

REAPHIRM PLANT SOURCE DHA - prenatal supplement capsule, gelatin coated
Everett Laboratories, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Product Information.

Contraindications

Reaphirm Plant Source DHA is contraindicated in patients with hypersensitivity to any of its components or color additives.

Folic acid is contraindicated in patients with untreated and uncomplicated pernicious anemia, and in those with anaphylactic sensitivity to folic acid.

Iron Therapy is contraindicated in patients with hemochromatosis and patients with iron storage disease or the potential for iron storage disease due to chronic hemolytic anemia (e.g., inherited anomalies of hemoglobin structure or synthesis and/or red cell enzyme deficiencies, etc.), pyridoxine responsive anemia, or cirrhosis of the liver.

Cyanocobalamin is contraindicated in patients with sensitivity to cobalt or to cyanocobalamin (Vitamin B12).

Refer to MM1carton label

Boxed Warning

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

WARNINGS/PRECAUTIONS:

Reaphirm Plant Source DHA should be used with caution in patients with known sensitivity or allergy to soy.

Vitamin D supplementation should be used with caution in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones. High doses of vitamin D can lead to elevated levels of calcium that reside in the blood and soft tissues. Bone pain, high blood pressure, formation of kidney stones, renal failure, and increased risk of heart disease can occur.

Iodine should be used with caution in patients with an overactive thyroid.

Prolonged use of iron salts may produce iron storage disease.

Folic acid, especially in doses above 0.1 mg daily, may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestations remain progressive.

The use of folic acid doses above 1 mg daily may precipitate or exacerbate the neurological damage of vitamin B12 deficiency.

Consumption of more than 3 grams of omega-3 fatty acids per day from all sources may lead to excessive bleeding. Supplemental intake of omega-3 fatty acids such as DHA exceeding 2 grams per day is not recommended.

Avoid Overdosage. Keep out of the reach of children.

Drug Interactions:

Medications for an overactive thyroid (anti-thyroid drugs) used in conjunction with iodine supplementation may lead to hypothyroidism.

Medications for hypertension used in conjunction with iodine supplementation may increase potassium.

High doses of folic acid may result in decreased serum levels of the anticonvulsant drugs.

Vitamin D supplementation should not be given with large amounts of calcium in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathyroidism and those who form calcium-containing kidney stones.

Zinc can inhibit the absorption of certain antibiotics; take at least 2 hours apart to minimize interactions.

Consult appropriate references for additional specific vitamin-drug interactions.

Information for Patients: Patients should be counseled to disclose all medical conditions, including use of all medications, vitamins and supplements, pregnancy, and breast-feeding.

Pediatric Use: Not for pediatric use.

Adverse Reactions

Adverse reactions have been reported with specific vitamins and minerals, but generally at doses substantially higher than those in Reaphirm Plant Source DHA. Reported adverse events include skin ailments, gastrointestinal complaints, glucose abnormalities, and visual problems.

Dosage and Administration

Before, during and after pregnancy, one softgel capsule daily, or as directed by a physician.

How Supplied

Reaphirm Plant Source DHA is available as a dark blue, oval shaped softgel capsule imprinted "EV3010". Available in Box of Unit-Dose pack of 30 (5 child resistant blister cards of 6 softgel capsules).

Store at room temperature, approximately 15-30C (59-86F), avoid excessive heat.

