

WinolipTM EZ

Bempedoic Acid and Ezetimibe



Presentation

WinolipTM EZ : Each film coated tablet contains Bempedoic Acid INN 180 mg & Ezetimibe USP 10 mg tablet.

Description

WinolipTM EZ Film Coated Tablet is a preparation of Bempedoic Acid & Ezetimibe. 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.

Ezetimibe is a potent and selective inhibitor of cholesterol absorption that has been shown to reduce the overall delivery of cholesterol to the liver, thereby promoting the synthesis of LDL receptors, with a subsequent reduction of serum LDL-C.

Indications

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

Administer Bempedoic Acid 180 mg & Ezetimibe 10 mg tablet orally once daily with or without food.

Side Effects

- Upper respiratory tract infection
- Muscle Spasms
- Hyperuricemia
- Back pain
- Abdominal pain or discomfort
- Bronchitis
- Pain in extremity
- Anemia
- Elevated liver enzymes

Precaution and Warning

Elevations in serum uric acid have occurred. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate. Tendon rupture has occurred. Discontinue Bempedoic acid & Ezetimibe at the first sign of tendon rupture. Avoid combination in patients who have a history of tendon disorders or tendon rupture.

Drug Interactions

Simvastatin: Avoid concomitant use of Bempedoic Acid & Ezetimibe with simvastatin greater than 20 mg.

Pravastatin: Avoid concomitant use of Bempedoic acid & Ezetimibe with pravastatin greater than 40 mg.

Contraindications

WinolipTM EZ is contraindicated in patients with known hypersensitivity to any component of this drug

Use in Pregnancy and Lactation

Discontinue Bempedoic Acid & Ezetimibe when pregnancy is recognized unless the benefits of therapy outweigh the potential risk to the fetus. There are no available data on Bempedoic Acid & Ezetimibe use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There is no information regarding the presence of Bempedoic Acid & Ezetimibe in human or animal milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. Breastfeeding is not recommended during treatment with Bempedoic Acid & Ezetimibe.

Storage

Do not store above 30 °C temperature. Keep away from light and out of the reach of children.

Commercial Pack

WinolipTM EZ Film Coated Tablet: Each box contains 3 ALU-ALU blister strips of 10 tablets.