

PREGEN DHA- beta carotene, vitamin a palmitate, ascorbic acid, cholecalciferol, .alpha.-tocopherol, d-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, biotin, calcium pantothenate, calcium carbonate, iron, potassium iodide, magnesium oxide, zinc oxide, cupric oxide, and fish oil capsule, gelatin coated
Emerald Therapeutics, LLC

PreGen DHA

72919-083-30

Prenatal/Postnatal/Folate Health

Dietary Supplement

Dispensed by Prescription¹

1 This product is a prescription-folate with or without other dietary ingredients that - due to increased folate levels increased risk associated with masking B12 deficiency (pernicious anemia) requires administration under the care of a licensed medical practitioner (64 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)

Supplement Facts		
Serving Size: 1 Softgel		
Serving Per Container:		
	Amount Per Serving	% Daily Value
Calories	5	
Total Fat	0.5 g	<1%
Cholesterol	25 mg	8%
Vitamin A (50% Beta-Carotene, 50% Retinyl Palmitate)	1200 mcg RAE	133%
Vitamin C (as Ascorbic Acid)	60 mg	67%
Vitamin D (as Cholecalciferol)	10 mcg	50%
Vitamin E (as d-Alpha Tocopherol)	20.1 mg	134%
Thiamin (B1) (from Thiamine Mononitrate)	1.7 mg	142%
Riboflavin (B2)	2 mg	154%
Niacin (as Niacinamide)	20 mg	125%
Vitamin B6 (from Pyridoxine Hydrochloride)	2.5 mg	147%
	1700 mcg	

Folate (1000 mcg Folic Acid)	1700 mcg DFE	425%
Vitamin B12 (as Cyanocobalamin)	8 mcg	333%
Biotin	300 mcg	1000%
Pantothenic Acid (from d-Calcium Pantothenate)	10 mg	200%
Calcium (from Calcium Carbonate)	200 mg	15%
Iron (from Carbonyl Iron)	28 mg	156%
Iodine (from Potassium Iodide)	150 mcg	100%
Magnesium (from Magnesium Oxide)	50 mg	12%
Zinc (from Zinc Oxide)	15 mg	136%
Copper (Copper Oxide)	2 mg	222%
<i>Eicosapentaenoic Acid (as EE) (from Fish Oil)</i>	200 mg	*
<i>Docosahexaenoic Acid (as EE) (from Fish Oil)</i>	35 mg	*

* Daily Values not established

Other Ingredients: Bovine Gelatin, Glycerin, Yellow Beeswax, Purified Water, Soy Lecithin, Annatto.

Allergens: Fish (Anchovy, Sardine, Tuna), Soy.

Does Not Contain: Peanuts, Tree Nuts, Shellfish, Eggs, Milk, Wheat.

INDICATIONS

PreGen DHA is a prescription dietary supplement for use throughout pregnancy, during the postnatal period for both lactating and non-lactating mothers, and throughout the childbearing years. PreGen DHA may be useful in improving the nutritional status of women prior to conception.

PreGen DHA is prescription dietary supplement formulated for the clinical dietary management of suboptimal nutritional status in patients where advanced folate supplementation is required and nutritional supplementation in physiologically stressful conditions for maintenance of good health.

PreGen DHA is formulated as a prescription dietary supplement for use in the dietary management of patients with nutritional deficiencies or are in need of nutritional supplementation.

CONTRAINDICATIONS

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

PRECAUTIONS

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 1.0 mg

daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations progress.

WARNING: Ingestion of more than 3 grams of omega-3 fatty acids (such as DHA) 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.

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

You should call your doctor for medical advice about serious adverse events. To report adverse side effects or to obtain product information, contact Emerald Therapeutics, LLC at 1-800-970-1991.

DOSAGE AND ADMINISTRATION

Usual adult dose is 1 softgel taken orally once daily or as prescribed by a licensed medical practitioner.

HOW SUPPLIED

Child-resistant bottles of 30 softgels (72919083-30²). Softgel is oblong shaped and orange reddish in color with possible dark spots.

