State Boards of Pharmacy ,

Regarding the name change of Omacor to Lovaza and your request for information that may help educate your pharmacists, I've attached:

1. Document that addresses most of the questions that have arisen
2. Picture of the capsule (identical for both Omacor and Lovaza).

Immediately below, for your personal edification, are some of the questions that I've been fielding from various retail settings.

OMACOR is changing to LOVAZA. New name, new NDC#s, but it is the same medication.

Why is the name changing?

- Patient safety is of utmost importance
- Reliant Pharmaceuticals is taking this step at the request of the FDA in response to a limited number of prescribing and dispensing errors due to similarity in the name between OMACOR and Amicar

Same efficacy, safety and tolerability

- Size, strength and ingredients of the OMACOR gel capsule will remain unchanged. Only the name and NDC#s are changing

When?

- LOVAZA will begin shipping mid-July. Please sell through existing OMACOR until stock is exhausted or if you have a specific prescription for LOVAZA
- Reliant will begin marketing to physicians and industry August 1, 2007

I hope the attached information will be helpful to you in providing important information to your pharmacists. Please contact me if there are any questions or concerns. Thank you.

Sincerely,

Ron Moore
Associate Director Trade
Reliant Pharmaceuticals Inc

The name OMACOR® (Omega-3-acid ethyl esters) will be LOVAZA™

Dear Pharmacy Professional:

At Reliant Pharmaceuticals, Inc., patient safety is of paramount importance, which is why we are changing the name of OMACOR to LOVAZA. Reliant Pharmaceuticals, Inc. is taking this step at the request of the US Food and Drug Administration (FDA) and in response to a limited number of reports of prescribing and dispensing errors[1] due to similarity in name between the company's OMACOR® (omega-3-acid ethyl esters) capsules and Xanodyne Pharmaceuticals' Amicar® (aminocaproic acid).[2] The name change is intended to minimize the potential for such errors in the future. Packaging bearing the name LOVAZA will be available in pharmacies later this summer.

OMACOR		
Current NDC (65726)	Was Brand Name	Pkg Size
65726-0424-15	Was OMACOR	60
65726-0424-27	Was OMACOR	120

LOVAZA		
Current NDC (65726)	**New Brand Name**	Pkg Size
65726-0425-15	Will be LOVAZA	60
65726-0425-27	Will be LOVAZA	120

Indications and usage

OMACOR is indicated as an adjunct to diet to reduce very high (≥500 mg/dL) triglyceride (TG) levels in adult patients. Diseases contributory to hyperlipidemia (such as hypothyroidism or diabetes mellitus) should be looked for and adequately treated. Certain drugs (estrogen, thiazide diuretics and beta blockers) are sometimes associated with very significant rises in serum TG levels. Discontinuation of the specific agent may obviate the need for specific HTG drug therapy.

Use of lipid-regulating agents should be considered only when reasonable attempts have been made to obtain satisfactory results with non-drug methods, including addressing excess body weight and excess alcohol intake. The patient should be advised that use of lipid-regulating agents does not reduce the importance of adhering to diet. (See PRECAUTIONS section of full prescribing information.)

The effect of OMACOR on the risk of pancreatitis in patients with very high TG levels has not been evaluated; and the risk of cardiovascular mortality and morbidity in patients with very high TG levels has not been determined.

Important Safety Information:

OMACOR is contraindicated in patients who exhibit hypersensitivity to any component of this medication. Lab studies should be performed to ascertain that the patient's TG levels are consistently abnormal before instituting OMACOR. OMACOR should be used with caution in patients with known sensitivity or allergy to fish. Lab studies should be performed periodically to measure patient's lipid (TG and LDL-C) and ALT levels during OMACOR therapy. OMACOR therapy should be withdrawn in patients who do not have an adequate response after 2 months of treatment. In some patients, OMACOR increased LDL-C. As with any lipid-regulating product, LDL-C levels should be monitored during OMACOR therapy. Some studies with omega-3-acids demonstrated prolongation of bleeding time, which did not exceed normal limits and did not produce clinically significant bleeding episodes. Patients receiving treatment with both OMACOR and anticoagulants should be monitored periodically. There are no adequate and well-controlled studies in pregnant or breastfeeding women. Use OMACOR during pregnancy only if the potential benefit justifies the potential risk to the fetus. Use caution when administering OMACOR to breastfeeding women. OMACOR was well-tolerated in controlled studies. The most common adverse events reported were: eructation, infection, flu syndrome, dyspepsia, rash, taste perversion, and back pain. Please see full prescribing information.

