

OVEEZA- folic acid, methylcobalamin, alpha lipoic acid, ubidecarenone, omega-3 fatty acids, icosapent, and doconexent capsule, liquid filled
TriVue Pharmaceuticals, Inc.

Oveeza

KEEP OUT OF REACH OF CHILDREN.

Manufactured for: TriVue Pharmaceuticals, Inc. Birmingham, AL 35235

This product is not an Orange Book product.

Dispensed by Prescription†

MADE IN CANADA

Rev. 04/2020*

TriVue Pharmaceuticals does not represent these product codes to be National Drug Codes (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.† This product is a prescription-folate with or without other dietary ingredients that – due to increased folate levels increased risk associated with masking of B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (61 FR 8760). 1-3 The most appropriate way to ensure pedigree reporting consistent with these regulatory guidelines and safety monitoring is to dispense this product only by prescription. This is not an Orange Book product. This product may be administered only under a physician's supervision and all prescriptions using this product shall be pursuant to state statutes as applicable. The ingredients, indication or claims of this product are not to be construed to be drug claims.1. Federal Register Notice of August 2, 1973 (38 FR 20750)2. Federal Register Notice of October 17, 1980 (45 FR 69043, 69044) 3. Federal Register Notice of March 5, 1996 (61 FR 8760)

Dosage

Usual adult dose is 1-2 softgels once daily with a meal, or as prescribed by a licensed medical practitioner. If you are pregnant or nursing, ask a healthcare professional.

KEEP OUT OF REACH OF CHILDREN

STORAGE

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.]

Manufactured for: TriVue Pharmaceuticals, Inc., Birmingham, AL 35235

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DESCRIPTION

Oveeza Softgels is an orally administered prescription dietary supplement for the clinical dietary management of suboptimal nutritional status in patients where advanced folate, vitamin B, and Omega-3 supplementation, and maintenance of good health is needed.

CONTRAINDICATIONS

Oveeza Softgels are contraindicated in patients with a known hypersensitivity to any of the ingredients.

WARNINGS AND PRECAUTIONS

PRECAUTION

Use with caution in patients that may have a medical condition, planning surgery, have bleeding problems, are pregnant, lactating, trying to conceive, under the age of 18, or taking other medications. Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress. Oveeza Softgels should only be used under the direction and supervision of a licensed medical practitioner. Ingestion of more than 3 grams of omega-3 fatty acids (such as DHA and EPA) per day has been shown to have potential antithrombotic effects, including an increased bleeding time and International Normalized Ratio (INR). Administration of omega-3 fatty acids should be avoided in patients taking anticoagulants and in those known to have an inherited or acquired predisposition to bleeding.

Potential for Allergic Reactions in Patients with Fish Allergy: It is not known whether patients with allergies to fish and/or shellfish are at increased risk of an allergic reaction to products containing omega-3 fatty acid ethyl esters, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), derived from fish oil. Inform patients with known hypersensitivity to fish and/or shellfish about the potential for allergic reactions to Oveeza and advise them to discontinue and seek medical attention if any reactions occur.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. You may at 1-844-487-4883 or the FDA by calling 1-800-FDA-1088.

DOSAGE AND ADMINISTRATION

Usual adult dose is 1-2 softgels once daily with a meal, or as prescribed by a licensed medical practitioner. Patients should be advised to swallow Oveeza Softgels whole. Do not break open, crush, dissolve, or chew Oveeza Softgels. Do Not Exceed the Recommended Dosage.

HOW SUPPLIED

Oveeza Softgels are available as brown, oblong softgels imprinted with "404" and are available in 30-count bottles (73480-404-30*).

STORAGE

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.] Protect from heat, light and moisture. Tamper Evident: Do not use if seal is broken or missing.