2 Emerald Therapeutics does not represent this product code to be National Drug Code (NDC). Product codes are formatted according to standard industry practice, to meet the formatting requirement by pedigree reporting and supply-chain control including pharmacies.

STORAGE AND HANDLING

STORAGE

Store at 20°- 25°C (68°- 77°F) excursions permitted to 15°- 30°C (59°- 86°F) [See USP Controlled Room Temperature.] Avoid excessive heat, light, and moisture.

TAMPER EVIDENT

Do not use if seal is broken or missing.

MADE IN USA

Distributed by:
Emerald Therapeutics, LLC
Birmingham, AL 35209
800-970-1991

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

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083111-0321

PRINCIPAL DISPLAY PANEL - 30 Capsule Bottle Label

72919-083-30

PreGen DHA

PRENATAL/POSTNATAL
DIETARY SUPPLEMENT

30 SOFTGELS

Dispensed by Prescription

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72919-083-30


PreGen DHA


**PRENATAL/POSTNATAL
DIETARY SUPPLEMENT**

30 SOFTGELS


Dispensed by Prescription

See package insert for full prescribing information.


Distributed by:
Emerald Therapeutics, LLC
Birmingham, AL 35209
(800) 970-1991
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MADE IN USA 083221-1020



PREGEN DHA

beta carotene, vitamin a palmitate, ascorbic acid, cholecalciferol, .alpha.-tocopherol, d-, thiamine mononitrate, riboflavin, niacinamide, pyridoxine hydrochloride, folic acid, cyanocobalamin, biotin, calcium pantothenate, calcium carbonate, iron, potassium iodide, magnesium oxide, zinc oxide, cupric oxide, and fish oil capsule, gelatin coated

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:72919-083
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Beta Carotene (UNII: 01YAE03M7J) (Beta Carotene - UNII:01YAE03M7J)	Beta Carotene	600 ug
Vitamin A Palmitate (UNII: 1D1K0N0VVC) (Vitamin A - UNII:81G40H8B0T)	Vitamin A	600 ug
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg
Cholecalciferol (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	10 ug
.ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9) (.ALPHA.-TOCOPHEROL, D- - UNII:N9PR3490H9)	.ALPHA.-TOCOPHEROL, D-	20.1 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	1.7 mg
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	2 mg
Niacinamide (UNII: 25X51I8RD4) (Niacinamide - UNII:25X51I8RD4)	Niacinamide	20 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	2.5 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1000 ug
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	8 ug
Biotin (UNII: 6SO6U10H04) (Biotin - UNII:6SO6U10H04)	Biotin	300 ug
Calcium Pantothenate (UNII: 568ET80C3D) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	10 mg
Calcium Carbonate (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	Calcium Carbonate	200 mg
Iron (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7)	Iron	28 mg
Potassium Iodide (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	Potassium Iodide	150 ug
Magnesium Oxide (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	Magnesium Oxide	50 mg
Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	15 mg
Cupric Oxide (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L)	CUPRIC CATION	2 mg
Fish Oil (UNII: XGF7L72M0F) (Fish Oil - UNII:XGF7L72M0F)	Fish Oil	235 mg

Inactive Ingredients

Ingredient Name	Strength
Gelatin Type B Bovine (150 Bloom) (UNII: F5AJW0ONK4)	
Glycerin (UNII: PDC6A3C0OX)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Water (UNII: 059QF0KO0R)	
Lecithin, Soybean (UNII: 1DI56QDM62)	
Annatto (UNII: 6PQP1V1B6O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:72919-083-30	30 in 1 BOTTLE		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
DIETARY SUPPLEMENT		10/30/2020	

Supplement Facts		
Serving Size :	Serving per Container :	
	Amount Per Serving	% Daily Value
color		
scoring	1	
shape		
size (solid drugs)	20 mm	

Labeler - Emerald Therapeutics, LLC (116948577)

Revised: 3/2021

Emerald Therapeutics, LLC