HIGHLIGHTS OF PRESCRIBING INFORMATION

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

OMTRYG (omega-3-acid ethyl esters) capsules, USP, for oral use
Initial U.S. Approval: 2004

---------- INDICATIONS AND USAGE ----------

OMTRYG is a combination of ethyl esters of omega-3 fatty acids, principally eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe hypertriglyceridemia (TG greater than or equal to 500 mg/dL). (1)

Limitations of Use:

- The effect of OMTRYG on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined. (1)
- The effect of OMTRYG on cardiovascular mortality and morbidity has not been determined. (1)

---------- DOSAGE AND ADMINISTRATION ----------

- The recommended daily dosage of OMTRYG is 4 capsules per day taken as a single dose or as 2 capsules given twice daily. Take OMTRYG with meals. (2)
- Swallow OMTRYG capsules whole. Do not break open, crush, dissolve or chew OMTRYG capsules. (2)
- Advise patients to initiate appropriate physical activity and a lipid-lowering diet before receiving OMTRYG and continue these during treatment with OMTRYG. (2)

---------- DOSAGE FORMS AND STRENGTHS ----------

Capsules: 1.2 grams. (3)

---------- CONTRAINDICATIONS ----------

Patients with known hypersensitivity (e.g., anaphylactic reaction) to omega-3-acid ethyl esters or any of the ingredients in OMTRYG. (4)

---------- WARNINGS AND PRECAUTIONS ----------

- In patients with hepatic impairment, monitor ALT and AST levels periodically during therapy. (5.1)
- OMTRYG may increase levels of low-density lipoprotein (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 omega-3-acid ethyl esters 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 Vertical Pharmaceuticals, LLC at 1-800-541-4802 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---------- DRUG INTERACTIONS ----------

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

SEE 17 FOR PATIENT COUNSELING INFORMATION AND FDA-APPROVED PATIENT LABELING

Revised: 06/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

OMTRYG™ (omega-3-acid ethyl esters) capsules, USP, is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe hypertriglyceridemia (TG greater than or equal to 500 mg/dL).

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

Laboratory studies should be done to ascertain that the lipid levels are consistently abnormal before instituting OMTRYG 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 OMTRYG on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.

The effect of OMTRYG on cardiovascular mortality and morbidity has not been determined.

2 DOSAGE AND ADMINISTRATION

- Assess TG levels before initiating therapy. Identify other causes (e.g., diabetes mellitus, hypothyroidism, or medications) of high TG levels and manage as appropriate *[see Indications and Usage (1)]*.
- Advise patients to initiate appropriate physical activity and a lipid-lowering diet before receiving OMTRYG and continue these during treatment with OMTRYG.
- The recommended daily dosage of OMTRYG is 4 capsules per day taken as a single dose or as 2 capsules given twice daily. Take OMTRYG with meals *[see Clinical Pharmacology (12.3)]*.
- Advise patients to swallow OMTRYG capsules whole. Do not break open, crush, dissolve or chew OMTRYG capsules.

3 DOSAGE FORMS AND STRENGTHS

OMTRYG (omega-3-acid ethyl esters) capsules, USP, are supplied as 1.2-gram, transparent, soft-gelatin capsules filled with light-yellow oil and bearing the designation TP0001.

4 CONTRAINDICATIONS

OMTRYG is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to omega-3-acid ethyl esters or any of the ingredients in OMTRYG.

5 WARNINGS AND PRECAUTIONS

5.1 Monitoring: Laboratory Tests

In patients with hepatic impairment, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels should be monitored periodically during therapy with OMTRYG.

In some patients, OMTRYG increases LDL-cholesterol levels. LDL-cholesterol levels should be monitored periodically during therapy with OMTRYG.

5.2 Potential for Allergic Reactions in Patients with Fish Allergy

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

5.3 Recurrent Atrial Fibrillation (AF) or Flutter

In a double-blind, placebo-controlled trial of 663 patients with symptomatic paroxysmal AF (n=542) or persistent AF (n=121), recurrent AF or flutter was observed in patients randomized to another omega-3-acid ethyl esters product who received 8 grams/day for 7 days and 4 grams/day thereafter for 23 weeks at a higher rate relative to placebo. Patients in this trial had median baseline TG levels of 127 mg/dL, had no substantial structural heart disease, were taking no anti-arrhythmic therapy (rate control permitted), and were in normal sinus rhythm at baseline.

