

**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

Initial U.S. Approval: 2004

**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 (≥500 mg/dL) hypertriglyceridemia. (1)

Limitations of Use: The effect of LOVAZA on cardiovascular mortality and morbidity in patients with elevated triglycerides 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**

1-gram transparent soft-gelatin capsules. (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)

**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.

**DRUG INTERACTIONS**

Omega-3-acids may prolong bleeding time. Patients taking LOVAZA and an anticoagulant or other drug affecting coagulation 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)
- Pediatric Use: The safety and effectiveness in pediatric patients have not been established. (8.4)

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

Revised: Month Year

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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.

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 LOVAZA therapy. Every attempt should be made to control serum  
9 lipids with appropriate diet, exercise, weight loss in obese patients, and control of any medical  
10 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:** The effect of LOVAZA on cardiovascular mortality and morbidity  
15 in patients with elevated triglycerides has not been determined.

16 **2 DOSAGE AND ADMINISTRATION**

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

23 The daily dose of LOVAZA is 4 grams per day. The daily dose may be taken as a single  
24 4-gram dose (4 capsules) or as two 2-gram doses (2 capsules given twice daily).

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

27 **3 DOSAGE FORMS AND STRENGTHS**

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

30 **4 CONTRAINDICATIONS**

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

33 **5 WARNINGS AND PRECAUTIONS**

34 **5.1 Monitoring: Laboratory Tests**

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

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

41 Laboratory studies should be performed periodically to measure the patient’s TG levels  
42 during therapy with LOVAZA.

43 **5.2 Fish Allergy**

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

48 **6 ADVERSE REACTIONS**

49 **6.1 Clinical Trials Experience**

50 Because clinical trials are conducted under widely varying conditions, adverse reaction  
51 rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical  
52 trials of another drug and may not reflect the rates observed in practice.

53 Adverse reactions reported in at least 3% and at a greater rate than placebo for patients  
54 treated with LOVAZA based on pooled data across 23 clinical studies are listed in Table 1.

55

56 **Table 1. Adverse Reactions Occurring at Incidence ≥3% and Greater than Placebo in**  
57 **Clinical Studies of LOVAZA**

BODY SYSTEM Adverse Event*	LOVAZA 4 grams/day (N = 655)		Placebo (N = 370)	
	n	%	n	%
Eructation	29	4	5	1
Dyspepsia	22	3	6	2
Taste perversion	27	4	1	<1

58 \* Studies included subjects with HTG and severe HTG.

59

60 Additional adverse reactions from clinical studies are listed below:

61 *Digestive System:* Constipation, gastrointestinal disorder, and vomiting.

62 *Metabolic and Nutritional Disorders:* Increased ALT and increased AST.

63 *Skin:* Pruritus and rash.

## 64 **6.2 Postmarketing Experience**

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

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

## 70 **7 DRUG INTERACTIONS**

### 71 **7.1 Anticoagulants or Other Drugs Affecting Coagulation**

72 Some studies with omega-3-acids demonstrated prolongation of bleeding time. The  
73 prolongation of bleeding time reported in these studies has not exceeded normal limits and did  
74 not produce clinically significant bleeding episodes. Clinical studies have not been done to  
75 thoroughly examine the effect of LOVAZA and concomitant anticoagulants. Patients receiving  
76 treatment with LOVAZA and an anticoagulant or other drug affecting coagulation should be  
77 monitored periodically (e.g., aspirin, NSAIDS, warfarin, coumarin).

## 78 **8 USE IN SPECIFIC POPULATIONS**

### 79 **8.1 Pregnancy**

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

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

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

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

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

101 In pregnant rabbits given oral gavage doses of 375, 750, and 1,500 mg/kg/day from  
102 gestation day 7 through 19, no findings were observed in the fetuses in groups given 375

103 mg/kg/day (2 times human systemic exposure following an oral dose of 4 grams/day based on a  
104 body surface area comparison). However, at higher doses, evidence of maternal toxicity was  
105 observed (4 times human systemic exposure following an oral dose of 4 grams/day based on a  
106 body surface area comparison).

