

## Another Useless Cholesterol Drug

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Bempedoic acid is one of a new class of non-statin drugs for lowering LDL cholesterol that targets the cholesterol biosynthesis pathway in the liver. The FDA approved it as a treatment for people who are statin intolerant or who have reached maximum tolerated statin therapy for treatment of high plasma cholesterol. Made by Esperion, the drug is available in two forms. Nexletol is made solely of bempedoic acid, and Nexlizet is a combination of bempedoic acid and ezetimibe (Zetia).

Esperion's website reports that "once-daily therapy was shown in a clinical trial to deliver" a 38% reduction in LDL-C compared to placebo.<sup>1</sup> When considering this information, it is important to keep in mind that plasma cholesterol is a surrogate marker, and drugging patients to lower it often does not result in any meaningful improvement in health outcomes.

According to an article published in the *New England Journal of Medicine*, a randomized controlled clinical trial that included 13,970 patients showed that treatment with bempedoic acid was associated with a lower risk of major cardiovascular events – deaths from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke, or coronary revascularization. According to the study, the relative risk reduction for heart attacks in patients taking Nexletol was almost 23%.<sup>2</sup> One could conclude from these trial results that this drug is a reasonable alternative to statins and might be even more effective. This would be a good thing since research shows that 399 patients out of 400 do not benefit from taking statins for primary prevention.<sup>3</sup>

But considering risk reduction for myocardial infarction in absolute terms shows that Nexletol is almost as useless as statins:

Nexletol group:	261 MI events in 6992 patients	3.7% risk
Placebo:	334 MI events in 6978 patients	4.8% risk
Absolute risk reduction:		1.1%
Relative risk reduction:		22.9%

In other words, the absolute risk reduction is clinically insignificant. In plain English: This drug is useless. The company's website includes information that states as much: "Limitations of use for both Nexletol and Nexlezet:

The effect of NEXLETOL and NEXLIZET on cardiovascular morbidity and mortality has not been determined."

Side effects listed on the site are a bit frightening in view of such a small benefit:

Side effects of Nexletol include hyperuricemia, tendon rupture, upper respiratory infections, muscle spasms, back pain, abdominal pain, bronchitis, pain in the

extremities, anemia, and elevated liver enzymes. Many of these are the same side effects that are caused by statin drugs.”

No one in their right mind would agree to take this drug if shown both the actual risk reduction and the side effects. On the other hand, many people would likely at least consider adopting a lower-fat, plant-centered diet if shown the benefits of doing so, which are considerably greater than drugs for most patients. The lack of true informed consent is one of the reasons why Americans are so sick, and why the erroneous perception of the lazy American who does not care about health and just wants to take a pill persists. The pill is falsely represented to be safe and effective, and the diet and lifestyle option is not even offered.

Reporting the benefit of drugs, supplements, and medical interventions in relative terms is very misleading, and relative risk reduction should not be the metric used in making treatment decisions.

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[https://www.nexlizethcp.com/?gclid=Cj0KCQjw\\_r6hBhDdARIsAMIDhV9YjqGzkaRcJPyg4wBWia8k7AVD41vBlcEWamNmBOMTDXqJaWnxRMaAid2EALw\\_wcB](https://www.nexlizethcp.com/?gclid=Cj0KCQjw_r6hBhDdARIsAMIDhV9YjqGzkaRcJPyg4wBWia8k7AVD41vBlcEWamNmBOMTDXqJaWnxRMaAid2EALw_wcB)

<sup>2</sup> Nissen SE, Lincoff AM, Brennan D et al. “Bempedoic Acid and Cardiovascular Outcomes in Statin-Intolerant Patients.” *NEJM* 2023 Mar; doi: 10.1056/NEJMoa2215024. Online ahead of print

<sup>3</sup> Byrne P, Cullinan J, Smith SM. “Statins for primary prevention of cardiovascular disease.” *BMJ* 2019 Oct;367:I5674