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

OMTRYG is not indicated for the treatment of AF or flutter.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

The following important adverse reactions are described below and elsewhere in the labeling:

- Potential for Allergic Reactions in Patients with Fish Allergy *[see Warnings and Precautions (5.1)]*
- Recurrent AF or Atrial Flutter *[see Warnings and Precautions (5.2)]*

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

The safety of OMTRYG has been established in adequate and well-controlled trials of another omega-3 acid ethyl esters product.

Adverse reactions reported in at least 3% and at a greater rate than placebo for patients treated with omega-3-acid ethyl esters based on pooled data across 23 clinical studies are listed in Table 1.

Table 1. Adverse Reactions Occurring at Incidence ≥3% and Greater than Placebo in Clinical Studies of Omega-3-Acid Ethyl Esters

Body System	Omega-3-Acid Ethyl Esters† (N = 655)		Placebo (N = 370)	
Adverse Reaction*	**n**	**%**	**n**	**%**
Eructation	29	4	5	1
Dyspepsia	22	3	6	2
Taste perversion	27	4	1	<1

* Studies included subjects with HTG and severe HTG.
† OMTRYG and omega-3-acid ethyl esters each contain, among other components, at least 900 mg per capsule of ethyl esters from omega-3 fatty acids sourced from fish oils.

Additional adverse reactions from clinical studies are listed below:

Digestive System: Constipation, gastrointestinal disorder, and vomiting.

Metabolic and Nutritional Disorders: Increased ALT and increased AST.

Skin: Pruritus and rash.

6.2 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of omega-3-acid ethyl esters. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

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

7 DRUG INTERACTIONS

7.1 Anticoagulants or Other Drugs Affecting Coagulation

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 OMTRYG and concomitant anticoagulants. Patients receiving treatment with OMTRYG and an anticoagulant or other drug affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary:

The available data from published case reports and the pharmacovigilance database on the use of omega-3-acid ethyl esters in pregnant women are insufficient to identify a drug-associated risk for major birth defects, miscarriage, or adverse maternal or fetal outcomes. In animal studies, omega-3-acid ethyl esters given orally to female rats prior to mating through lactation did not have adverse effects on reproduction or development when given at doses 5 times the maximum recommended human dose (MRHD) of approximately 4 grams/day, based on a body surface area comparison. Omega-3-acid ethyl esters given orally to rats and rabbits during organogenesis was not teratogenic at clinically relevant exposures, based on body surface area comparison *(see Data).*

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data:

Animal Data

In female rats given oral doses of omega-3-acid ethyl esters (100, 600, or 2,000 mg/kg/day) beginning 2 weeks prior to mating through lactation, no adverse effects were observed at 2,000 mg/kg/day (approximately 5 times the MRHD based on body surface area [mg/m^2]).

In a dose-ranging study, female rats given oral doses of omega-3-acid ethyl esters (1,000, 3,000, or 6,000 mg/kg/day) beginning 2 weeks prior to mating through Postpartum Day 7 had decreased live births (20% reduction) and pup survival to Postnatal Day 4 (40% reduction) at or greater than 3,000 mg/kg/day in the absence of maternal toxicity at 3,000 mg/kg/day (approximately 7 times the MRHD based on body surface area [mg/m^2]).

In pregnant rats given oral doses of omega-3-acid ethyl esters (1,000, 3,000, and 6,000 mg/kg/day) during organogenesis, no adverse effects were observed in fetuses at a maternally toxic dose (increased food consumption) of 6,000 mg/kg/day (approximately 14 times the MRHD based on body surface area [mg/m^2]). In pregnant rats given oral doses of omega-3-acid ethyl esters (100, 600, or 2,000 mg/kg/day) from gestation day 14 through lactation day 21, no adverse effects were seen at 2,000 mg/kg/day (approximately 5 times the MRHD based on body surface area [mg/m^2]).

In pregnant rabbits given oral doses of omega-3-acid ethyl esters (375, 750, or 1,500 mg/kg/day) during organogenesis, no adverse effects were observed in fetuses given 375 mg/kg/day (approximately 2 times the MRHD based on body surface area [mg/m^2]). However, at higher doses, increases in fetal skeletal variations and reduced fetal growth were evident at maternally toxic doses (reduced food consumption and body weight gain) greater than or equal to 750 mg/kg/day (approximately 4 times the MRHD) and embryolethality was evident at 1500 mg/kg/day (approximately 7 times the MRHD).