Sincerely,

Chuck Anadore
National Director
Trade Sales

Please visit www.OMACORrx.com for more information or contact us at 1-877-311-7515.

References:

1. Data on File. Reliant Pharmaceutical, Inc.
2. AMICAR® is a registered trademark of Xanodyne Pharmaceuticals, Inc.

Reliant PHARMACEUTICALS, INC.

Reliant Pharmaceuticals, Inc.
Liberty Corner, NJ 07938

OMACOR®
Omega-3-acid ethyl esters

 ROMA-2081 July 2007

Retail and Trade

FREQUENTLY ASKED QUESTIONS

Reliant Pharmaceuticals, Inc. Changing Name of Omacor® (omega-3-acid ethyl esters) to Lovaza™ (omega-3-acid ethyl esters)

Q1: **Why is Reliant Pharmaceuticals, Inc. changing the name of Omacor to Lovaza?**

A1: Reliant is taking this step at the request of the U.S. Food and Drug Administration (FDA) and in response to a limited number of reports of prescribing and dispensing errors[1] due to similarity in name between the company's Omacor capsules and Xanodyne Pharmaceuticals' Amicar® (aminocaproic acid).[2] Reliant is committed to patient safety, and the name change is intended to minimize the potential for such errors in the future.

Q2: What steps is Reliant taking to implement the name change?

A2: Reliant is committed to working with physicians, pharmacists and the FDA to protect patient safety. The company is implementing a comprehensive communications plan and has been working with the FDA to ensure that healthcare professionals, managed care groups, insurers and patients are made aware of the name change.[1] This includes alerting healthcare professionals via letter,[3,4,5] email and phone; through direct contact with sales representatives; on the Omacor Web site, www.OMACORrx.com; and through the media. Additionally, we expect that packaging bearing the name Lovaza will be available in pharmacies this summer.

Q3: When will capsules and prescriptions with the Lovaza name be available in pharmacies?

A3: Lovaza capsules are identical to the Omacor capsules that are currently available in pharmacies bearing the name REL900.[1] This will not change. We expect that packaging bearing the name Lovaza will be available in pharmacies this summer.

Q4: Will Lovaza have new National Drug Code (NDC) numbers?

A4: Yes, Lovaza will have new NDC numbers:

NDC (65726)	'Brand Name'	'Generic Name'	Str	'Form'	Pkg Size'
65726-0425-15	Lovaza	omega-3-acid ethyl esters	1gr	Gel Cap	60
65726-0425-27	Lovaza	omega-3-acid ethyl esters	1gr	Gel Cap	120

Q5: What is the difference between Omacor and Amicar?

A5: The indicated uses for Omacor and Amicar are very different.[6,7] Omacor is approved[8] as an adjunct to diet to reduce very high triglyceride levels (greater than or equal to 500 mg/dL) in adult patients.[6] Please see enclosed full prescribing information and important safety information on Omacor. According to the package insert that accompanies the product, Amicar is indicated for enhancing hemostasis when fibrinolysis contributes to bleeding.[7] For more information about Amicar, ask your healthcare provider or go to www.xanodyne.com.

Q6: Has there been any change to the gelcap itself?

A6: No, this is a name change only. The gelcap itself remains unchanged.

Q7: Where can I find more information about Lovaza and the name change?

A7: To learn more about Lovaza and the name change, please visit the Omacor Web site at www.OMACORrx.com or call 877-311-7515.

