

WHAT IS VASCEPA?

VASCEPA is a pure, proven, prescription drug consisting of icosapent ethyl, a proprietary single-molecule medicine. For more than a decade, VASCEPA has been developed and tested by Amarin. Since being launched in the U.S. in 2013, Vascepa has been prescribed millions of times and has been granted coverage by most insurers. If the VASCEPA cardiovascular outcomes study, REDUCE-IT[™], is successful, use of VASCEPA may expand substantially to help many more at-risk patients.¹

Development of VASCEPA leveraged Amarin's extensive experience in lipid sciences and the potential therapeutic benefits of polyunsaturated fatty acids. Such development challenged previously established norms to create a potent, yet safe, targeted single ingredient product in contrast to prior generation omega-3 mixtures and other prescription drugs. The use of VASCEPA is now supported by over 40 granted patents and by FDA designation in 2015 of VASCEPA's active ingredient as a New Chemical Entity. This means that no prior FDA-approved drug had the active ingredient contained in VASCEPA. Also, no prior drug with icosapent ethyl was ever characterized for FDA review and approved by the FDA to treat or prevent a medical condition.

Early stages of VASCEPA development included extensive investigation of high quality, FDA regulated proprietary manufacturing and packaging designed to protect the active ingredient from damage during the process and through dose administration in patients. Further study of VASCEPA included a broad range of laboratory and clinical studies, including two successfully completed Phase 3 studies, the MARINE study and the ANCHOR study, the results of which were published in 2011 and 2012, respectively.^{2,3} The aggregate cost of developing VASCEPA has exceeded \$500 million.

In 2012, the FDA approved VASCEPA as an adjunct to diet for the reduction of triglycerides in adult patients with very high triglyceride levels (>500 mg/dL a.k.a. hypertriglyceridemia).⁴ In 2013, Amarin commercially launched VASCEPA in the U.S. based on this initial indication and since then VASCEPA has been the fastest growing drug in this market segment. Amarin is pursuing commercialization of Vascepa outside the U.S. through strategic relationships with various companies.

Upon completion of the landmark REDUCE-IT cardiovascular outcomes study, assuming successful results, Amarin intends to seek broader labeling for VASCEPA. The drug may become the first therapy, as an adjunct to diet, proven to reduce cardiovascular events when used to treat patients who despite controlled LDL-cholesterol on stable statin therapy have persistent elevated triglyceride levels and other cardiovascular risk factors. It is this large, unmet medical need for potentially tens of millions of patients with dyslipidemia which development of VASCEPA has been targeting for many years.⁵

ABOUT VASCEPA (ICOSAPENT ETHYL) CAPSULES INDICATION & IMPORTANT SAFETY INFORMATION

WHAT IS VASCEPA?

VASCEPA is a prescription medicine used along with a low-fat and low-cholesterol diet to lower high levels of triglycerides (fats) in adults.

- It is not known if VASCEPA changes your risk of having inflammation of your pancreas (pancreatitis).
- It is not known if VASCEPA prevents you from having a heart attack or stroke.
- It is not known if VASCEPA is safe and effective in children.

For more information about VASCEPA, visit www.vascepa.com. Additional information on the VASCEPA cardiovascular outcomes trial, REDUCE-IT, and other VASCEPA clinical studies can be found at www.clinicaltrials.gov. The publication of the design of the REDUCE-IT trial is available at: <http://onlinelibrary.wiley.com/doi/10.1002/clc.22692/full>.

Please see second page for Vascepa's important safety and other prescribing information.

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IMPORTANT SAFETY INFORMATION

WHO SHOULD NOT TAKE VASCEPA?

- Do not take VASCEPA if you are allergic to icosapent ethyl or any of the ingredients in VASCEPA.

WHAT ARE THE POSSIBLE SIDE EFFECTS OF VASCEPA?

- It is not known if people who are allergic to fish or shellfish are also allergic to VASCEPA.
- If you have liver problems and are taking VASCEPA, your doctor should do blood tests during treatment.
- The most common side effect of VASCEPA is joint pain. Talk to your doctor for medical advice about side effects.

As with all drugs, you may experience a serious side effect when taking VASCEPA.

You may report side effects by calling 1-855-VASCEPA or the FDA at 1-800-FDA-1088.

Tell your doctor if you take medicines that affect your blood clotting (anticoagulants or blood thinners).

Take VASCEPA capsules whole. Do not break, crush, dissolve, or chew VASCEPA capsules before swallowing.

For more information on VASCEPA, click here to see the full Patient Information or call 1-855-VASCEPA (1-855-827-2372).

Sources:

1. Bhatt DL, Steg PG, Brinton EA, et al. Rationale and design of REDUCE-IT: Reduction of Cardiovascular Events with Icosapent Ethyl–Intervention Trial. *Clin Cardiol.* 2017;40:138-148.
2. Bays HE, Ballantyne CM, Kastelein JJ, Isaacsohn JL, Braeckman RA, Soni PN. Eicosapentaenoic acid ethyl ester (AMR101) therapy in patients with very high triglyceride levels (from the Multi-center, placebo-controlled, Randomized, double-blind, 12-week study with an open-label Extension [MARINE] trial). *Am J Cardiol.* 2011;108(5):682-690. Ballantyne CM, Bays HE, Kastelein JJ, et al. Efficacy and safety of eicosapentaenoic acid ethyl ester (AMR101) therapy in statin-treated patients with persistent high triglycerides (from the ANCHOR study). *Am J Cardiol.* 2012;110(7):984-992.
4. VASCEPA [package insert]. Bedminster, NJ: Amarin Pharma, Inc.; 2017.
5. Fan W, Philip S, Granowitz C, Toth P, Wong N. Prevalence and predictors of residual hypertriglyceridemia according to statin use in US adults [abstract 178]. *J Clin Lipidol.* 2018;12(2):530-531.

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