

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use LOVAZA safely and effectively. See full prescribing information for LOVAZA.

LOVAZA (omega-3-acid ethyl esters) Capsules, for oral use

Initial U.S. Approval: 2004

### RECENT MAJOR CHANGES

Indications and Usage, Limitations of Use (1) 06/2013

### INDICATIONS AND USAGE

LOVAZA is a combination of ethyl esters of omega 3 fatty acids, principally EPA and DHA, indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia (HTG). (1)

Limitations of Use:

- The effect of LOVAZA on the risk for pancreatitis has not been determined. (1)
- The effect of LOVAZA on cardiovascular mortality and morbidity has not been determined. (1)

### DOSAGE AND ADMINISTRATION

- The daily dose of LOVAZA is 4 grams per day taken as a single 4-gram dose (4 capsules) or as two 2-gram doses (2 capsules given twice daily). (2)
- Patients should be advised to swallow LOVAZA capsules whole. Do not break open, crush, dissolve, or chew LOVAZA. (2)

### DOSAGE FORMS AND STRENGTHS

Capsules: 1-gram (3)

### CONTRAINDICATIONS

LOVAZA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to LOVAZA or any of its components. (4)

### WARNINGS AND PRECAUTIONS

- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy. (5.1)
- LOVAZA may increase levels of LDL. Monitor LDL levels periodically during therapy. (5.1)
- Use with caution in patients with known hypersensitivity to fish and/or shellfish. (5.2)
- There is a possible association between LOVAZA and more frequent recurrences of symptomatic atrial fibrillation or flutter in patients with paroxysmal or persistent atrial fibrillation, particularly within the first months of initiating therapy. (5.3)

### ADVERSE REACTIONS

The most common adverse reactions (incidence  $>3\%$  and greater than placebo) were eructation, dyspepsia, and taste perversion. (6)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### DRUG INTERACTIONS

Omega-3-acids may prolong bleeding time. Patients taking LOVAZA and an anticoagulant or other drug affecting coagulation (e.g., anti-platelet agents) should be monitored periodically. (7.1)

### USE IN SPECIFIC POPULATIONS

- Pregnancy: Use during pregnancy only if the potential benefit justifies the potential risk to the fetus. (8.1)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 05/2014

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\*Sections or subsections omitted from the full prescribing information are not listed.

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## 1 FULL PRESCRIBING INFORMATION

### 2 1 INDICATIONS AND USAGE

3 LOVAZA<sup>®</sup> (omega-3-acid ethyl esters) is indicated as an adjunct to diet to reduce  
4 triglyceride (TG) levels in adult patients with severe ( $\geq 500$  mg/dL) hypertriglyceridemia (HTG).

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

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

#### 14 **Limitations of Use:**

15 The effect of LOVAZA on the risk for pancreatitis has not been determined.

16 The effect of LOVAZA on cardiovascular mortality and morbidity has not been  
17 determined.

### 18 2 DOSAGE AND ADMINISTRATION

- 19 • Assess triglyceride levels carefully before initiating therapy. Identify other causes (e.g.,  
20 diabetes mellitus, hypothyroidism, medications) of high triglyceride levels and manage as  
21 appropriate [*see Indications and Usage (1)*].
- 22 • Patients should be placed on an appropriate lipid-lowering diet before receiving LOVAZA,  
23 and should continue this diet during treatment with LOVAZA. In clinical studies, LOVAZA  
24 was administered with meals.

25 The daily dose of LOVAZA is 4 grams per day. The daily dose may be taken as a single  
26 4-gram dose (4 capsules) or as two 2-gram doses (2 capsules given twice daily).

27 Patients should be advised to swallow LOVAZA capsules whole. Do not break open,  
28 crush, dissolve, or chew LOVAZA.

### 29 3 DOSAGE FORMS AND STRENGTHS

30 LOVAZA (omega-3-acid ethyl esters) capsules are supplied as 1-gram transparent, soft-  
31 gelatin capsules filled with light-yellow oil and bearing the designation LOVAZA.

