DAR DRUG ASSESSMENT REPORT **02 / 2024**

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dtbn

VAZKEPA®

ICOSAPENT ETHYL (OMEGA-3) FOR HYPERTRIGLYCERIDEMIA

Dubious benefit/risk balance. It doesn't add up.

REPORTS [IN SPANISH]

IMPORTANT THERAPEUTIC INNOVATION

MODEST THERAPEUTIC INNOVATION

SOME ADDED VALUE IN SPECIFIC SITUATIONS

NO THERAPEUTIC INNOVATION

INSUFFICIENT EVIDENCE

PRODUCT INFORMATION

WHAT IS IT?

Prodrug of the omega-3 acid. Contains sorbitol, maltitol and soy lecithin.

INDICATION

Prevention of cardiovascular (CV) events in adult statin-treated patients at high CV risk with elevated triglycerides (TG) (≥ 150 mg/dl) and established CV disease or diabetes mellitus with at least one other CV risk factor. In Spain, it is funded for arteriosclerotic disease* diagnosed patients with optimized treatment and LDL-c levels > 40 mg/dl and ≤ 100 mg/dl and TG levels remain high (≥ 150 mg/dl) despite intensive treatment with statins +/- other lipid-lowering therapies with the maximum tolerated doses.

POSOLOGY AND METHOD OF ADMINISTRATION

Two capsules twice daily, orally with or following a meal.

SPECIAL POPULATIONS

No dose adjustment is necessary in elderly patients or patients with renal or hepatic impairment. Not recommended during pregnancy, breast-feeding or pediatric population.

EFFICACY

There are no direct comparisons with other strategies used in patients with high CV risk and hypertriglyceridemia, such as statins or fibrates. With a median follow-up of 4.9 years, icosapent ethyl reduced the risk by 24.8% (HR 0.75; 95% CI: 0.68 to 0.83) compared to the control group with mineral oil in the primary composite endpoint MACE-5 (CV death, non-fatal MI, non-fatal stroke, coronary revascularization or hospitalization for unstable angina), with an absolute reduction in risk (ARR) of 4.8% (NNT = 21). The results are similar for the secondary composite endpoint MACE-3 (CV death, non-fatal MI or non-fatal stroke) in which the risk was reduced by 26.5% (HR 0.74; 95% CI: 0.65 to 0 .83), with an ARR of 3.6% (NNT = 28). No differences were found in total mortality.

RISKS

The most common side effects shown in clinical trials were bleeding (11.8%), peripheral edema (7.8%), atrial fibrillation (5.8%), constipation (5.4%), arthromyalgia (4.3%), gout (4.3%) and rash (3.0%). Caution in patients with antithrombotic treatment because increased the risk of bleeding; and the risk of atrial fibrillation and flutter in patients with a medical history. Periodic ECG monitoring. Contraindicated in patients who are allergic to soy or peanuts and fructose intolerance. Caution in known hypersensitivity to fish and/or shellfish.

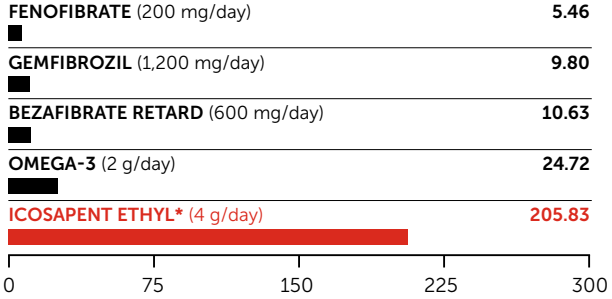
PLACE IN THERAPY

Difficult to establish clinical benefit and place in therapy due to the absence of comparative studies, the limitations of the trial (highly selected population not optimized with statins and/or ezetimibe and use of a non-inert placebo) and the increased risk of fibrillation and atrial flutter and bleeding.

PRESENTATIONS

Vazkepa® 998 mg 120 soft capsules.

30-day treatment cost (€) (*) Reported price



(*) Atherosclerotic disease: acute coronary disease (such as myocardial infarction (MI) or unstable angina requiring hospitalization), coronary revascularization, chronic coronary disease, ischemic stroke or peripheral arterial disease.

Servicio Navarro de Salud Osasunbidea

INTERNATIONAL SOCIETY OF DRUG BULLETINS

This information is subject to modifications depending on the evolution of scientific knowledge. Notify the suspicions of adverse reactions in www.notificaram.es **[Evaluated in April 2023]**