8.2 Lactation

Risk Summary

Published studies have detected omega-3 fatty acids, including EPA and DHA, in human milk. Lactating women receiving oral omega-3 fatty acids for supplementation have resulted in higher levels of omega-3 fatty acids in human milk. There are no data available on the effects of OMTRYG on the breastfed infant or on milk production.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for OMTRYG and any potential adverse effects on the breastfed child from OMTRYG or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

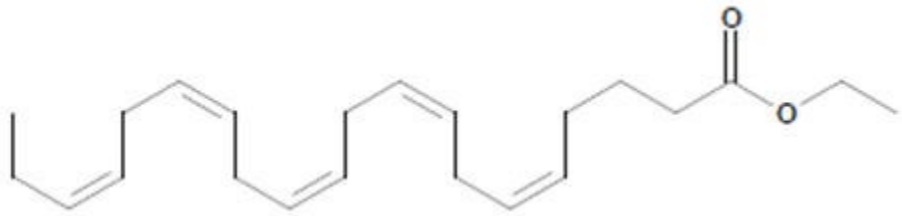
8.5 Geriatric Use

A limited number of patients older than 65 years were enrolled in the clinical studies of omega-3-acid ethyl esters. Safety and efficacy findings in subjects older than 60 years did not appear to differ from those of younger adult patients.

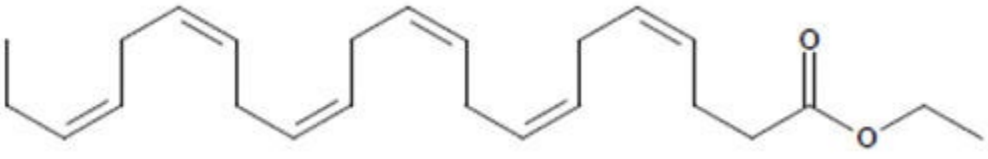
11 DESCRIPTION

OMTRYG, a lipid-regulating agent, is supplied as a liquid-filled gel capsule for oral administration. Each OMTRYG capsule contains 1.2 grams of omega-3-acid ethyl esters type A, USP, liquid concentrate consisting of at least 900 mg omega-3-acid ethyl esters sourced from fish oils. These are predominantly a combination of ethyl esters of eicosapentaenoic acid (EPA - approximately 465 mg) and docosahexaenoic acid (DHA - approximately 375 mg).

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 EPA 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. The structural formula of DHA ethyl ester is:



OMTRYG capsules also contain the following inactive ingredients: 4.6 mg α-tocopherol (in a carrier of sunflower oil), gelatin, glycerol, and purified water (components of the capsule shell).

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of OMTRYG is not completely understood. Potential mechanisms of action include inhibition of acyl-CoA:1,2-diacylglycerol acyltransferase, increased mitochondrial and peroxisomal ß-oxidation in the liver, decreased lipogenesis in the liver, and increased plasma lipoprotein lipase activity. Omega-3-acid ethyl esters may reduce the synthesis of TG 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.

12.3 Pharmacokinetics

Absorption:

When OMTRYG was administered under fasted condition, on average the peak (C_{max}) and total (AUC_{0-72h}) exposure were lower by up to 20 to 80-fold, respectively, for total plasma EPA, and lower by up to 2 to 4-fold, respectively, for total plasma DHA, in comparison to those observed under fed condition (high-fat high-calorie meal). Therefore, OMTRYG should be taken with food.

In healthy volunteers and in patients with hypertriglyceridemia, EPA and DHA were absorbed when administered as ethyl esters orally. Omega-3-acids administered as ethyl esters 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.

Specific Populations:

Age: Uptake of EPA and DHA into serum phospholipids in subjects treated with omega-3-acid ethyl esters was independent of age (<49 years versus ≥49 years).

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

Pediatric Patients: Pharmacokinetics of OMTRYG have not been studied.

Patients with Renal or Hepatic Impairment: OMTRYG has not been studied in patients with renal or hepatic impairment.

