 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 may occur, Asian patients, concomitant use of fibrates.

WARNINGS & PRECAUTIONS: Potential risk of myopathy with concomitant use of statins, Renal Effects: Additional monitoring for adverse reactions may be warranted in these patients when Bempedoic acid is administered, Contraception: Patients should be advised to stop taking Bempedoic acid before

stopping contraceptive measures if they plan to become pregnant, Hepatic impairment: Due to the unknown effects of the increased exposure to ezetimibe in patients with moderate to severe hepatic impairment Bempedoic acid is not recommended in these patients. Lactose Intolerance: Bempedoic acid contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency, or glucose-galactose malabsorption should not take this medicinal product. Hyperuricemia**:** Bempedoic Acid inhibits renal tubular OAT2 and may increase blood uric acid levels. Tendon Rupture: Bempedoic Acid is associated with an increased risk of tendon rupture or injury. Skeletal muscle effects: Risks increase with use of 40 mg dose, advanced age (≥65), hypothyroidism, renal impairment, and combination use with cyclosporine, darolutamide, regorafenib, certain anti-viral medicines or their combinations. While on treatment: The risk of myopathy during treatment with Rosuvastatin may be increased with concurrent administration of some other lipid-lowering therapies (fibrates or niacin), gemfibrozil, cyclosporine, lopinavir/ritonavir, or atazanavir/ritonavir. Concomitant Coumarin Anticoagulants: In patients taking coumarin anticoagulants and rosuvastatin concomitantly, INR should be determined before starting rosuvastatin and frequently enough during early therapy to ensure that no significant alteration of INR occurs.

DRUG INTERACTIONS: No interaction studies have been performed for Bempedoic Acid + Rosuvastatin tablets.

ADVERSE REACTIONS: Bempedoic Acid: Anaemia, Haemoglobin decreased, gout, Hyperuricaemia, Aspartate aminotransferase increased, Alanine aminotransferase increased, Liver function test increased, Pain in extremity, Blood creatinine increased, Blood urea increased, Glomerular filtration rate decreased. **Rosuvastatin:** Thrombocytopenia, Hypersensitivity reactions including angioedema, Diabetes mellitus, Depression, Headache, Dizziness, Polyneuropathy, Memory loss, Peripheral neuropathy, Sleep disturbances (including insomnia and nightmares), Cough, Dyspnoea, Constipation, Nausea, Abdominal pain, Pancreatitis, DiarrhoeaIncreased hepatic transaminases, Jaundice, Hepatitis, Pruritus, Rash, Urticaria, Stevens-Johnson syndrome, Myalgia, Myopathy (including myositis), Rhabdomyolysis, Lupus-like syndrome, Muscle rupture, Arthralgia, Immune-mediated necrotising myopathy, Tendon disorders, sometimes complicated by rupture, Haematuria, Gynaecomastia, Asthenia, Oedema.

MARKETED BY:

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(Additional information is available on request)