### 32 4 CONTRAINDICATIONS

33 LOVAZA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic  
34 reaction) to LOVAZA or any of its components.

35 **5 WARNINGS AND PRECAUTIONS**

36 **5.1 Monitoring: Laboratory Tests**

37 In patients with hepatic impairment, alanine aminotransferase (ALT) and aspartate  
38 aminotransferase (AST) levels should be monitored periodically during therapy with LOVAZA.  
39 In some patients, increases in ALT levels without a concurrent increase in AST levels were  
40 observed.

41 In some patients, LOVAZA increases LDL-C levels. LDL-C levels should be monitored  
42 periodically during therapy with LOVAZA.

43 Laboratory studies should be performed periodically to measure the patient's TG levels  
44 during therapy with LOVAZA.

45 **5.2 Fish Allergy**

46 LOVAZA contains ethyl esters of omega-3 fatty acids (EPA and DHA) obtained from the  
47 oil of several fish sources. It is not known whether patients with allergies to fish and/or shellfish,  
48 are at increased risk of an allergic reaction to LOVAZA. LOVAZA should be used with caution  
49 in patients with known hypersensitivity to fish and/or shellfish.

50 **5.3 Recurrent Atrial Fibrillation (AF) or Flutter**

51 In a double-blind, placebo-controlled trial of 663 subjects with symptomatic paroxysmal  
52 AF (n = 542) or persistent AF (n = 121), recurrent AF or flutter was observed in subjects  
53 randomized to LOVAZA who received 8 grams/day for 7 days and 4 grams/day thereafter for 23  
54 weeks at a higher rate relative to placebo. Subjects in this trial had median baseline triglycerides  
55 of 127 mg/dL, had no substantial structural heart disease, were taking no anti-arrhythmic therapy  
56 (rate control permitted), and were in normal sinus rhythm at baseline.

57 At 24 weeks, in the paroxysmal AF stratum, there were 129 (47%) first recurrent  
58 symptomatic AF or flutter events on placebo and 141 (53%) on LOVAZA [primary endpoint,  
59 HR 1.19; 95% CI: 0.93, 1.35]. In the persistent AF stratum, there were 19 (35%) events on  
60 placebo and 34 (52%) events on LOVAZA [HR 1.63; 95% CI: 0.91, 2.18]. For both strata  
61 combined, the HR was 1.25; 95% CI: 1.00, 1.40. Although the clinical significance of these  
62 results is uncertain, there is a possible association between LOVAZA and more frequent  
63 recurrences of symptomatic atrial fibrillation or flutter in patients with paroxysmal or persistent  
64 atrial fibrillation, particularly within the first 2 to 3 months of initiating therapy.

65 LOVAZA is not indicated for the treatment of AF or flutter.

66 **6 ADVERSE REACTIONS**

67 **6.1 Clinical Trials Experience**

68 Because clinical trials are conducted under widely varying conditions, adverse reaction  
69 rates observed in the clinical trials of a drug cannot be directly compared with rates in the  
70 clinical trials of another drug and may not reflect the rates observed in practice.

71 Adverse reactions reported in at least 3% and at a greater rate than placebo for subjects  
72 treated with LOVAZA based on pooled data across 23 clinical trials are listed in Table 1.

73  
74  
75

**Table 1. Adverse Reactions Occurring at Incidence  $\geq 3\%$  and Greater than Placebo in Clinical Trials of LOVAZA**

Adverse Reaction <sup>a</sup>	LOVAZA (N = 655)		Placebo (N = 370)	
	n	%	n	%
Eructation	29	4	5	1
Dyspepsia	22	3	6	2
Taste perversion	27	4	1	<1

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77

<sup>a</sup> Trials included subjects with HTG and severe HTG.

78  
79  
80  
81

Additional adverse reactions from clinical trials are listed below:

Digestive System: Constipation, gastrointestinal disorder and vomiting.

Metabolic and Nutritional Disorders: Increased ALT and increased AST.