Drug-Drug Interaction Studies:

Simvastatin: In a 14-day study of 24 healthy adult subjects, daily co-administration of simvastatin 80 mg with 4 capsules of omega-3-acid ethyl esters did not affect the extent (AUC) or rate (C_{max}) of exposure to simvastatin or the major active metabolite, beta-hydroxy simvastatin, at steady state.

Atorvastatin: In a 14-day study of 50 healthy adult subjects, daily co-administration of atorvastatin 80 mg with 4 capsules of omega-3-acid ethyl esters did not affect AUC or C_{max} of exposure to atorvastatin, 2-hydroxyatorvastatin, or 4-hydroxyatorvastatin at steady state.

Rosuvastatin: In a 14-day study of 48 healthy adult subjects, daily co-administration of rosuvastatin 40 mg with 4 capsules of omega-3-acid ethyl esters did not affect AUC or C_{max} of exposure to rosuvastatin at steady state.

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

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a rat carcinogenicity study with oral gavage doses of 100, 600, and 2,000 mg/kg/day, 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 grams/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, and 2,000 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 2,000 mg/kg/day (5 times the MRHD of approximately 4 grams/day based on body surface area).

14 CLINICAL STUDIES

14.1 Severe Hypertriglyceridemia

A randomized, double-blind, placebo-controlled study was conducted to evaluate the efficacy of OMTRYG compared with both placebo and an omega-3-acid ethyl esters product in 254 patients with severe hypertriglyceridemia (500-1500 mg/dL). Patients entered a 6-week wash-out/dietary lead-in period and then were randomized to 12-week treatment with either OMTRYG, omega-3-acid ethyl esters, or placebo (vegetable oil), each administered as 4 capsules once daily. Each capsule of both OMTRYG and omega-3-acid ethyl esters contains, among other components, at least 900 mg of ethyl esters from omega-3 fatty acids sourced from fish oils. The primary endpoint was percent change in serum TG from baseline to Week 12. The secondary endpoints were percent change in non-HDL-C, VLDL-C, LDL-C, and HDL-C from baseline to Week 12. Overall, the mean age was 51 years, 72% were men, 92% were White, the mean BMI was 33 kg/m^2, and 21% were taking a statin. The baseline median TG level was 675 mg/dL, mean LDL-C was 87 mg/dL, and mean HDL-C was 30 mg/dL.

OMTRYG statistically significantly reduced TG at Week 12 compared with placebo (p-value <0.05). The changes in the major lipid parameters for the groups receiving OMTRYG, omega-3-acid ethyl esters, and placebo are shown in Table 2.

Table 2. Median Baseline and Percent Change From Baseline in Lipid Parameters in Patients with Severe Hypertriglyceridemia (≥500 mg/dL)

	OMTRYG N = 104		Omega-3-Acid Ethyl Esters N=103		Placebo N = 43		Median difference from Placebo	
Parameter	**BL**	**% Change**	**BL**	**% Change**	**BL**	**% Change**	**OMTRYG vs. Placebo**	**Omega-3-Acid EE vs. Placebo**
TG	702	-24.7	655	-26.8	624	-17.4	-12.2*	-14.0*
Non-HDL-C	237	-9.2	210	-3.6	222	-0.8	-8.5	-3.5
TC	270	-8.1	244	-1.0	250	-0.8	-6.9	-1.9
VLDL-C	153	-21.2	117	-18.0	114	+5.6	-28.7**	-23.7*
HDL-C	28	0.0	30	0.0	30	0.0	+3.9	+5.2
LDL-C	78	+20.3	85	+12.8	94	-5.9	+24.7**	+18.9*

BL = Baseline (mg/dL) median; % Change = Median Percent Change from Baseline; Median difference from placebo = Hodges Lehmann median of all pairwise differences from placebo
* $p<0.05$, ** $p<0.01$, statistically significant difference between treatment groups based on the pre-specified Hommel method for controlling Type 1 error among the secondary endpoints.

The effects of omega-3-acid ethyl esters 4 capsules per day were assessed in 2 randomized, placebo-controlled, double-blind, parallel-group studies of 84 adult patients (42 on omega-3-acid ethyl esters, 42 on placebo) with severe hypertriglyceridemia. Patients whose baseline TG levels were between 500 and 2,000 mg/dL were enrolled in these 2 studies of 6 and 16 weeks duration. The median TG 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.

