BEMPESTA EZ

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only
abbreviated prescribing information for BEMPESTA EZ (Bempedoic Acid & Ezetimibe Tablets 180 mg +10mg) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES Bempedoic Acid+Ezetimibe Tablet contains bempedoic acid and ezetimibe. Bempedoic Acid+Ezetimibe Tablet reduces elevated LDL-C through inhibition of cholesterol synthesis in the liver and absorption in the intestine.

INDICATION: It is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C.

DOSAGE AND ADMINISTRATION: The recommended dosage of Bempedoic Acid+Ezetimibe Tablet, in combination with maximally tolerated statin therapy, is one tablet orally once daily.

CONTRAINDICATION: BEMPEDOIC ACID+EZETIMIBE TABLET is contraindicated in patients with a known hypersensitivity to ezetimibe tablets. Hypersensitivity reactions including anaphylaxis, angioedema, rash and urticaria have been reported with ezetimibe.

WARNINGS & PRECAUTIONS: *Hyperuricemia* **:** Bempedoic acid, a component of BEMPEDOIC ACID+EZETIMIBE TABLET, inhibits renal tubular OAT2 and may increase blood uric acid levels. In clinical trials, 26% of bempedoic acid-treated patients with normal baseline uric acid values (versus 9.5% placebo) experienced hyperuricemia one or more times, and 3.5% of patients experienced clinically significant. *Tendon Rupture*: Bempedoic acid, a component of BEMPEDOIC ACID+EZETIMIBE TABLET, is associated with an increased risk of tendon rupture or injury. In clinical trials, tendon rupture occurred in 0.5% of patients treated with bempedoic acid versus 0% of placebo-treated patients and involved the rotator cuff (the shoulder), biceps tendon, or Achilles tendon. Tendon rupture occurred within weeks to months of starting bempedoic acid.

DRUG INTERACTIONS: *Simvastatin:* BEMPEDOIC ACID+EZETIMIBE TABLET with simvastatin causes an increase in simvastatin concentration and may increase the risk of simvastatin-related myopathy. *Pravastatin:* Concomitant use of BEMPEDOIC ACID+EZETIMIBE TABLET with pravastatin causes an increase in pravastatin. *Cyclosporine:* Concomitant use of BEMPEDOIC ACID+EZETIMIBE TABLET and cyclosporine increases ezetimibe and cyclosporine concentrations.). *Fibrates:* Both fenofibrate and ezetimibe may increase cholesterol excretion into the bile, leading to cholelithiasis. *Cholestyramine:* Concomitant use of BEMPEDOIC ACID+EZETIMIBE TABLET and cholestyramine decreases ezetimibe.

ADVERSE REACTIONS: Hyperuricemia, Tendon Rupture, Upper respiratory tract infection, Hyperuricemiaa, Back pain, Abdominal pain or discomfort, Bronchitis, Atrial Fibrillation, Hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria; erythema multiforme myalgia, thrombocytopenia; pancreatitis.

MARKETED BY:

TORRENT PHARMACEUTICALS LTD.

IN/ BEMPESTA EZ 180 mg & 10 mg /Aug-2024/01/ABPI
(Additional information is available on request)