

Nexletol[™] (bempedoic acid) – New drug approval

- On February 21, 2020, [Esperion announced](#) the FDA approval of [Nexletol \(bempedoic acid\)](#), 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 low-density lipoprotein cholesterol (LDL-C).
 - The effect of Nexletol on cardiovascular morbidity and mortality has not been determined.
- Nexletol is a first-in-class adenosine triphosphate-citrate lyase inhibitor that lowers LDL-C by reducing cholesterol biosynthesis and up-regulating the LDL receptors.
- The efficacy of Nexletol was evaluated in two randomized, double-blind, placebo-controlled studies in 3,009 adult patients with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who were on maximally tolerated statin therapy. The primary efficacy endpoint was the percent change from baseline to week 12 in LDL-C.
 - In study 1, the difference between Nexletol and placebo in mean percent change in LDL-C from baseline to week 12 was -18% (95% CI: -20, -16; p < 0.001).
 - In study 2, the difference between Nexletol and placebo in mean percent change in LDL-C from baseline to week 12 was -17 % (95% CI: -21, -14; p < 0.001).
- Warnings and precautions for Nexletol include hyperuricemia and tendon rupture.
- The most common adverse reactions (≥ 2% and greater than placebo) with Nexletol use were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes.
- The recommended dose of Nexletol, in combination with maximally tolerated statin therapy, is 180 mg administered orally once daily.
- Esperion's second LDL-C lowering medicine, a bempedoic acid/[ezetimibe](#) combination tablet, is currently under review by the FDA; a decision is expected by February 26, 2020.
- Esperion plans to launch Nexletol on March 30, 2020. Nexletol will be available as a 180 mg tablet.