### 107 **8.3 Nursing Mothers**

108 It is not known whether omega-3-acid ethyl esters are excreted in human milk. Because  
109 many drugs are excreted in human milk, caution should be exercised when LOVAZA is  
110 administered to a nursing woman.

### 111 **8.4 Pediatric Use**

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

### 113 **8.5 Geriatric Use**

114 A limited number of patients older than 65 years were enrolled in the clinical studies of  
115 LOVAZA. Safety and efficacy findings in subjects older than 60 years did not appear to differ  
116 from those of subjects younger than 60 years.

## 117 **9 DRUG ABUSE AND DEPENDENCE**

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

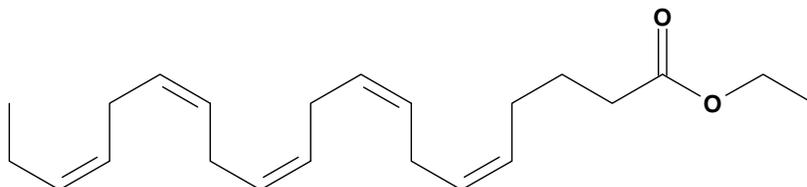
## 119 **10 OVERDOSAGE**

120 In the event of an overdose, the patient should be treated symptomatically, and general  
121 supportive care measures instituted, as required.

## 122 **11 DESCRIPTION**

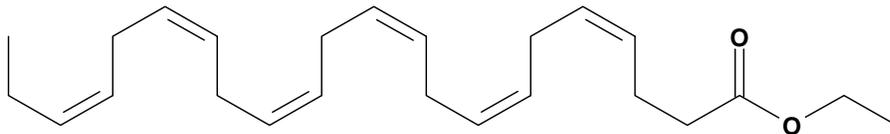
123 LOVAZA, a lipid-regulating agent, is supplied as a liquid-filled gel capsule for oral  
124 administration. Each 1-gram capsule of LOVAZA contains at least 900 mg of the ethyl esters of  
125 omega-3 fatty acids sourced from fish oils. These are predominantly a combination of ethyl  
126 esters of eicosapentaenoic acid (EPA - approximately 465 mg) and docosahexaenoic acid (DHA  
127 - approximately 375 mg).

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



130  
131

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



134  
135  
136 LOVAZA capsules also contain the following inactive ingredients: 4 mg  $\alpha$ -tocopherol (in  
137 a carrier of soybean oil), and gelatin, glycerol, and purified water (components of the capsule  
138 shell).

## 139 **12 CLINICAL PHARMACOLOGY**

### 140 **12.1 Mechanism of Action**

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

### 147 **12.3 Pharmacokinetics**

148 In healthy volunteers and in patients with hypertriglyceridemia, EPA and DHA were  
149 absorbed when administered as ethyl esters orally. Omega-3-acids administered as ethyl esters  
150 (LOVAZA) induced significant, dose-dependent increases in serum phospholipid EPA content,  
151 though increases in DHA content were less marked and not dose-dependent when administered  
152 as ethyl esters.

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

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

157 **Pediatric:** Pharmacokinetics of LOVAZA in pediatric patients have not been  
158 established [see *Use in Specific Populations (8.4)*].

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

161 **Drug-Drug Interactions: Simvastatin:** In a 14-day study of 24 healthy adult subjects,  
162 daily co-administration of simvastatin 80 mg with LOVAZA 4 grams did not affect the extent  
163 (AUC) or rate ( $C_{max}$ ) of exposure to simvastatin or the major active metabolite, beta-hydroxy  
164 simvastatin at steady state.

165 **Atorvastatin:** In a 14-day study of 50 healthy adult subjects, daily co-administration  
166 of atorvastatin 80 mg with LOVAZA 4 grams did not affect AUC or  $C_{max}$  of exposure to  
167 atorvastatin, 2-hydroxyatorvastatin, or 4-hydroxyatorvastatin at steady state.