Skin: Pruritus and rash.

## 82 **6.2 Postmarketing Experience**

83 In addition to adverse reactions reported from clinical trials, the events described below  
84 have been identified during post-approval use of LOVAZA. Because these events are reported  
85 voluntarily from a population of unknown size, it is not possible to reliably estimate their  
86 frequency or to always establish a causal relationship to drug exposure.

87 The following events have been reported: anaphylactic reaction, hemorrhagic diathesis.

## 88 **7 DRUG INTERACTIONS**

### 89 **7.1 Anticoagulants or Other Drugs Affecting Coagulation**

90 Some trials with omega-3-acids demonstrated prolongation of bleeding time. The  
91 prolongation of bleeding time reported in these trials has not exceeded normal limits and did not  
92 produce clinically significant bleeding episodes. Clinical trials have not been done to thoroughly  
93 examine the effect of LOVAZA and concomitant anticoagulants. Patients receiving treatment  
94 with LOVAZA and an anticoagulant or other drug affecting coagulation (e.g., anti-platelet  
95 agents) should be monitored periodically.

## 96 **8 USE IN SPECIFIC POPULATIONS**

### 97 **8.1 Pregnancy**

98 Pregnancy Category C: There are no adequate and well-controlled studies in pregnant  
99 women. It is unknown whether LOVAZA can cause fetal harm when administered to a pregnant  
100 woman or can affect reproductive capacity. LOVAZA should be used during pregnancy only if  
101 the potential benefit to the patient justifies the potential risk to the fetus.

102 Animal Data: Omega-3-acid ethyl esters have been shown to have an embryocidal effect  
103 in pregnant rats when given in doses resulting in exposures 7 times the recommended human  
104 dose of 4 grams/day based on a body surface area comparison.

105 In female rats given oral gavage doses of 100, 600, and 2,000 mg/kg/day beginning 2  
106 weeks prior to mating and continuing through gestation and lactation, no adverse effects were  
107 observed in the high-dose group (5 times human systemic exposure following an oral dose of 4  
108 grams/day based on body surface area comparison).

109 In pregnant rats given oral gavage doses of 1,000, 3,000, and 6,000 mg/kg/day from  
110 gestation day 6 through 15, no adverse effects were observed (14 times human systemic  
111 exposure following an oral dose of 4 grams/day based on a body surface area comparison).

112 In pregnant rats given oral gavage doses of 100, 600, and 2,000 mg/kg/day from gestation  
113 day 14 through lactation day 21, no adverse effects were seen at 2,000 mg/kg/day (5 times the  
114 human systemic exposure following an oral dose of 4 grams/day based on a body surface area  
115 comparison). However, decreased live births (20% reduction) and decreased survival to postnatal  
116 day 4 (40% reduction) were observed in a dose-ranging study using higher doses of 3,000  
117 mg/kg/day (7 times the human systemic exposure following an oral dose of 4 grams/day based  
118 on a body surface area comparison).

119 In pregnant rabbits given oral gavage doses of 375, 750, and 1,500 mg/kg/day from  
120 gestation day 7 through 19, no findings were observed in the fetuses in groups given 375  
121 mg/kg/day (2 times human systemic exposure following an oral dose of 4 grams/day based on a  
122 body surface area comparison). However, at higher doses, evidence of maternal toxicity was  
123 observed (4 times human systemic exposure following an oral dose of 4 grams/day based on a  
124 body surface area comparison).

### 125 **8.3 Nursing Mothers**

126 Studies with omega-3-acid ethyl esters have demonstrated excretion in human milk. The  
127 effect of this excretion on the infant of a nursing mother is unknown; caution should be exercised  
128 when LOVAZA is administered to a nursing mother. An animal study in lactating rats given oral  
129 gavage <sup>14</sup>C-ethyl EPA demonstrated that drug levels were 6 to 14 times higher in milk than in  
130 plasma.