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[1] Data on file. Reliant Pharmaceuticals, Inc.
[2] Amicar® is a registered trademark of Xanodyne Pharmaceuticals, Inc.
[3] Alert: Omacor Capsules and Amicar Tablets Medication Error. 11/05. Accessed 1/29/07. Available at: http://www.omacorrx.com/HCP/OMACOR_Physician_Letter.pdf.
[4] Alert: Omacor Capsules and Amicar Tablets Dispensing Error. 11/05. Accessed 1/29/07. Available at: http://www.omacorrx.com/HCP/Pharmacist_Letter_Nov_2005.pdf.
[5] Immediate Attention Required, Dispensing Errors Alert, Omacor Capsules and Amicar Tablets Dispensing Errors. 2/24/06. Accessed 1/29/07. Available at: http://www.omacorrx.com/HCP/OMACOR_Pharmacist_Letter.pdf.
[6] Omacor [package insert]. Liberty Corner, NJ: Reliant Pharmaceuticals, Inc; 2005.
[7] Amicar [package insert]. Newport, KY: Xanodyne Pharmaceuticals, Inc; 2005.
[8] Center for Drug Evaluation and Research: Approval Package for Application Number 21-654. Approval Letter(s). From Dr. Robert J. Meyer Director, Office of New Drug Evaluation. 11/10/04. Accessed 1/29/07. Available at: http://www.fda.gov/cder/foi/nda/2004/21-654_Omacor_Approv.pdf.

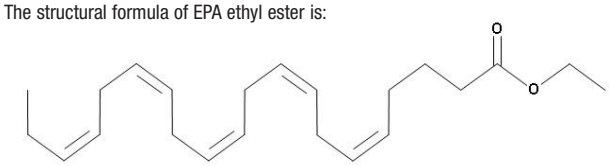
14251511
LOVAZA™
(omega-3-acid ethyl esters)
Capsules

LOVAZA™
(omega-3-acid ethyl esters)
Capsules
14251511
14251511

LOVAZA™
(omega-3-acid ethyl esters) Capsules

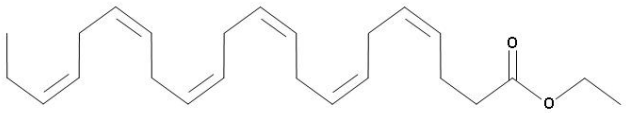
DESCRIPTION
Lovaza, a lipid-regulating agent, is supplied as a liquid-filled gel capsule for oral administration. Each one gram capsule of Lovaza (omega-3-acid ethyl esters) contains at least 900 mg of the ethyl esters of omega-3 fatty acids. These are predominantly a combination of ethyl esters of eicosapentaenoic acid (EPA - approximately 465 mg) and docosahexaenoic acid (DHA - approximately 375 mg).

The structural formula of EPA ethyl ester is:



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

The structural formula of DHA ethyl ester is:



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

Lovaza capsules also contain the following inactive ingredients: 4 mg α-tocopherol (in a carrier of partially hydrogenated vegetable oils including soybean oil), and gelatin, glycerol, and purified water (components of the capsule shell).

CLINICAL PHARMACOLOGY
Mechanism of Action:
The mechanism of action of Lovaza is not completely understood. Potential mechanisms of action include inhibition of acyl CoA:1,2-diacylglycerol acyltransferase and increased peroxisomal β-oxidation in the liver. Lovaza may reduce the synthesis of triglycerides (TGs) in the liver because EPA and DHA are poor substrates for the enzymes responsible for TG synthesis, and EPA and DHA inhibit esterification of other fatty acids.

Pharmacokinetic and Bioavailability Studies:
In healthy volunteers and in patients with hypertriglyceridemia (HTG), EPA and DHA were absorbed when administered as ethyl esters orally. Omega-3-acids administered as ethyl esters (Lovaza) induced significant, dose-dependent increases in serum phospholipid EPA content, though increases in DHA content were less marked and not dose-dependent when administered as ethyl esters. Uptake of EPA and DHA into serum phospholipids in subjects treated with Lovaza was independent of age (<49 years vs. ≥49 years). Females tended to have more uptake of EPA into serum phospholipids than males. Pharmacokinetic data on Lovaza in children are not available.