168            *Rosuvastatin*: In a 14-day study of 48 healthy adult subjects, daily co-administration  
169 of rosuvastatin 40 mg with LOVAZA 4 grams did not affect AUC or C<sub>max</sub> of exposure to  
170 rosuvastatin at steady state.

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

### 173 **13 NONCLINICAL TOXICOLOGY**

#### 174 **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

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

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

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

### 190 **14 CLINICAL STUDIES**

#### 191 **14.1 Severe Hypertriglyceridemia**

192            The effects of LOVAZA 4 grams per day were assessed in 2 randomized, placebo-  
193 controlled, double-blind, parallel-group studies of 84 adult patients (42 on LOVAZA, 42 on  
194 placebo) with very high triglyceride levels. Patients whose baseline triglyceride levels were  
195 between 500 and 2,000 mg/dL were enrolled in these 2 studies of 6 and 16 weeks duration. The  
196 median triglyceride and LDL-C levels in these patients were 792 mg/dL and 100 mg/dL,  
197 respectively. Median HDL-C level was 23.0 mg/dL.

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

200

201 **Table 2. Median Baseline and Percent Change From Baseline in Lipid Parameters in**  
 202 **Patients with Very High TG Levels ( $\geq 500$  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

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

204 Difference = LOVAZA Median % Change – Placebo Median % Change

205

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

210 The effect of LOVAZA on the risk of pancreatitis in patients with very high TG levels  
 211 has not been evaluated.

212 The effect of LOVAZA on cardiovascular mortality and morbidity in patients with  
 213 elevated TG levels has not been determined.

#### 214 **14.2 Other Clinical Experience**

215 The effects of LOVAZA 4 grams per day as add-on therapy to treatment with simvastatin  
 216 were evaluated in a randomized, placebo-controlled, double-blind, parallel-group study of 254  
 217 adult patients (122 on LOVAZA and 132 on placebo) with persistent high triglycerides (200 to  
 218 499 mg/dL) despite simvastatin therapy. Patients were treated with open-label simvastatin 40 mg  
 219 per day for 8 weeks prior to randomization to control their LDL-C to no greater than 10% above  
 220 NCEP ATP III goal and remained on this dose throughout the study. Following 8 weeks of open-  
 221 label treatment with simvastatin, patients were randomized to either LOVAZA 4 grams per day  
 222 or placebo for an additional 8 weeks with simvastatin co-therapy. The median baseline  
 223 triglyceride and LDL-C levels in these patients were 268 mg/dL and 89 mg/dL, respectively.  
 224 Median baseline non-HDL-C and HDL-C levels were 138 mg/dL and 45 mg/dL, respectively.

225 The changes in the major lipoprotein lipid parameters for the groups receiving LOVAZA  
 226 plus simvastatin or placebo plus simvastatin are shown in Table 3.

227

228 **Table 3. Response to the Addition of LOVAZA 4 grams per day to Ongoing Simvastatin**  
 229 **40 mg per day Therapy in Patients with High Triglycerides (200 to 499 mg/dL)**

Parameter	LOVAZA + Simvastatin N = 122			Placebo + Simvastatin N = 132			Difference	P-Value
	BL	EOT	Median % Change	BL	EOT	Median % Change		
Non-HDL-C	137	123	-9.0	141	134	-2.2	-6.8	<0.0001
TG	268	182	-29.5	271	260	-6.3	-23.2	<0.0001
TC	184	172	-4.8	184	178	-1.7	-3.1	<0.05
VLDL-C	52	37	-27.5	52	49	-7.2	-20.3	<0.05
Apo-B	86	80	-4.2	87	85	-1.9	-2.3	<0.05
HDL-C	46	48	+3.4	43	44	-1.2	+4.6	<0.05
LDL-C	91	88	+0.7	88	85	-2.8	+3.5	=0.05

230 BL = Baseline (mg/dL); EOT = End of Treatment (mg/dL); Median % Change = Median Percent  
 231 Change from Baseline; Difference = LOVAZA Median % Change – Placebo Median % Change  
 232

233 LOVAZA 4 grams per day significantly reduced non-HDL-C, TG, TC, VLDL-C, and  
 234 Apo-B levels and increased HDL-C and LDL-C from baseline relative to placebo.

