Pr Vascepa® (icosapent ethyl) | Power to reduce the risk of cardiovascular events[1]

Vascepa® (n=4,089) demonstrated reductions in the risk of CV events vs. placebo (n=4,090) (both in combination with statins)[1]*

2° endpoints

CV death[†‡]

↓**20**% [HR 0.80; 95% CI (0.66, 0.98)]

(event n=174 vs. 213)

Non-fatal MI[†]

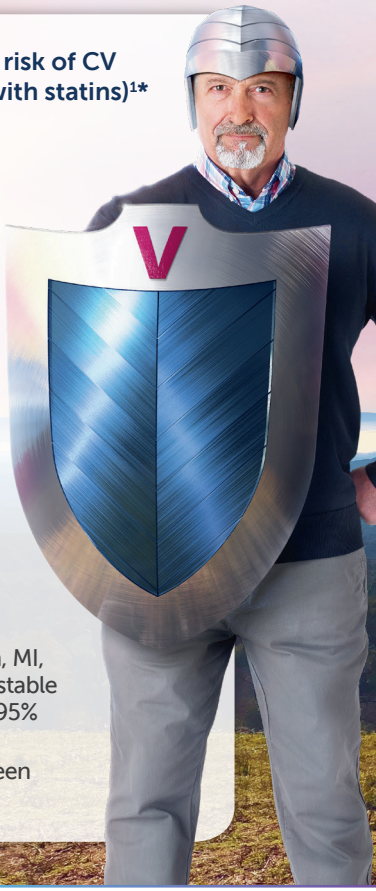
↓**30**% [HR 0.70; 95% CI (0.59, 0.82)]

(event n=174 vs. 213)

Non-fatal stroke[†]

↓**29**% [HR 0.71; 95% CI (0.54, 0.94)]

(event n=85 vs. 118)



Vascepa® demonstrated a **significant 25% reduction** on instantaneous risk of time to 1st occurrence of CV death, MI, stroke, coronary revascularization, or hospitalization for unstable angina (5-point MACE) for Vascepa® vs. placebo (HR 0.75 [95% CI: 0.68, 0.83]; $p < 0.0001$) (NNT = 21, 1° endpoint)[1]*.

There was no statistically significant difference in risk between the Vascepa® and placebo groups for all-cause mortality.

A placebo-controlled trial with a 4.9-year median follow-up of **statin-treated adult patients** with **elevated triglycerides** and **a high risk of cardiovascular events** due to established CV disease or diabetes with ≥1 other CV risk factor.[1]*

Vascepa® (icosapent ethyl [IPE]) is indicated to reduce the risk of cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization or hospitalization for unstable angina) in statin-treated patients with elevated triglycerides, who are at high risk of cardiovascular events due to:

- established cardiovascular disease, or
- diabetes, and at least one other cardiovascular risk factor[1]

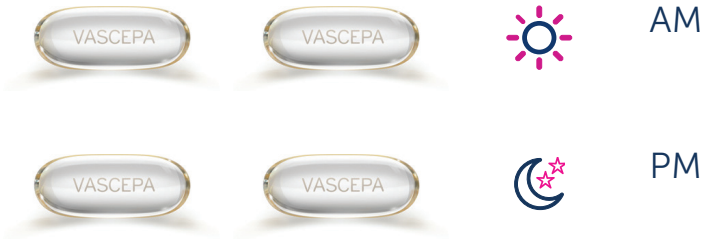
See the recommendations in the updated *2021 CCS Dyslipidemia Guidelines*[2] and *2020 Canadian Stroke best practice*[3]

Dosing and Administration[1]

One dose twice daily, no titration

Vascepa®: Only one dosage, 4 grams per day[1]

two 1 gram capsules



Administration

Patients should be advised to take Vascepa® with food and swallow capsules whole. Patients should not break open, crush, dissolve, or chew Vascepa®.

If the patient misses their dose they should take it as soon as they remember. They should not double the dose when they take their next dose.

VASCEPA® Assistance Program

Vascepa® coverage information[6]

Vascepa® is listed by all major private insurance plans.

For information on VASCEPA Assistance Program, call 1-833-999-6333

- The program offers additional financial support by paying a portion of Vascepa® prescription. The program representative will enrol your patient over the phone, assist with insurer forms and provide further information about the program.

General warning and precaution

Vascepa® is not the same as products that contain omega-3 fatty acids. Vascepa® should not be substituted with, or combined with, other products that contain omega-3 fatty acids.

Patients should be cautioned not to take products that contain omega-3 fatty acids while taking Vascepa® without first consulting their attending physician.

This Program may change or end at the manufacturer's discretion.

Clinical use:
Not indicated for pediatric use.
Use in geriatrics is not associated with differences in safety or effectiveness, but greater sensitivity of some older individuals cannot be ruled out.

Relevant warnings and precautions:
- Not recommended in combination with or substituted for other products that contain omega-3 fatty acids
- Increased incidence of bleeding
- Caution in patients with known hypersensitivity to fish and/or shellfish
- Periodic monitoring of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels in patients with hepatic impairment is recommended during therapy with Vascepa®
- Fertility
- Not recommended in pregnancy and nursing

For more information:
Please consult the Vascepa® Product Monograph at https://health-products.canada.ca/dpd-bdpp/index-eng.jsp for important information relating to adverse reactions, drug interactions, and dosing/administration information, which have not been discussed in this piece.

The Product Monograph is also available by calling HLS Therapeutics Inc. at 1-833-266-3423.

To learn more about Vascepa®
visit ***vascepa.ca***

* 8,179 statin-treated adult patients with elevated serum triglyceride levels (≥1.5 mmol/L to <5.6 mmol/L) who were also at high risk for atherothrombotic events. Patients either had established CVD or were at high risk for CVD and were randomized to either Vascepa® or placebo. Patients with established cardiovascular disease were at least 45 years of age and had a documented history of coronary artery disease, cerebrovascular or carotid disease, or peripheral artery disease. Patients with other risk factors for cardiovascular disease were at least 50 years of age and had diabetes and at least one additional major cardiovascular risk factor. Most patients at baseline were taking at least one other cardiovascular medication, including anti-hypertensives (95.0%), anti-platelet agents (79.4%), beta blockers (70.7%), angiotensin-converting enzyme (ACE) inhibitors (51.9%), and angiotensin receptor blockers (ARB) (27.0%), with 77.5% taking either an ACE inhibitor or ARB. At baseline, while on stable background lipid-lowering therapy, the median LDL-C was 1.9 mmol/L.
† Incidence rates of CV events per 100 patient years (Vascepa® vs. placebo): cardiovascular death, 1.0 vs. 1.2; non-fatal myocardial infarction, 1.4 vs. 2.0; non-fatal stroke, 0.5 vs. 0.7.
‡ CV death includes adjudicated cardiovascular deaths and deaths of undetermined causality.
CCS, Canadian Cardiovascular Society; CI, confidence interval; CV, cardiovascular; CVD, cardiovascular disease; HR, hazard ratio; LDL-C, low-density lipoprotein cholesterol; MACE, major adverse cardiovascular event; MI, myocardial infarction.

References:
1. HLS Therapeutics Inc. Vascepa® Product Monograph. December 30, 2019. **2**. Pearson GJ, et al. 2021 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult. *Can J Cardiol.* 2021; S0828-282X (21)00165-3. **3**. Canadian Stroke Best Practice Recommendations: Secondary Prevention of Stroke Update 2020. Can. J. Neurol. Sci. Accepted 2021.

HLS Therapeutics®

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REVIEWED BY PAAB

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