Introducing data regarding ANCHOR population: TG 200 - 499 on statin

Highly Purified EPA: Mechanism and Clinical Data

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Indication and Limitations of Use
VASCEPA® (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥500 mg/dL) hypertriglyceridemia.

- The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.
- The effect of VASCEPA on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

*Amarin may disclose truthful, non-misleading information not included in the VASCEPA Prescribing Information to healthcare professionals pursuant to a federal court order issued August 7, 2015 in *Amarin et al. v. FDA et al.* S.D.N.Y. (1:15-cv-03588-PAE).

** Any healthcare professional who is not a pediatrician of any kind, neonatologist; orthopedist/sports medicine any type; radiologist any type; podiatrist; chiropractor; anesthesiologist; pathologist; ophthalmologist; allergist; dermatologist; surgeon; dentist; psychiatrist or urologist, including their supporting staff.

See full Prescribing Information for more information on VASCEPA or go to www.vascepa.com.

See second page for additional safety information and required disclosures.

Vascepa® (icosapent ethyl)
AMARIN Kowa

Important Safety Information for VASCEPA

- VASCEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCEPA or any of its components.
- Use with caution in patients with known hypersensitivity to fish and/or shellfish.
- The most common reported adverse reaction (incidence >2% and greater than placebo) was arthralgia (2.3% VASCEPA, 1.0% placebo).
- Patients receiving treatment with VASCEPA and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.
- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy.
- Patients should be advised to swallow VASCEPA capsules whole; not to break open, crush, dissolve, or chew VASCEPA.
- Adverse events may be reported by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.

Important information for HCPs about VASCEPA as an add-on to statins in patients with high (200-499 mg/dL) TG levels

- Supportive but not conclusive research shows that consumption of EPA and DHA omega-3 fatty acids may reduce the risk of coronary heart disease. VASCEPA should not be taken in place of a healthy diet and lifestyle or statin therapy.
- The ANCHOR trial demonstrates that VASCEPA lowers TG levels in patients with high (≥200 mg/dL and <500 mg/dL) TG levels not controlled by diet and statin therapy.
- In the ANCHOR trial, VASCEPA 4 g/day significantly reduced TG, non–HDL-C, Apo B, VLDL-C, TC, and HDL-C levels from baseline relative to placebo in patients with high (≥200 mg/dL and <500 mg/dL) TG levels not controlled by diet and statin therapy.
- The reduction in TG observed with VASCEPA was not associated with elevations in LDL-C relative to placebo.
- VASCEPA is not FDA-approved for the treatment of statin-treated patients with mixed dyslipidemia and high (≥200 mg/dL and <500 mg/dL) TG levels due to current uncertainty regarding the benefit, if any, of drug-induced changes in lipid/lipoprotein parameters beyond statin-lowered LDL-C on cardiovascular risk among statin-treated patients with residually high TG. No prospective study has been conducted to test and support what, if any, benefit exists.
- Recent cardiovascular outcomes trials (ACCORD Lipid, AIM-HIGH, and HPS2-THRIVE), while not designed to test the effect of lowering TG levels in patients with high TG levels after statin therapy, each failed to demonstrate incremental cardiovascular benefit of adding a second lipid-altering drug (fenofibrate or formulations of niacin), despite raising HDL-C and reducing TG levels, among statin-treated patients with well-controlled LDL-C.
- VASCEPA is not FDA-approved to reduce the risk of coronary heart disease.
- The effect of VASCEPA on the risk of cardiovascular mortality and morbidity has not been determined.
- A cardiovascular outcomes study of VASCEPA designed to evaluate the efficacy of VASCEPA in reducing cardiovascular mortality and morbidity in a high-risk patient population on statin therapy is currently underway (REDUCE-IT).
- VASCEPA may not be eligible for reimbursement under government healthcare programs (such as Medicare and Medicaid) to reduce the risk of coronary heart disease or for treatment of statin-treated patients with mixed dyslipidemia and high (≥200 mg/dL and <500 mg/dL) TG levels. We encourage you to check that for yourself.
- The ANCHOR trial was sponsored by Amarin Pharma, Inc. and its affiliates.

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