NEXLETOL™ (bempedoic acid) tablets

NEXLIZET™ (bempedoic acid and ezetimibe) tablets

NEXLETOL and NEXLIZET:

Oral, Nonstatin Therapies for Lowering LDL-C

DATE:
Thursday, August 13, 2020

LOCATION:
VIRTUAL WEBCAST (ET)

TIME:
6:30 PM ET Start Time

SPEAKERS:
Khalid Sheikh, MD, MBA, FACC, FNLA, FASE
Health First Institute for Cardiovascular Wellness and Disease Prevention

https://ExcelSB.com/Registration
Event Code: 1536
Please RSVP by August 6, 2020

Please join us for an engaging program to learn more about a treatment option approved by the US Food and Drug Administration (FDA).

ESPERION

Please see Indication and Important Safety Information on the following page.

INDICATION

NEXLETOL and NEXLIZET are indicated as adjuncts 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. Limitations of Use: The effect of NEXLETOL and NEXLIZET on cardiovascular morbidity and mortality has not been determined.

IMPORTANT SAFETY INFORMATION

Dosage Form and Quantity: NEXLETOL is available as an oral tablet containing 180 mg of bempedoic acid, taken once a day with or without food. NEXLIZET is available as an oral tablet containing 180 mg of bempedoic acid and 10 mg of ezetimibe, taken once a day with or without food.

Contraindications: NEXLETOL has no contraindications. NEXLIZET 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 and Precautions: Hyperuricemia: Bempedoic acid, a component of NEXLETOL and NEXLIZET, may increase blood uric acid levels. Hyperuricemia may occur early in treatment and persist throughout treatment, and may lead to the development of gout, especially in patients with a history of gout.

Tendon Rupture: Bempedoic acid is associated with an increased risk of tendon rupture, most commonly involving the biceps tendon, rotator cuff, or Achilles tendon. Tendon rupture occurred within weeks to months of starting bempedoic acid. Tendon rupture may occur more frequently in patients over 60 years of age, patients taking corticosteroid or fluoroquinolone drugs, patients with renal failure and patients with previous tendon disorders.

Adverse Events: In NEXLETOL clinical trials, the most commonly reported adverse events were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes. Events reported less frequently, but still more often than in placebo, included benign prostatic hyperplasia and atrial fibrillation.

In the NEXLIZET clinical trial, the most commonly reported adverse events observed with NEXLIZET, but not observed in clinical trials of bempedoic acid or ezetimibe, a component of NEXLIZET, and occurring more frequently than in placebo, were urinary tract infection, nasopharyngitis, and constipation.

Adverse events reported in clinical trials of ezetimibe, and occurring at an incidence greater than in placebo, included upper respiratory tract infection, diarrhea, arthralgia, sinusitis, pain in extremity, fatigue, and influenza. Other adverse events reported in postmarketing use of ezetimibe included hypersensitivity reactions, including anaphylaxis, angioedema, rash, and urticaria; erythema multiforme; myalgia; elevated creatine phosphokinase; myopathy/rhabdomyolysis; elevations in liver transaminases; hepatitis; abdominal pain; thrombocytopenia; pancreatitis; nausea; dizziness; paresthesia; depression; headache; cholelithiasis; cholecystitis.

Laboratory Tests: Treatment with bempedoic acid was associated with persistent changes in laboratory tests within the first four weeks of treatment, including increases in creatinine and blood urea nitrogen, decreases in hemoglobin and leukocytes, increases in platelet counts, increases in liver enzymes (AST and/or ALT), and increases in creatine kinase. Laboratory abnormalities generally did not require medical intervention. Laboratory test values generally returned to baseline following discontinuation of treatment.

Drug Interactions:

Simvastatin and Pravastatin: Concomitant use with bempedoic acid results in increased concentrations and increased risk of simvastatin or pravastatin-related myopathy. Use of either NEXLETOL or NEXLIZET with greater than 20 mg of simvastatin or 40 mg of pravastatin should be avoided.

Cyclosporine: Caution should be exercised when using NEXLIZET and cyclosporine concomitantly due to increased exposure to both ezetimibe and cyclosporine. Monitor cyclosporine concentrations in patients receiving NEXLIZET and cyclosporine. In patients treated with cyclosporine, the potential effects of the increased exposure to ezetimibe from concomitant use should be carefully weighed against the benefits of alterations in lipid levels provided by NEXLIZET.

Fibrates: Coadministration of NEXLIZET with fibrates other than fenofibrate is not recommended. Fenofibrate and ezetimibe may increase cholesterol excretion into the bile, leading to cholelithiasis. If cholelithiasis is suspected in a patient receiving NEXLIZET and fenofibrate, gallbladder studies are indicated and alternative lipid-lowering therapy should be considered.

Cholestyramine: Concomitant use of NEXLIZET and cholestyramine decreases ezetimibe concentration. This may result in a reduction of efficacy. Administer NEXLIZET either at least 2 hours before, or at least 4 hours after, bile acid sequestrants.

Special Populations: It is not recommended that NEXLETOL or NEXLIZET be taken during breastfeeding. A pregnant patient should consult with their healthcare provider about whether to continue treatment during the pregnancy. The safety and efficacy of NEXLETOL and NEXLIZET have not been established in patients under the age of 18. Patients over 65 accounted for nearly 60% of patients in NEXLETOL clinical trials and 50% of patients in the NEXLIZET clinical trial. No adjustments in dosing are required for age, or for patients with mild or moderate renal impairment or mild hepatic impairment for NEXLETOL or NEXLIZET. No adjustments in dosing are required for patients with moderate hepatic impairment for NEXLETOL. NEXLIZET is not recommended for patients with moderate or severe hepatic impairment.

NEXLETOL and NEXLIZET are available only by prescription.

To report SUSPECTED ADVERSE REACTIONS, contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch or ESPERION at 833-377-7633 (833 ESPRMED).

Please see Full Prescribing Information for NEXLETOL at https://pi.esperion.com/nexletol/nexletol-pi.pdf and for NEXLIZET at https://pi.esperion.com/nexlizet/nexlizet-pi.pdf

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