235 **16 HOW SUPPLIED/STORAGE AND HANDLING**

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

238 Bottles of 60: NDC 0173-0783-01

239 Bottles of 120: NDC 0173-0783-02

240

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

243 **17 PATIENT COUNSELING INFORMATION**

244 *See FDA-approved patient labeling (17.2).*

245 **17.1 Information for Patients**

- 246 • LOVAZA should be used with caution in patients with known sensitivity or allergy to fish  
 247 and/or shellfish [see *Warnings and Precautions (5.3)*].
- 248 • Patients should be advised that use of lipid-regulating agents does not reduce the importance  
 249 of adhering to diet [see *Dosage and Administration (2)*].
- 250 • Patients should be advised not to alter LOVAZA capsules in any way and to ingest intact  
 251 capsules only [see *Dosage and Administration (2)*].

252 **17.2 FDA-Approved Patient Labeling**

253 Patient labeling is provided as a tear-off leaflet at the end of this full prescribing  
 254 information.

255

256 Manufactured for GlaxoSmithKline by:

257 Catalent Pharma Solutions  
258 2725 Scherer Drive  
259 St. Petersburg, FL 33716-1016  
260  
261 Accucaps Industries Limited  
262 2125 Ambassador Drive  
263 Windsor, Ontario, Canada N9B 3R5  
264  
265 Banner Pharmaceuticals Inc.  
266 4125 Premier Drive  
267 High Point, NC 27265  
268  
269 Distributed by:



270  
271 GlaxoSmithKline  
272 Research Triangle Park, NC 27709  
273  
274 LOVAZA is a registered trademark of the GlaxoSmithKline group of companies.  
275  
276 ©Year GlaxoSmithKline. All rights reserved.  
277  
278 Month Year  
279 LVZ:XPI

280 PHARMACIST-DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

281

282

283

284

285

286

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

287 Read the Patient Information that comes with LOVAZA before you start taking it, and each time

288 you get a refill. There may be new information. This leaflet does not take the place of talking

289 with your doctor about your condition or treatment.

290

291 **What is LOVAZA?**

292 LOVAZA is a prescription medicine, called a lipid-regulating medicine, for adults. LOVAZA is

293 made of omega-3 fatty acids from oils of fish, such as salmon and mackerel. Omega-3 fatty acids

294 are substances that your body needs but cannot produce itself.

295

296 LOVAZA is used along with a low-fat and low-cholesterol diet to lower very high triglycerides

297 (fats) in your blood. Before taking LOVAZA, talk to your healthcare provider about how you

298 can lower high blood fats by:

- 299 • losing weight, if you are overweight
- 300 • increasing physical exercise
- 301 • lowering alcohol use
- 302 • treating diseases such as diabetes and low thyroid (hypothyroidism)
- 303 • adjusting the dose or changing other medicines that raise triglyceride levels such as certain
- 304 blood pressure medicines and estrogens

305

306 Treatment with LOVAZA has not been shown to prevent heart attacks or strokes.

307

308 LOVAZA has not been studied in children under the age of 18 years.

309

310 **Who should not take LOVAZA?**

311 Do not take LOVAZA if you:

- 312 • **are allergic to LOVAZA or any of its ingredients.** See the end of this leaflet for a complete
- 313 list of ingredients in LOVAZA.

314

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

316 **Tell your doctor about all of your medical conditions, including if you:**

- 317 • drink more than 2 glasses of alcohol daily.
- 318 • have diabetes.
- 319 • have a thyroid problem called hypothyroidism.

- 320 • have a liver problem.
- 321 • have a pancreas problem.
- 322 • are allergic to fish and/or shellfish. LOVAZA may not be right for you.
- 323 • are pregnant, or planning to become pregnant. It is not known if LOVAZA can harm your
- 324 unborn baby.
- 325 • are breastfeeding. It is not known if LOVAZA passes into your milk and if it can harm your
- 326 baby.