### 131 **8.4 Pediatric Use**

132 Safety and effectiveness in pediatric patients have not been established.

### 133 **8.5 Geriatric Use**

134 A limited number of subjects older than 65 years were enrolled in the clinical trials of  
135 LOVAZA. Safety and efficacy findings in subjects older than 60 years did not appear to differ  
136 from those of subjects younger than 60 years.

## 137 **9 DRUG ABUSE AND DEPENDENCE**

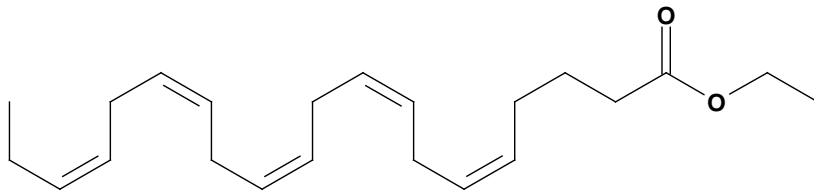
138 LOVAZA does not have any known drug abuse or withdrawal effects.

## 139 **11 DESCRIPTION**

140 LOVAZA, a lipid-regulating agent, is supplied as a liquid-filled gel capsule for oral  
141 administration. Each 1-gram capsule of LOVAZA contains at least 900 mg of the ethyl esters of  
142 omega-3 fatty acids sourced from fish oils. These are predominantly a combination of ethyl

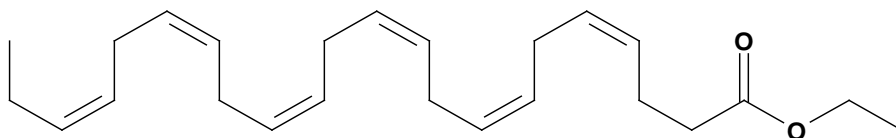
143 esters of eicosapentaenoic acid (EPA - approximately 465 mg) and docosahexaenoic acid (DHA  
144 - approximately 375 mg).

145 The empirical formula of EPA ethyl ester is  $C_{22}H_{34}O_2$ , and the molecular weight of EPA  
146 ethyl ester is 330.51. The structural formula of EPA ethyl ester is:



147  
148

149 The empirical formula of DHA ethyl ester is  $C_{24}H_{36}O_2$ , and the molecular weight of DHA  
150 ethyl ester is 356.55. The structural formula of DHA ethyl ester is:



151  
152

153 LOVAZA capsules also contain the following inactive ingredients: 4 mg  $\alpha$ -tocopherol (in  
154 a carrier of soybean oil), and gelatin, glycerol, and purified water (components of the capsule  
155 shell).

## 156 **12 CLINICAL PHARMACOLOGY**

### 157 **12.1 Mechanism of Action**

158 The mechanism of action of LOVAZA is not completely understood. Potential  
159 mechanisms of action include inhibition of acyl-CoA:1,2-diacylglycerol acyltransferase,  
160 increased mitochondrial and peroxisomal  $\beta$ -oxidation in the liver, decreased lipogenesis in the  
161 liver, and increased plasma lipoprotein lipase activity. LOVAZA may reduce the synthesis of  
162 triglycerides in the liver because EPA and DHA are poor substrates for the enzymes responsible  
163 for TG synthesis, and EPA and DHA inhibit esterification of other fatty acids.

### 164 **12.3 Pharmacokinetics**

165 In healthy volunteers and in subjects with hypertriglyceridemia, EPA and DHA were  
166 absorbed when administered as ethyl esters orally. Omega-3-acids administered as ethyl esters  
167 (LOVAZA) induced significant, dose-dependent increases in serum phospholipid EPA content,  
168 though increases in DHA content were less marked and not dose-dependent when administered  
169 as ethyl esters.

170 Specific Populations: **Age:** Uptake of EPA and DHA into serum phospholipids in  
171 subjects treated with LOVAZA was independent of age (<49 years versus  $\geq$ 49 years).

172 **Gender:** Females tended to have more uptake of EPA into serum phospholipids than  
173 males. The clinical significance of this is unknown.