Rx Only

Manufactured for

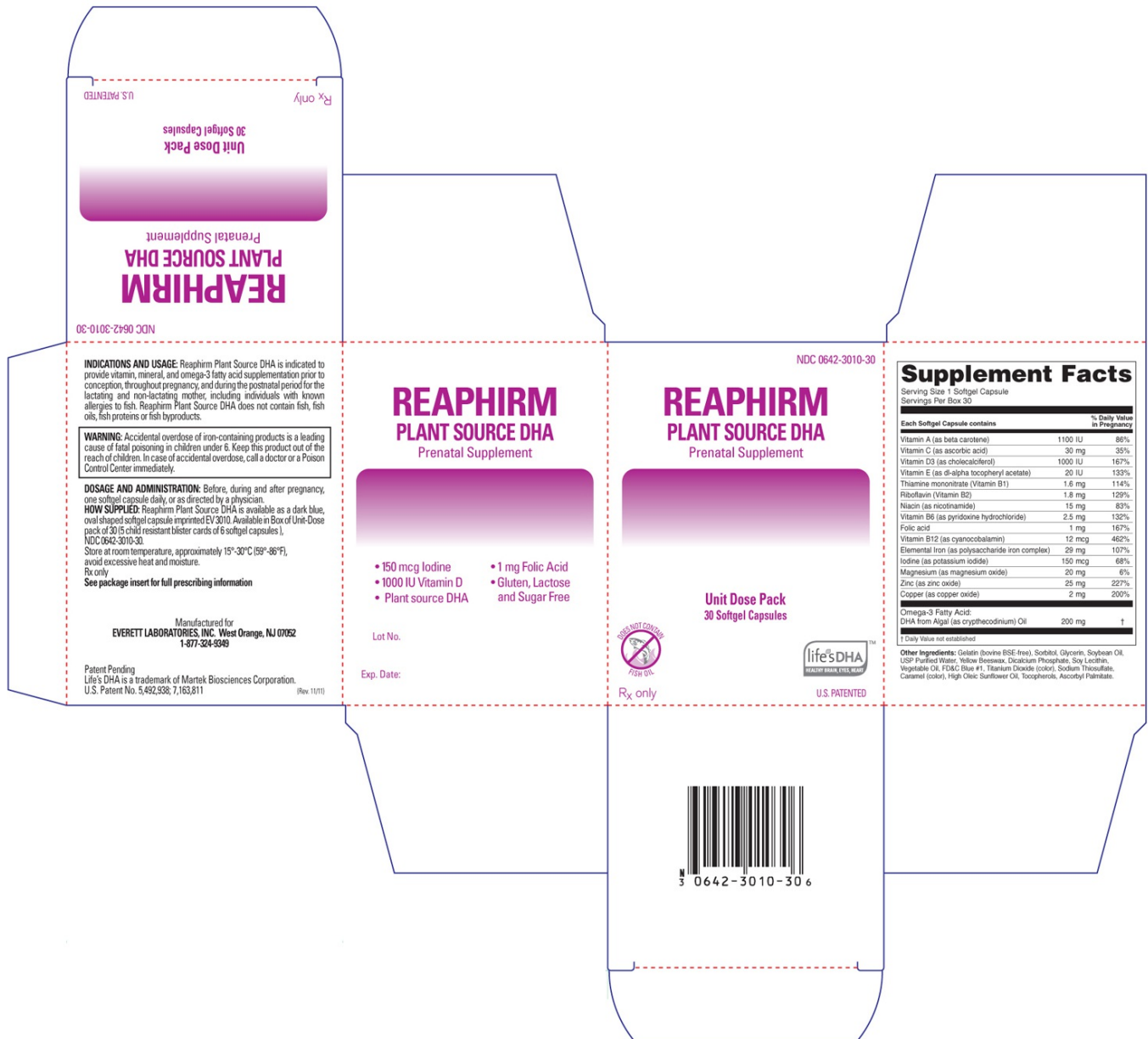
EVERETT LABORATORIES, INC.

West Orange, NJ 07052

1-877-324-9349

Principal Display Panel

reaphirm111128carton_lcr



REAPHIRM PLANT SOURCE DHA
prenatal supplement capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0642-3010
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Vitamin A (UNII: 81G40H8B0T) (Beta Carotene - UNII:01YAE03M7J)	Beta Carotene	1100 [iU]
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	30 mg
Thiamine Mononitrate (UNII: 8K0I04919X) (Thiamine - UNII:X66NSO3N35)	Thiamine Mononitrate	1.6 mg
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	1.8 mg
Niacin (UNII: 2679MF687A) (Niacinamide - UNII:25X51I8RD4)	Niacinamide	15 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1B16Z)	Pyridoxine	2.5 mg
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	.012 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1 mg
Iodine (UNII: 9679TC07X4) (Iodine - UNII:9679TC07X4)	Iodine	0.150 mg
Magnesium (UNII: I38ZP9992A) (Magnesium Oxide - UNII:3A3U0GI71G)	Magnesium Oxide	20 mg
Zinc (UNII: J41CSQ7QDS) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc Oxide	25 mg
Copper (UNII: 789U1901C5) (Cupric Oxide - UNII:V1XJQ704R4)	Cupric Oxide	2 mg
Vitamin D (UNII: 9VU1KI44GP) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	1000 [iU]
Omega-3 Fatty Acids (UNII: 71M78END5S) (Doconexent - UNII:ZAD9OKH9JC)	Doconexent	200 mg
Vitamin E (UNII: H4N855PNZ1) (Alpha-Tocopherol - UNII:H4N855PNZ1)	Alpha-Tocopherol	20 [iU]
Iron (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7)	Iron	29 mg

Inactive Ingredients

Ingredient Name	Strength
Gelatin (UNII: 2G86QN327L)	
Sorbitol (UNII: 506T60A25R)	
Glycerin (UNII: PDC6A3C0OX)	
Soybean Oil (UNII: 241ATL177A)	
Water (UNII: 059QF0K00R)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Anhydrous Dibasic Calcium Phosphate (UNII: L11K75P92J)	
Lecithin, Soybean (UNII: 1D156QDM62)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Sodium Thiosulfate (UNII: HX1032V43M)	
Sunflower Oil (UNII: 3W1JG795YI)	
Tocopherol (UNII: R0ZB2556P8)	
Ascorbyl palmitate (UNII: QN83US2B0N)	
Caramel (UNII: T9D99G2B1R)	
FD&C Blue NO. 1 (UNII: H3R47K3TBD)	
Corn Oil (UNII: 8470G57WFM)	

Product Characteristics

Color	blue (Dark Blue)	Score	no score
Shape	OVAL (size 12 Oval Capsule)	Size	10mm
Flavor		Imprint Code	EV30 10
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:0642-3010-30	5 in 1 BOX		
1		6 in 1 BLISTER PACK		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
unapproved drug other			12/05/2011	

Labeler - Everett Laboratories, Inc. (071170534)

Registrant - Everett Laboratories, Inc. (071170534)

Revised: 11/2011

Everett Laboratories, Inc.