Generic Name:
Icosapent ethyl
Trade Name:
Vascepa
Company:
Amarin
Notes:

Amarin announced that it has received FDA approval for its icosapent ethyl capsules. The capsules are indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia, defined as triglycerides greater than or equal to 500 mg/dL. This new product is an ultra-pure omega-3 fatty acid product, comprising not less than 96% eicosapentaenoic acid in a 1-g capsule. The recommended daily dose is 4 g/d, taken as 2 capsules twice daily.

Approval was based on data from the MARINE clinical trial, a randomized, placebo-controlled, double-blind, parallel-group study of adult patients with very high fasting triglyceride levels, between 500 mg/dL and 2,000 mg/dL. Patients treated for 12 weeks with the 4-g dose of icosapent ethyl demonstrated a statistically significant placebo-adjusted median triglyceride reduction of 33% ($P < 0.001$) and did not show an increase in LDL cholesterol levels compared with placebo. In addition, treatment with icosapent ethyl 4 g/d showed statistically significant placebo-adjusted median reductions from baseline in non-HDL cholesterol levels (18%), total cholesterol (16%), very low density lipoprotein cholesterol (29%), and apolipoprotein B (9%).

Arthralgia was the most commonly reported adverse reaction in patients treated with icosapent ethyl.

The manufacturer anticipates commercial launch of the product early in the first quarter of 2013.

Medication Monitor Categories:
New Drug Approvals
Use:

Treatment of severe hypertriglyceridemia