174 **Pediatric:** Pharmacokinetics of LOVAZA have not been studied.

175            *Renal or Hepatic Impairment:* LOVAZA has not been studied in patients with renal  
176 or hepatic impairment.

177            Drug-Drug Interactions: *Simvastatin:* In a 14-day trial of 24 healthy adult subjects,  
178 daily coadministration of simvastatin 80 mg with LOVAZA 4 grams did not affect the extent  
179 (AUC) or rate ( $C_{max}$ ) of exposure to simvastatin or the major active metabolite, beta-hydroxy  
180 simvastatin at steady state.

181            *Atorvastatin:* In a 14-day trial of 50 healthy adult subjects, daily coadministration of  
182 atorvastatin 80 mg with LOVAZA 4 grams did not affect AUC or  $C_{max}$  of exposure to  
183 atorvastatin, 2-hydroxyatorvastatin, or 4-hydroxyatorvastatin at steady state.

184            *Rosuvastatin:* In a 14-day trial of 48 healthy adult subjects, daily coadministration of  
185 rosuvastatin 40 mg with LOVAZA 4 grams did not affect AUC or  $C_{max}$  of exposure to  
186 rosuvastatin at steady state.

187            In vitro studies using human liver microsomes indicated that clinically significant  
188 cytochrome P450-mediated inhibition by EPA/DHA combinations are not expected in humans.

## 189    **13    NONCLINICAL TOXICOLOGY**

### 190    **13.1    Carcinogenesis, Mutagenesis, Impairment of Fertility**

191            In a rat carcinogenicity study with oral gavage doses of 100, 600, and 2,000 mg/kg/day,  
192 males were treated with omega-3-acid ethyl esters for 101 weeks and females for 89 weeks  
193 without an increased incidence of tumors (up to 5 times human systemic exposures following an  
194 oral dose of 4 grams/day based on a body surface area comparison). Standard lifetime  
195 carcinogenicity bioassays were not conducted in mice.

196            Omega-3-acid ethyl esters were not mutagenic or clastogenic with or without metabolic  
197 activation in the bacterial mutagenesis (Ames) test with *Salmonella typhimurium* and  
198 *Escherichia coli* or in the chromosomal aberration assay in Chinese hamster V79 lung cells or  
199 human lymphocytes. Omega-3-acid ethyl esters were negative in the in vivo mouse micronucleus  
200 assay.

201            In a rat fertility study with oral gavage doses of 100, 600, and 2,000 mg/kg/day, males  
202 were treated for 10 weeks prior to mating and females were treated for 2 weeks prior to and  
203 throughout mating, gestation, and lactation. No adverse effect on fertility was observed at 2,000  
204 mg/kg/day (5 times human systemic exposure following an oral dose of 4 grams/day based on a  
205 body surface area comparison).

## 206    **14    CLINICAL STUDIES**

### 207    **14.1    Severe Hypertriglyceridemia**

208            The effects of LOVAZA 4 grams per day were assessed in 2 randomized, placebo-  
209 controlled, double-blind, parallel-group trials of 84 adult subjects (42 on LOVAZA, 42 on  
210 placebo) with very high triglyceride levels. Subjects whose baseline triglyceride levels were  
211 between 500 and 2,000 mg/dL were enrolled in these 2 trials of 6 and 16 weeks' duration. The  
212 median triglyceride and LDL-C levels in these subjects were 792 mg/dL and 100 mg/dL,  
213 respectively. Median HDL-C level was 23.0 mg/dL.

214 The changes in the major lipoprotein lipid parameters for the groups receiving LOVAZA  
215 or placebo are shown in Table 2.