Drug Interactions:
Cytochrome P450-Dependent Monooxygenase Activities: The effect of a mixture of free fatty acids (FFA), EPA/DHA and their FFA-albumin conjugate on cytochrome P450-dependent monooxygenase activities was assessed in human liver microsomes. At the 23 μM concentration, FFA resulted in a less than 32% inhibition of CYP1A2, 2A6, 2C9, 2C19, 2D6, 2E1, and 3A. At the 23 μM concentration, the FFA-albumin conjugate resulted in a less than 20% inhibition of CYP2A6, 2C19, 2D6, and 3A, with a 68% inhibition being seen for CYP2E1. Since the free forms of the EPA and DHA are undetectable in the circulation (<1 μM), clinically significant drug-drug interactions due to inhibition of P450 mediated metabolism EPA/DHA combinations are not expected in humans.

CLINICAL STUDIES
The effects of Lovaza 4 g per day were assessed in two randomized, placebo-controlled, double-blind, parallel-group studies of 84 adult patients (42 on Lovaza, 42 on placebo) with very high triglyceride levels (Table 1). Patients whose baseline triglyceride levels were between 500 and 2000 mg/dL were enrolled in these two studies of 6 and 16 weeks duration. The median triglyceride and LDL-C levels in these patients were 792 mg/dL and 100 mg/dL, respectively. Median HDL-C level was 23.0 mg/dL.

Table 1. Median Baseline and Percent Change From Baseline in Lipid Parameters in Patients with Very High TG Levels (500 mg/dL)

	TG		LDL-C		CHOL		HDL-C		VLDL-C		non-HDL-C	
	BL	% Chg	BL	% Chg	BL	% Chg	BL	% Chg	BL	% Chg	BL	% Chg
Placebo	788	+6.7	108	-4.8	314	-1.7	24	0.0	175	-0.9	292	-3.6
Lovaza 4 g/day	816	-44.9	89	+44.5	296	-9.7	22	+9.1	175	-41.7	271	-13.8
Difference		-51.6		+49.3		-8.0		+9.1		-40.8		-10.2

BL = Baseline (mg/dL); % Chg = Percent Change from Baseline; Difference = Lovaza - Placebo

LOVAZA™
(omega-3-acid ethyl esters) Capsules

Lovaza 4 g per day reduced median TG, VLDL-C, and non-HDL-C levels and increased median HDL-C from baseline relative to placebo. Lovaza treatment to reduce very high TG levels may result in elevations in LDL-C and non-HDL-C in some individuals. Patients should be monitored to ensure that the LDL-C level does not increase excessively.

The effect of Lovaza on the risk of pancreatitis in patients with very high TG levels has not been evaluated. The effect of Lovaza on cardiovascular mortality and morbidity in patients with very high TG levels has not been determined.

INDICATIONS AND USAGE
Lovaza is indicated as an adjunct to diet to reduce very high (500 mg/dL) triglyceride (TG) levels in adult patients.

Usage Considerations:
According to accepted clinical guidelines, excess body weight and excess alcohol intake may be important factors in hypertriglyceridemia (HTG) and should be addressed before initiating any drug therapy. Physical exercise can be an important ancillary measure. Diseases contributory to hyperlipidemia (such as hypothyroidism or diabetes mellitus) should be looked for and adequately treated. Estrogen therapy, thiazide diuretics, and beta blockers are sometimes associated with massive rises in plasma TG levels. In such cases, discontinuation of the specific etiologic agent may obviate the need for specific drug therapy for HTG.

The use of lipid-regulating agents should be considered only when reasonable attempts have been made to obtain satisfactory results with non-drug methods. If the decision is made to use lipid-regulating agents, the patient should be advised that use of lipid-regulating agents does not reduce the importance of adhering to diet. (See PRECAUTIONS).

CONTRAINDICATIONS
Lovaza is contraindicated in patients who exhibit hypersensitivity to any component of this medication.

PRECAUTIONS
General:
Initial Therapy: Laboratory studies should be performed to ascertain that the patient's TG levels are consistently abnormal before instituting Lovaza therapy. Every attempt should be made to control serum TG levels with appropriate diet, exercise, weight loss in overweight patients, and control of any medical problems (such as diabetes mellitus and hypothyroidism) that may be contributing to the patient's TG abnormalities. Medications known to exacerbate HTG (such as beta blockers, thiazides, and estrogens) should be discontinued or changed, if possible, before considering TG-lowering drug therapy.

