

FIRST TIME GENERIC APPROVAL

Brand Name	Vascepa®
Generic Name	icosapent ethyl
Drug Manufacturer	Teva Pharmaceuticals USA Inc.

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic Approval

FDA APPROVAL DATE

May 21, 2020

LAUNCH DATE

November 5, 2020

REVIEW DESIGNATION

Standard

TYPE OF REVIEW

Abbreviated New Drug Application (ANDA): 209525

DISPENSING RESTRICTIONS

None

Overview

INDICATION FOR USE

It is an ethyl ester of eicosapentaenoic acid (EPA) indicated:

- As an adjunct to maximally tolerated statin therapy to reduce the risk of myocardial infarction, stroke, coronary revascularization, and unstable angina requiring hospitalization in adult patients with elevated triglyceride (TG) levels (≥ 150 mg/dL) and
 - established cardiovascular disease or
 - diabetes mellitus and 2 or more additional risk factors for cardiovascular disease.
- As an adjunct to diet to reduce TG levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

Limitations of Use:

- The effect on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

MECHANISMS OF ACTION

Reduction in the hepatic production of triglyceride-rich very low-density lipoproteins. Possible cellular mechanisms include inhibition of acyl CoA:1,2 diacylglycerol acyltransferase, increased hepatic mitochondrial and peroxisomal beta-oxidation, and a reduction in the hepatic synthesis of triglycerides. The mechanisms contributing to reduction of cardiovascular events are not completely understood but are likely multifactorial (e.g., increased

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eicosapentaenoic acid [EPA] composition from carotid plaques, increased circulating EPA/arachidonic acid ratio, inhibition of platelet aggregation).

DOSAGE FORMS AND STRENGTHS

Capsules: 0.5 gram and 1 gram

DOSE & ADMINISTRATION

Assess lipid levels before initiating therapy. Identify other causes of high triglyceride levels and manage as appropriate.

Patients should engage in appropriate nutritional intake and physical activity before receiving, which should continue during treatment.

The daily dose is 4 grams per day taken as either:

- Four 0.5-gram capsules twice daily with food, or
- Two 1-gram capsules twice daily with food.

Advise patients to swallow capsules whole. Do not break open, crush, dissolve, or chew.