216

217 **Table 2. Median Baseline and Percent Change From Baseline in Lipid Parameters in**  
218 **Subjects With Severe Hypertriglyceridemia ( $\geq 500$  mg/dL)**

Parameter	LOVAZA N = 42		Placebo N = 42		Difference
	BL	% Change	BL	% Change	
TG	816	-44.9	788	+6.7	-51.6
Non-HDL-C	271	-13.8	292	-3.6	-10.2
TC	296	-9.7	314	-1.7	-8.0
VLDL-C	175	-41.7	175	-0.9	-40.8
HDL-C	22	+9.1	24	0.0	+9.1
LDL-C	89	+44.5	108	-4.8	+49.3

219 BL = Baseline (mg/dL); % Change = Median Percent Change from Baseline;

220 Difference = LOVAZA Median % Change – Placebo Median % Change.

221

222 LOVAZA 4 grams per day reduced median TG, VLDL-C, and non-HDL-C levels and  
223 increased median HDL-C from baseline relative to placebo. Treatment with LOVAZA to reduce  
224 very high TG levels may result in elevations in LDL-C and non-HDL-C in some individuals.  
225 Patients should be monitored to ensure that the LDL-C level does not increase excessively.

226 The effect of LOVAZA on the risk of pancreatitis has not been determined.

227 The effect of LOVAZA on cardiovascular mortality and morbidity has not been  
228 determined.

## 229 **16 HOW SUPPLIED/STORAGE AND HANDLING**

230 LOVAZA (omega-3-acid ethyl esters) capsules are supplied as 1-gram, transparent, soft-  
231 gelatin capsules filled with light-yellow oil and bearing the designation LOVAZA.

232 Bottles of 120: NDC 0173-0783-02.

233

234 Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP  
235 Controlled Room Temperature]. Do not freeze. Keep out of reach of children.

## 236 **17 PATIENT COUNSELING INFORMATION**

237 Advise the patient to read the FDA-approved patient labeling (Patient Information).

### 238 Information for Patients:

- 239 • LOVAZA should be used with caution in patients with known sensitivity or allergy to fish  
240 and/or shellfish [see *Warnings and Precautions* (5.2)].
- 241 • Advise patients that use of lipid-regulating agents does not reduce the importance of adhering  
242 to diet [see *Dosage and Administration* (2)].
- 243 • Advise patients not to alter LOVAZA capsules in any way and to ingest intact capsules only  
244 [see *Dosage and Administration* (2)].



- 245 • Instruct patients to take LOVAZA as prescribed. If a dose is missed, advise patients to take it  
246 as soon as they remember. However, if they miss one day of LOVAZA, they should not  
247 double the dose when they take it.

248

249 Manufactured for:



250

251 GlaxoSmithKline

252 Research Triangle Park, NC 27709

253

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258 LVZ:XXPI

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**PATIENT INFORMATION**  
**LOVAZA<sup>®</sup> (lō-vā-ză)**  
**(omega-3-acid ethyl esters)**  
**Capsules**

Read this Patient Information before you start taking LOVAZA, and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

**What is LOVAZA?**

LOVAZA is a prescription medicine used along with a low fat and low cholesterol diet to lower very high triglyceride (fat) levels in adults.

It is not known if LOVAZA changes your risk of having inflammation of your pancreas (pancreatitis).

It is not known if LOVAZA prevents you from having a heart attack or stroke.

It is not known if LOVAZA is safe and effective in children.

**Who should not take LOVAZA?**

Do not take LOVAZA if you are allergic to omega-3-acid ethyl esters or any of the ingredients in LOVAZA. See the end of this leaflet for a complete list of ingredients in LOVAZA.

**What should I tell my doctor before taking LOVAZA?**

**Before you take LOVAZA, tell your doctor if you:**

- have diabetes.
- have a low thyroid problem (hypothyroidism).
- have a liver problem.
- have a pancreas problem.
- have a certain heart rhythm problem called atrial fibrillation or flutter.
- are allergic to fish or shellfish. It is not known if people who are allergic to fish or shellfish are also allergic to LOVAZA.
- are pregnant or plan to become pregnant. It is not known if LOVAZA will harm your unborn baby.

- 300 • are breastfeeding or plan to breastfeed. LOVAZA can pass into your  
301 breast milk. You and your doctor should decide if you will take LOVAZA or  
302 breastfeed.