Continued Therapy: Laboratory studies should be performed periodically to measure the patient's TG levels during Lovaza therapy. Lovaza therapy should be withdrawn in patients who do not have an adequate response after 2 months of treatment.

Information for Patients:
Lovaza should be used with caution in patients with known sensitivity or allergy to fish. Patients should be advised that use of lipid-regulating agents does not reduce the importance of adhering to diet.

Laboratory Tests:
In some patients, increases in alanine aminotransferase (ALT) levels without a concurrent increase in aspartate aminotransferase (AST) levels were observed. Alanine aminotransferase levels should be monitored periodically during Lovaza therapy. In some patients, Lovaza increased low-density lipoprotein cholesterol (LDL-C) levels. As with any lipid-regulating product, LDL-C levels should be monitored periodically during Lovaza therapy.

Drug Interactions:
Anticoagulants: Some studies with omega-3-acids demonstrated prolongation of bleeding time. The prolongation of bleeding time reported in these studies has not exceeded normal limits and did not produce clinically significant bleeding episodes. Clinical studies have not been done to thoroughly examine the effect of Lovaza and concomitant anticoagulants. Patients receiving treatment with both Lovaza and anticoagulants should be monitored periodically.

Cytochrome P450-Dependent Monooxygenase Activities: Omega-3-fatty acid containing products have been shown to increase hepatic concentrations of cytochrome P450 and activities of certain P450 enzymes in rats. The potential of Lovaza to induce P450 activities in humans has not been studied.

Carcinogenesis, Mutagenesis, Impairment of Fertility:
In a rat carcinogenicity study with oral gavage doses of 100, 600, 2000 mg/kg/day by oral gavage, males were treated with omega-3-acid ethyl esters for 101 weeks and females for 89 weeks without an increased incidence of tumors (up to 5 times human systemic exposures following an oral dose of 4 g/day based on a body surface area comparison). Standard lifetime carcinogenicity bioassays were not conducted in mice.

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

In a rat fertility study with oral gavage doses of 100, 600, 2000 mg/kg/day, males were treated for 10 weeks prior to mating and females were treated for 2 weeks prior to and throughout

mating, gestation and lactation. No adverse effect on fertility was observed at 2000 mg/kg/day (5 times human systemic exposure following an oral dose of 4 g/day based on a body surface area comparison).

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

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

In female rats given oral gavage doses of 100, 600, 2000 mg/kg/day beginning two weeks prior to mating and continuing through gestation and lactation, no adverse effects were observed in the high dose group (5 times human systemic exposure following an oral dose of 4 g/day based on body surface area comparison).

In pregnant rats given oral gavage doses of 1000, 3000, 6000 mg/kg/day from gestation day 6 through 15, no adverse effects were observed (14 times human systemic exposure following an oral dose of 4 g/day based on a body surface area comparison).

In pregnant rats given oral gavage doses of 100, 600, 2000 mg/kg/day from gestation day 14 through lactation day 21, no adverse effects were seen at 2000 mg/kg/day (5 times the human systemic exposure following an oral dose of 4 g/day based on a body surface area comparison). However, decreased live births (20% reduction) and decreased survival to postnatal day 4 (40% reduction) were observed in a dose-ranging study using higher doses of 3000 mg/kg/day (7 times the human systemic exposure following an oral dose of 4 g/day based on a body surface area comparison).

In pregnant rabbits given oral gavage doses of 375, 750, 1500 mg/kg/day from gestation day 7 through 19, no findings were observed in the fetuses in groups given 375 mg/kg/day (2 times human systemic exposure following an oral dose of 4 g/day based on a body surface area comparison). However, at higher doses, evidence of maternal toxicity was observed (4 times human systemic exposure following an oral dose of 4 g/day based on a body surface area comparison).

Nursing Mothers:
It is not known whether omega-3-acid ethyl esters are excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Lovaza is administered to a woman who is breastfeeding.

Pediatric Use:
Safety and effectiveness in pediatric patients under 18 years of age have not been established.

Geriatric Use:
A limited number of patients over 65 years of age were enrolled in the clinical studies. In the pooled analyses, safety and efficacy findings in subjects over 60 years of age (approximately 25% of the study population) did not appear to differ from those of subjects less than 60 years of age.

