DAR DRUG ASSESSMENT REPORT 01 / 2024

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▼NILEMDO® / NUSTENDI®

BEMPEDOIC ACID AND BEMPEDOIC ACID/EZETIMIBE FOR HYPERCHOLESTEROLAEMIA

A mystery for the treatment of hypercholesterolaemia.

REPORTS [IN SPANISH]

IMPORTANT THERAPEUTIC INNOVATION

MODEST THERAPEUTIC INNOVATION

SOME ADDED VALUE IN SPECIFIC SITUATIONS

NO THERAPEUTIC INNOVATION

INSUFFICIENT EVIDENCE

PRODUCT INFORMATION NILEMDO®

PRODUCT INFORMATION NUSTENDI®

WHAT IS IT?

Prodrug that inhibits adenosine triphosphate citrate lyase by reducing intracellular cholesterol, increasing the number of LDL receptors on the cell surface, decreasing plasma LDL cholesterol (LDL-c) concentration.

INDICATION

Adults with primary heterozygous familial hypercholesterolaemia (HeFH) and non-familial or mixed dyslipidaemia, as an adjunct to diet: a) in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-c goals with the maximum tolerated dose of statin b) alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom an estatin is contraindicated.
Funded in HeFH or with atherosclerotic vascular disease not controlled with the maximum dose of statin and ezetimibe, or with ezetimibe in case of intolerance or contraindication to statins.

POSOLOGY AND METHOD OF ADMINISTRATION

One film-coated tablet of bempedoic acid 180 mg or bempedoic acid/ezetimibe 180/10 mg taken once daily. Each film-coated tablet should be taken orally with or without food. When bempedoic acid is coadministered with simvastatin, simvastatin dose should be limited to 20 mg daily (or 40 mg daily for patients with high risk for cardiovascular (CV) complications, when the benefits are expected to outweigh the potential risks.

SPECIAL POPULATIONS

No dose adjustment is necessary in elderly patients or patients with mild or moderate renal and hepatic impairment. Treatment with bempedoic acid should be discontinued if an increase in transaminases of > 3× ULN persists. Bempedoic acid is contraindicated during pregnancy. Women of childbearing potential must use effective contraception during treatment.

EFFICACY

In all clinical trials conducted in monotherapy, the effect on LDL-c reduction was consistent, with reductions at week 12 compared to placebo in both studies of statin-intolerant patients and in patients at high CV risk in combination with statins. The fix-dose combination of bempedoic acid/ezetimibe in patients with high CV risk and hyperlipidaemia significantly reduced LDL-c at week 12 compared to placebo. 27.6 % of patients treated with the combination achieved the LDL-c goal < 70mg/dL compared to 7.8% with bempedoic acid monotherapy and 9.7% with ezetimibe monotherapy. In a study in patients intolerant to statins (at the maximum tolerated dose), it showed a 13.3% reduction compared to placebo in the MACE compound (CV death, non-fatal infarction, non-fatal stroke or coronary revascularization). The NNT was 64 patients (95% CI 39 to 211).

RISKS

Bempedoic acid was well tolerated. The most frequent adverse reactions were: muscle and kidney alterations, diarrhoea, increased liver enzymes and creatine, hyperuricaemia, gout, anaemia and decreased haemoglobin.

PLACE IN THERAPEUTICS

Option in patients at high or very high CV risk when LDL-c goals cannot be achieved despite intensive treatment with statins and ezetimibe, or ezetimibe in the case of intolerance or contraindication to statins.

PRESENTATIONS

Nustendi® 180 mg/10 mg; 28 film-coated tablets (78.24€)
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