The changes in the major lipoprotein lipid parameters for the groups receiving omega-3-acid ethyl esters or placebo are shown in Table 3.

Table 3. Median Baseline and Percent Change From Baseline in Lipid Parameters in Patients with Severe Hypertriglyceridemia (≥500 mg/dL)

Parameter	Omega-3-Acid Ethyl Esters* 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

BL = Baseline (mg/dL); % Change = Median Percent Change from Baseline;
Difference = Omega-3-acid ethyl esters Median % Change – Placebo Median % Change
* OMTRYG and omega-3-acid ethyl esters each contain, among other components, at least 900 mg per capsule of ethyl esters from omega-3 fatty acids sourced from fish oils.

Omega-3-acid ethyl esters reduced median TG, VLDL-C, and non-HDL-C levels and increased HDL-C from baseline relative to placebo. Treatment with omega-3-acid ethyl esters 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 OMTRYG on the risk of pancreatitis has not been evaluated.

The effect of OMTRYG on cardiovascular mortality and morbidity has not been determined.

16 HOW SUPPLIED/STORAGE AND HANDLING

OMTRYG (omega-3-acid ethyl esters) capsules, USP, 1.2 grams, are supplied as type A transparent soft-gelatin capsules filled with light-yellow oil and bearing the designation TP0001.

Bottles of 120: NDC 68025-078-12

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

Dispense in a tight, light-resistant container.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved Patient Labeling (Patient Information)

- Use OMTRYG with caution in patients with known sensitivity or allergy to fish and/or shellfish *[see Warnings and Precautions (5.2)]*.
- Advise patients that use of lipid-regulating agents does not reduce the importance of adhering to diet *[see Dosage and Administration (2)]*.

- Advise patients to take OMTRYG as prescribed. If a dose is missed, patients should take it as soon as they remember. However, if they miss one day of OMTRYG, they should not double the dose when they take it.
- Advise patients to take OMTRYG capsules with meals *[see Dosage and Administration (2)]*.
- Advise patients to swallow OMTRYG capsules whole. Do not break, open, crush, dissolve or chew OMTRYG *[see Dosage and Administration (2)]*.

Cut along the dotted line to remove Patient Information.

Manufactured for:

Vertical Pharmaceuticals, LLC
Alpharetta, GA 30005

89919-02

OMTRYG is a trademark of Osmotica Kereskedelmi és Szolgáltató Kft

PHARMACIST-DETACH HERE AND GIVE INSTRUCTIONS TO PATIENT

PATIENT INFORMATION

OMTRYG™ (om' trig)
(Omega-3-Acid Ethyl Esters)
Capsules, USP for oral use

Read this Patient Information before you start taking OMTRYG, 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 OMTRYG?

OMTRYG 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 OMTRYG changes your risk of having inflammation of your pancreas (pancreatitis).

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

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

Who should not take OMTRYG?

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

What should I tell my doctor before taking OMTRYG?

Before you take OMTRYG, 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 OMTRYG.
- are pregnant or plan to become pregnant. It is not known if OMTRYG will harm your unborn baby.
- are breastfeeding or plan to breastfeed. OMTRYG can pass into your breast milk. You and your doctor should decide if you will take OMTRYG or breastfeed.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicine, vitamins, and herbal supplements.

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

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

How should I take OMTRYG?

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

What are the possible side effects of OMTRYG?

OMTRYG may cause serious side effects, including:

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

The most common side effects of OMTRYG include:

- burping
- upset stomach
- a change in your sense of taste

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

These are not all the possible side effects of OMTRYG. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1 800-FDA-1088 or Vertical Pharmaceuticals, LLC at 1-800-541-4802.

How should I store OMTRYG?

- Store OMTRYG at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
- Do not freeze OMTRYG.
- Safely throw away medicine that is out of date or no longer needed.

Keep OMTRYG and all medicines out of the reach of children.

General information about the safe and effective use of OMTRYG

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

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

For more information call Customer Service at 1-800-541-4802.

What are the ingredients in OMTRYG?

Active Ingredient: omega-3-acid ethyl esters, mostly EPA and DHA

Inactive Ingredients: alpha-tocopherol (in sunflower oil), gelatin, glycerol, purified water

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

Manufactured for:

Vertical Pharmaceuticals, LLC
Alpharetta, GA 30005

89919-02-PPI

Rev. 06/2025