ADVERSE REACTIONS

Treatment-emergent adverse events reported in at least 1% of patients treated with Lovaza 4 g per day or placebo during 8 randomized, placebo-controlled, double-blind, parallel-group studies for HTG are listed in Table 2. Adverse events led to discontinuation of treatment in 3.5% of patients treated with Lovaza and 2.6% of patients treated with placebo.

Table 2. Adverse Events in Randomized, Placebo-Controlled, Double-Blind, Parallel-Group Studies for Hypertriglyceridemia that Used Lovaza 4 g per Day

BODY SYSTEM	Lovaza (N = 226)		Placebo* (N = 228)	
Adverse Event	**n**	**%**	**n**	**%**
Subjects with at least 1 adverse event	80	35.4	63	27.6
Body as a whole				
Back pain	5	2.2	3	1.3
Flu syndrome	8	3.5	3	1.3
Infection	10	4.4	5	2.2
Pain	4	1.8	3	1.3
Cardiovascular				
Angina pectoris	3	1.3	2	0.9
Digestive				
Dyspepsia	7	3.1	6	2.6
Eructation	11	4.9	5	2.2
Skin				
Rash	4	1.8	1	0.4
Special senses				
Taste perversion	6	2.7	0	0.0

Adverse events were coded using COSTART, version 5.0. Subjects were counted only once for each body system and for each preferred term.
*Placebo was corn oil for all studies.

LOVAZA™
(omega-3-acid ethyl esters) Capsules

Additional adverse events reported by 1 or more patients from 22 clinical studies for HTG are listed below:

BODY AS A WHOLE: Enlarged abdomen, asthenia, body odor, chest pain, chills, suicide, fever, generalized edema, fungal infection, malaise, neck pain, neoplasm, rheumatoid arthritis, sudden death, and viral infection.
CARDIOVASCULAR SYSTEM: Arrhythmia, bypass surgery, cardiac arrest, hyperlipidemia, hypertension, migraine, myocardial infarction, myocardial ischemia, occlusion, peripheral vascular disorder, syncope, and tachycardia.
DIGESTIVE SYSTEM: Anorexia, constipation, dry mouth, dysphagia, colitis, fecal incontinence, gastritis, gastroenteritis, gastrointestinal disorder, increased appetite, intestinal obstruction, melena, pancreatitis, tenesmus, and vomiting.
HEMATOLOGIC-LYMPHATIC SYSTEM: Lymphadenopathy.
METABOLIC AND NUTRITIONAL DISORDERS: Edema, hyperglycemia, increased ALT, and increased AST.
MUSCULOSKELETAL SYSTEM: Arthralgia, arthritis, myalgia, pathological fracture, and tendon disorder.
NERVOUS SYSTEM: Central nervous system neoplasia, depression, dizziness, emotional lability, facial paralysis, insomnia, vasodilatation, and vertigo.
RESPIRATORY SYSTEM: Asthma, bronchitis, increased cough, dyspnea, epistaxis, laryngitis, pharyngitis, pneumonia, rhinitis, and sinusitis.
SKIN: Alopecia, eczema, pruritus, and sweating.
SPECIAL SENSES: Cataract.
UROGENITAL SYSTEM: Cervix disorder, endometrial carcinoma, epididymitis, and impotence.

DRUG ABUSE AND DEPENDENCE

Lovaza does not have any known drug abuse or withdrawal effects.

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

Patients should be placed on an appropriate lipid-lowering diet before receiving Lovaza, and should continue this diet during treatment with Lovaza. In clinical studies, Lovaza was administered with meals.

The daily dose of Lovaza is 4 g per day. The daily dose may be taken as a single 4-g dose (4 capsules) or as two 2-g doses (2 capsules given twice daily).

HOW SUPPLIED

Lovaza (omega-3-acid ethyl esters) capsules are supplied as 1-gram transparent soft-gelatin capsules filled with light-yellow oil and bearing the designation REL900 in bottles of 60 (NDC 65726-425-15) and 120 (NDC 65726-425-27).

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

Rx only

Revised: April 2007

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