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Selecting an Omega-3 Product for Therapeutic Use: An Opportunity to Educate Patients

UNMET NEEDS IN THE MANAGEMENT OF DYSLIPIDEMIA

Statins are the gold standard in the management of dyslipidemia, due to accumulated evidence supporting their efficacy in lowering low-density lipoprotein cholesterol (LDL-C) levels and reducing atherosclerotic cardiovascular risk.^{1,2} However, despite the effectiveness of statins in terms of LDL-C lowering, residual risk of cardiovascular events remains.³⁻¹⁰ Addressing this residual cardiovascular risk represents an important unmet need.¹¹ After initiating statin therapy, many physicians treat dyslipidemia further by next targeting triglycerides.

Managing Elevated Triglycerides

Omega-3 fatty acids are a popular therapeutic option for reducing triglyceride levels.^{12,13} Although omega-3 fatty acids are present in nonprescription fish oil dietary supplements, as well as in refined prescription omega-3 products, patients may not be aware of the important differences between fish oil dietary supplements and prescription omega-3 products.^{11,12,14} Pharmacists can educate their patients on these important differences and provide guidance regarding appropriate selection of available products.¹⁴

Omega-3 Fatty Acids: Benefits and Sources

Fish oil contains omega-3 fatty acids, such as eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), which are the most studied forms of omega-3 fatty acids.^{12,13} Both EPA and DHA lower serum triglycerides; however, DHA has been shown to raise LDL-C levels in some patients and EPA has been shown to have a neutral effect on LDL-C levels.^{12,15}

EPA and DHA are present in FDA-approved prescription products, all of which contain purified forms of these omega-3 fatty acids. However, only VASCEPA® (icosapent ethyl) is a pure EPA product.¹⁶ Lovaza (omega-3-acid ethyl esters) and its generic equivalents contain a mixture of EPA and DHA.¹⁷ Additionally, Lovaza is only partially purified and contains other non-omega-3 components, some of which have not been characterized.¹⁸

Prescription and OTC products are different than dietary supplements. Dietary supplements are regulated as food, not as FDA-approved drugs.¹⁴ The FDA does not require dietary supplements to demonstrate safety and efficacy in clinical trials, and, as noted by the FDA, they are not intended to diagnose, treat, cure, or prevent any disease.^{14,19} More than 350 nonprescription fish oil dietary supplements are available; these products contain EPA, DHA, saturated fats, and other ingredients.^{11,20}

ABOUT VASCEPA

VASCEPA is an ethyl ester of EPA that is indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia, and it is the first nonstatin, prescription omega-3 fatty acid shown to reduce triglyceride levels without increasing LDL-C levels.^{15-17,21} Each 1-g capsule of VASCEPA contains 1 g of EPA; the capsules do not contain DHA.¹⁶ VASCEPA is also the first and only prescription omega-3 that is available as a 0.5-g capsule for patients who need or prefer a smaller dosing option.¹⁶

DIFFERENCES BETWEEN PRESCRIPTION PRODUCTS AND NONPRESCRIPTION DIETARY SUPPLEMENTS

Variations in the composition and quality of fish oil supplements may present a barrier to achieving therapeutic goals.¹¹ Typically, fish oil supplements have a low concentration of active ingredients, with an EPA concentration of 18% and a DHA concentration of 12%. Undisclosed impurities, saturated fats, and different omega mixtures in typical fish oil supplements account for 70% of the product composition.^{22,23} To achieve dose equivalence of 4 g per day of prescription EPA, patients need to take at least 20 1-g units of a fish oil supplement with 18% EPA to attempt to receive the amount of EPA in a daily dose of VASCEPA.¹⁶

In addition to potency, quality may be an important factor in product selection. Fish oils, like all supplements, are not regulated as thoroughly as prescription products. The lack of rigorous oversight by the FDA may result in a less consistent batch-to-batch quality and/or contamination.²⁴ Unlike dietary supplements, prescription omega-3 products are subject to stringent FDA regulatory oversight and provide reliable and consistent quality.^{11,14}

Prescription omega-3 products have proven safety, lipid-lowering efficacy and can be prescribed with confidence to patients with elevated triglycerides, including those who are already taking a statin.^{11,14} These prescription products provide patients with a reliable and consistent source of omega-3 fatty acids that helps patients to achieve therapeutic goals without the uncertainties or pill burden concerns of fish oil supplements.^{11,14}

ROLE OF THE PHARMACIST

Fish oil products are among the most frequently consumed dietary supplements in the United States. In fact, consumption has increased nearly 10-fold over the past decade.²⁵ As one of the most trusted health care providers, pharmacists are in a good position

KEY POINTS: PRESCRIPTION OMEGA-3 PRODUCTS VERSUS FISH OIL DIETARY SUPPLEMENTS ^{11,14,19,22,23}	
Prescription Omega-3 Products	Fish Oil Dietary Supplements
<ul style="list-style-type: none">• FDA-approved drugs, subject to stringent FDA regulatory oversight, and provide reliable and consistent quality.^{11,14}• Prescription omega-3 products have proven safety and lipid-lowering efficacy.^{11,14}• For patients receiving treatment to address a medical condition, only a prescription omega-3 product is appropriate, as fish oil dietary supplements are not intended for that purpose.• These refined products provide patients with a reliable and consistent source of omega-3 fatty acids that enables patients to achieve therapeutic goals without the uncertainties or pill burden concerns of fish oil supplements.^{11,14}	<ul style="list-style-type: none">• Dietary supplements; not OTC medications or FDA-approved drugs.¹⁴• Dietary supplements are not required by the FDA to demonstrate safety and efficacy in clinical trials and are not intended to diagnose, treat, cure, or prevent any disease.^{14,19}• Most have a low concentration of active ingredients, with an EPA concentration of 18% and a DHA concentration of 12%. Undisclosed impurities, saturated fats, and different omega mixtures in typical fish oil supplements account for 70% of the product composition.^{22,23}• May contain contaminants, such as toxins and oxidized lipids.¹¹

DHA = docosahexaenoic acid; EPA = eicosapentaenoic acid.

to provide patients with information regarding omega-3 fatty acid products. Pharmacists can educate patients about their choices and explain the differences between prescription omega-3 products and fish oil supplements.¹⁴ For patients receiving treatment to address a medical condition, only a prescription omega-3 product is appropriate, as fish oil dietary supplements are not intended for

that purpose. The appropriate use of a prescription product, such as VASCEPA, can help patients achieve lower triglyceride levels.^{14,16} There is also a savings program that can lower commercial patients' out-of-pocket cost to as little as \$9.

References are available online at *PharmacyTimes.com*.

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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 cardiovascular mortality and morbidity or on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

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.

See full Prescribing Information for more information on VASCEPA.