303

304 **Tell your doctor about all the medicines you take**, including prescription  
305 and non-prescription medicine, vitamins, and herbal supplements.

306

307 LOVAZA can interact with certain other medicines that you are taking. Using  
308 LOVAZA with medicines that affect blood clotting (anticoagulants or blood  
309 thinners) may cause serious side effects.

310

311 Know the medicines you take. Keep a list of them to show your doctor and  
312 pharmacist when you get a new medicine.

313

#### 314 **How should I take LOVAZA?**

- 315 • Take LOVAZA exactly as your doctor tells you to take it.  
316 • You should not take more than 4 capsules of LOVAZA each day. Either  
317 take all 4 capsules at one time, or 2 capsules two times a day.  
318 • Do not change your dose or stop LOVAZA without talking to your doctor.  
319 • Take LOVAZA with or without food.  
320 • Take LOVAZA capsules whole. Do not break, crush, dissolve, or chew  
321 LOVAZA capsules before swallowing. If you cannot swallow LOVAZA  
322 capsules whole, tell your doctor. You may need a different medicine.  
323 • Your doctor may start you on a diet that is low in saturated fat,  
324 cholesterol, carbohydrates, and low in added sugars before giving you  
325 LOVAZA. Stay on this diet while taking LOVAZA.  
326 • Your doctor should do blood tests to check your triglyceride, bad  
327 cholesterol and liver function levels while you take LOVAZA.

328

#### 329 **What are the possible side effects of LOVAZA?**

##### 330 **LOVAZA may cause serious side effects, including:**

- 331 • increases in the results of blood tests used to check your liver function  
332 (ALT and AST) and your bad cholesterol levels (LDL-C).  
333 • increases in the frequency of a heart rhythm problem (atrial fibrillation or  
334 flutter) may especially happen in the first few months of taking LOVAZA if  
335 you already have that problem.

336

337 The most common side effects of LOVAZA include:

- 338 • burping  
339 • upset stomach

340 • a change in your sense of taste

341  
342 Talk to your doctor if you have a side effect that bothers you or does not go  
343 away.

344  
345 These are not all the possible side effects of LOVAZA. For more information,  
346 ask your doctor or pharmacist.

347  
348 Call your doctor for medical advice about side effects. You may report side  
349 effects to FDA at 1-800-FDA-1088.

350  
351 **How should I store LOVAZA?**

- 352 • Store LOVAZA at room temperature between 68°F to 77°F (20°C to  
353 25°C).  
354 • Do not freeze LOVAZA.  
355 • Safely throw away medicine that is out of date or no longer needed.

356  
357 **Keep LOVAZA and all medicines out of the reach of children.**

358  
359 **General information about the safe and effective use of LOVAZA**

360 Medicines are sometimes prescribed for purposes other than those listed in a  
361 Patient Information leaflet. Do not use LOVAZA for a condition for which it  
362 was not prescribed. Do not give LOVAZA to other people, even if they have  
363 the same symptoms you have. It may harm them.

364  
365 This Patient Information Leaflet summarizes the most important information  
366 about LOVAZA. If you would like more information, talk with your doctor.  
367 You can ask your doctor or pharmacist for information about LOVAZA that is  
368 written for health professionals.

369  
370 For more information go to [www.LOVAZA.com](http://www.LOVAZA.com) or call 1-888-825-5249.

371  
372 **What are the ingredients in LOVAZA?**

373 Active Ingredient: omega-3-acid ethyl esters, mostly EPA and DHA  
374 Inactive Ingredients: alpha-tocopherol (in soybean oil), gelatin, glycerol,  
375 purified water.

376

377 This patient labeling has been approved by the U.S. Food and Drug  
378 Administration.

379

380 Manufactured for:



381

382 GlaxoSmithKline

383 Research Triangle Park, NC 27709

384

385 LOVAZA is a registered trademark of the GSK group of companies.

386

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388

389 Month year

390 LVZ: XPIL