

LOVAZA®(omega-3-acid ethyl esters) or VASCEPA®(icosapent ethyl)

Available 1 gram capsule

INDICATIONS and USAGE:

LOVAZA:

LOVAZA® (omega-3-acid ethyl esters) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

Usage Considerations: Patients should be placed on an appropriate lipid-lowering diet before receiving LOVAZA and should continue this diet during treatment with LOVAZA.

Laboratory studies should be done to ascertain that the lipid levels are consistently abnormal before instituting LOVAZA therapy. Every attempt should be made to control serum lipids with appropriate diet, exercise, weight loss in obese patients, and control of any medical problems such as diabetes mellitus and hypothyroidism that are contributing to the lipid abnormalities. Medications known to exacerbate hypertriglyceridemia (such as beta blockers, thiazides, estrogens) should be discontinued or changed if possible prior to consideration of triglyceride-lowering drug therapy.

Limitations of Use:

- The effect of LOVAZA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.
- The effect of LOVAZA on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

VASCEPA:

VASCEPA is an ethyl ester of eicosapentaenoic acid (EPA) indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

Usage Considerations: Patients should be placed on an appropriate lipid-lowering diet and exercise regimen before receiving VASCEPA and should continue this diet and exercise regimen with VASCEPA.

Attempts should be made to control any medical problems such as diabetes mellitus, hypothyroidism, and alcohol intake that may contribute to lipid abnormalities. Medications known to exacerbate hypertriglyceridemia (such as beta blockers, thiazides, estrogens) should be discontinued or changed, if possible, prior to consideration of TG-lowering drug therapy.

Limitations of Use:

- The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.
- The effect of VASCEPA on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

Criteria for Approval:

1. Diagnosis from the 'Indication and Usage' section and must be supported by documentation from the patient's medical record; **AND**
2. Submit documentation of severe hypertriglyceridemia, including at least one laboratory test result within the last 12 months; **AND**
3. Submit dates of a trial and failure of a fibrate or niacin for 30 days or provide letter of medical necessity for non-trial ; **AND**
4. Age restrictions apply, must be 18 years of age or older

Length of Authorization:

Coverage may be approved for 12 months.

Dispensing Limit:

The dispensing limit is a 30 day supply of medication with the following **Quantity Limit** of four (4) capsules per day.

Reminder: You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <http://www.fda.gov/Safety/MedWatch/default.htm> or call 1-800-FDA-1088

References:

Lovaza® package insert is available at: < <https://www.gsksource.com/gskprm/htdocs/documents/LOVAZA-PI-PIL.PDF> >
Accessed 10/09/13

Vascepa® package insert is available at: < <https://www.vascepa.com/> >
Accessed 10/08/13