Oveeza Softgels - Dietary Supplement Dispensed by Prescription†

Supplement Facts		
Serving Size: 2 Softgels	Servings per Bottle: 15	
Amount Per Serving		% Daily Value
	1,667 mcg DFE	
Folate (as folic acid)	(1 mg Folic Acid)	417%
Vitamin B12 (as	500 mcg	10,000%

methylcobalamin)	500 mcg	20,834%
Alpha Lipoic Acid (ALA)	100 mg	*
CoEnzyme Q-10 (ubiquinone)	100 mg	*
Total Omega-3 Fatty Acids	1125 mg	*
Eicosapentaenoic Acid (EPA)	600 mg	
Docosahexaenoic Acid (DHA)	450 mg	

* Daily Values (DV) not established.

OTHER INGREDIENTS Lecithin, Beeswax, Gelatin (Bovine), Glycerin, Annatto Ext, Titanium Dioxide, Purified water. CONTAINS: Fish and Soy.

PRINCIPAL DISPLAY PANEL - 30 Softgel Bottle Label

73480-404-30

OVEEZA
Softgels

Dietary Supplement

Dispensed by Prescription

30 Softgels

TRIVUE
PHARMACEUTICALS, INC.

Dosage: Usual adult dose is 1-2 softgels once daily with a meal, or as prescribed by a licensed medical practitioner.
If you are pregnant or nursing, ask a healthcare professional.

KEEP OUT OF REACH OF CHILDREN

STORAGE: Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature.]

Manufactured for:
TriVue Pharmaceuticals, Inc.,
Birmingham, AL 35235
MADE IN CANADA Rev. 04/2020



73480-404-30

OVEEZA

Softgels

Dietary Supplement

Dispensed by Prescription

30 Softgels



Supplement Facts

Serving Size: 2 Softgels Servings per Bottle: 15

Amount Per Serving	%Daily Value
Folate (as folic acid) 1,667 mcg DFE (1 mg Folic Acid)	417%
Vitamin B12 (as methylcobalamin) 500 mcg	20,834%
Alpha Lipoic Acid (ALA) 100 mg	*
CoEnzyme Q-10 (ubiquinone) 100 mg	*
Total Omega-3 Fatty Acids 1125 mg	*
Eicosapentaenoic Acid (EPA) 600 mg	
Docosahexaenoic Acid (DHA) 450 mg	

*Daily Values (DV) not established.

OTHER INGREDIENTS: Lecithin, Beeswax, Gelatin(Bovine), Glycerin, Annatto Ext, Titanium Dioxide, Purified water.

CONTAINS: Fish and Soy

Lift Here

OVEEZA

folic acid, methylcobalamin, alpha lipoic acid, ubidecarenone, omega-3 fatty acids, icosapent, and doconexent capsule, liquid filled

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:73480-404
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	0.5 mg
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	250 ug
ALPHA LIPOIC ACID (UNII: 73Y7P0K73Y) (ALPHA LIPOIC ACID - UNII:73Y7P0K73Y)	ALPHA LIPOIC ACID	50 mg
UBIDECARENONE (UNII: EJ27X76M46) (UBIDECARENONE - UNII:EJ27X76M46)	UBIDECARENONE	50 mg
OMEGA-3 FATTY ACIDS (UNII: 71M78END5S) (OMEGA-3 FATTY ACIDS - UNII:71M78END5S)	OMEGA-3 FATTY ACIDS	563 mg
ICOSAPENT (UNII: AAN7QOV9EA) (ICOSAPENT - UNII:AAN7QOV9EA)	ICOSAPENT	300 mg
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	225 mg

Inactive Ingredients

Ingredient Name	Strength
HYDROGENATED SOYBEAN LECITHIN (UNII: H1109Z9J4N)	
Yellow Wax (UNII: 2ZA36H0S2V)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
ANNATTO (UNII: 6PQP1V1B6O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:73480-404-30	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		04/30/2020	

Supplement Facts

Serving Size : **Serving per Container :**

	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	16 mm	

imprint

Labeler - TriVue Pharmaceuticals, Inc. (114003376)

Revised: 5/2020

TriVue Pharmaceuticals, Inc.