327

328 Tell your doctor about all the medicines you take, including prescription and non-prescription  
329 medicine, vitamins, and herbal supplements. LOVAZA and certain other medicines can interact.  
330 Especially tell your doctor if you take medicines that affect clotting such as anticoagulants or  
331 blood thinners. Examples of these medicines include aspirin, nonsteroidal anti-inflammatory  
332 agents (NSAIDS), warfarin, coumarin, and clopidogrel (PLAVIX<sup>®</sup>).

333

334 Know all the medicines you take. Keep a list of them with you to show your doctor and  
335 pharmacist.

336

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

- 338 • Take LOVAZA exactly as prescribed. Do not change your dose or stop LOVAZA without  
339 talking to your doctor.
- 340 • The usual dose of LOVAZA is 4 capsules:
  - 341 • Take all 4 capsules at the same time, or
  - 342 • Take 2 capsules two times a day
- 343 • Take LOVAZA at the same time or times each day.
- 344 • Take LOVAZA with or without food. You may find it easier to take LOVAZA with food.
- 345 • Do not take more than 4 capsules a day. Taking more than 4 capsules per day may increase  
346 the chance of side effects.
- 347 • Take LOVAZA capsules whole. Do not break, crush, dissolve, or chew LOVAZA capsules  
348 before swallowing. If you cannot swallow LOVAZA capsules whole, tell your doctor. You  
349 may need a different medicine.
- 350 • Your doctor should start you on a low-fat and low-cholesterol diet before giving you  
351 LOVAZA. Stay on this low-fat and low-cholesterol diet while taking LOVAZA.
- 352 • Your doctor should do blood tests to check your triglyceride and cholesterol levels during  
353 treatment with LOVAZA.
- 354 • If you have liver disease, your doctor should do blood tests to check your liver function  
355 during treatment with LOVAZA.
- 356 • If you miss a dose of LOVAZA, take it as soon as you remember. However, if you miss one  
357 day of LOVAZA, do not double your dose when you next take it.
- 358 • If you take too much LOVAZA or overdose, call your doctor or Poison Control Center right  
359 away.

360

361 **What are the possible side effects of LOVAZA?**

362 The most common side effects with LOVAZA are burping, upset stomach, a change in your  
363 sense of taste, and skin rash.

364

365 LOVAZA may affect certain blood tests. It may change:

- 366 • one of the tests to check liver function (ALT)
- 367 • one of the tests to measure cholesterol levels (LDL-C)

368

369 Talk to your doctor if you have side effects that bother you or that will not go away. You may  
370 report side effects to FDA at 1-800-FDA-1088.

371

372 These are not all the side effects with LOVAZA. For more information, ask your doctor or  
373 pharmacist.

374

375 **How should I store LOVAZA?**

- 376 • Store LOVAZA at room temperature, 59° to 86° F (15° to 30° C). Do not freeze.
- 377 • Do not keep medicine that is out of date or that you no longer need.
- 378 • **Keep LOVAZA out of the reach of children.** Be sure that if you throw medicines away, it  
379 is out of the reach of children.

380

381 **General information about LOVAZA**

382 Medicines are sometimes prescribed for conditions that are not mentioned in patient information  
383 leaflets. Do not use LOVAZA for a condition for which it was not prescribed. Do not give  
384 LOVAZA to other people, even if they have the same problem you have. It may harm them.

385

386 This leaflet summarizes the most important information about LOVAZA. If you would like more  
387 information, talk with your doctor. You can ask your doctor or pharmacist for information about  
388 LOVAZA that is written for health professionals or go to [www.LOVAZA.com](http://www.LOVAZA.com).

389

390 **What are the ingredients in LOVAZA?**

391 Active Ingredient: Omega-3-acid ethyl esters

392 Inactive Ingredients: Gelatin, glycerol, purified water, alpha-tocopherol (in soybean oil)

393

394 LOVAZA is a registered trademark of the GlaxoSmithKline group of companies.

395 PLAVIX is a registered trademark of Sanofi-Synthelabo.

396

397 Manufactured for GlaxoSmithKline by:

398 Catalent Pharma Solutions

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