VITAFOL PLUS- omega-3 fatty acids, niacin, .alpha.-tocopherol, vitamin d, lauric acid, vitamin a, ascorbic acid, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamin, iron, zinc, copper, iodine, magnesium, and folic acid capsule, liquid filled
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.

Vitafol®-Plus
Prenatal Supplement with DHA

Rx only

Composition

Each Softgel Capsule Contains:

Vitamins and Minerals:	
Vitamin A (as beta carotene)	1100 IU
Vitamin C (as ascorbic acid)	12 mg
Vitamin D3 (as cholecalciferol)	1000 IU
Vitamin E (as dl-alpha tocopheryl acetate)	10 IU
Thiamin (Vitamin B1) (as thiamine mononitrate)	1.6 mg
Riboflavin (Vitamin B2)	1.8 mg
Niacin (as nicotinamide)	15 mg
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg
Folic Acid	1 mg
Vitamin B12 (as cyanocobalamin)	12 mcg
Elemental Iron (as polysaccharide iron complex)	27mg
Iodine (as potassium iodide)	200 mcg
Magnesium (as magnesium oxide)	5 mg
Zinc (as zinc oxide)	15 mg
Copper (as copper oxide)	2 mg
Lauric Acid	60 mg
Omega-3 FATTY ACID	
DHA from Algal (crypthecodinium) Oil	200 mg

Other Ingredients

Gelatin, Sorbitol, Glycerin, Soybean Oil, USP Purified Water, Yellow Beeswax, Soy Lecithin, FD&C Blue #1, Titanium Dioxide (color), High Oleic Sunflower Oil, Tocopherols, Ascorbyl Palmitate, FD&C Yellow #5, FD&C Red #40.

INDICATIONS AND USAGE

Vitafol®-Plus is indicated to provide vitamin, mineral and omega-3 fatty acid supplementation prior to conception, throughout pregnancy, and during the postnatal period for the lactating and non-lactating mother, including individuals with known allergies to fish. Vitafol®-Plus does not contain fish, fish oils, fish proteins or fish byproducts.

CONTRAINDICATIONS

Vitafol®-Plus 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 B-12)

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.

WARNING/PRECAUTIONS

Vitafol-Plus 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 carbamazepine, fosphenytoin, phenytoin, phenobarbitol, and valproic acid. Folic acid may decrease a patient's response to methotrexate.

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 pregnancy and breast-feeding, and the use of all medications and dietary supplements.

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 Vitafol®-Plus. However, allergic and idiosyncratic reactions are possible at any dose. 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

Vitafol®-Plus is available as a purple, oval shaped softgel capsule imprinted EV0092. Available in Box of Unit-Dose pack of 30 (5 child resistant blister cards of 6 softgel capsules) (NDC0642-0092-30), and as professional samples (NDC0642-0092-01). Store at room temperature, approximately 15°-30°C (59°-86°F). Avoid excessive heat, moisture and protect from light.

Rx only

Manufactured for
EVERETT LABORATORIES, INC.
West Orange, NJ 07052
1-877-324-9349

Patent Pending
Vitafol® is a trademark of Everett Laboratories, Inc.

life's DHA is a trademark of DSM.
U.S. Patent No. 5,492,938; 7,163,811

(Rev. 03/12)

PRINCIPAL DISPLAY PANEL - 30 Capsule Carton

NDC 0642-0092-30

Vitafol®-*Plus*
Prenatal Supplement with DHA

Small, All-In-One,
Once Daily Softgel Capsule

EV0092

Actual Size

DOES NOT CONTAIN
FISH OIL

life's **DHA**
HEALTHY BRAIN, EYES, HEART™

Unit Dose Pack
30 Softgel Capsules

Rx only
Patent Pending

NDC 0642-0092-30

Vitafol®-Plus

Prenatal Supplement with DHA

Small, All-In-One, Once Daily Softgel Capsule

EV0092

Actual Size

DOES NOT CONTAIN FISH OIL

life's DHA™ HEALTHY BRAIN, EYES, HEART

Unit Dose Pack
30 Softgel Capsules

Rx only

Patent Pending

Supplement Facts

Serving Size 1 Softgel Capsule
Servings Per Box 30

Each Softgel Capsule contains		% Daily Value In Pregnancy
Vitamin A (as beta carotene)	1100 IU	22%
Vitamin C (as ascorbic acid)	12 mg	14%
Vitamin D3 (as cholecalciferol)	1000 IU	167%
Vitamin E (as dl-alpha tocopheryl acetate)	10 IU	67%
Thiamin (Vitamin B1) (as thiamine mononitrate)	1.6 mg	114%
Riboflavin (Vitamin B2)	1.8 mg	129%
Niacin (as nicotinamide)	15 mg	83%
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg	132%
Folic Acid	1 mg	167%
Vitamin B12 (as cyanocobalamin)	12 mcg	462%
Elemental Iron (as polysaccharide iron complex)	27 mg	100%
Iodine (as potassium iodide)	200 mcg	91%
Magnesium (as magnesium oxide)	5 mg	1.4%
Zinc (as zinc oxide)	15 mg	136%
Copper (as copper oxide)	2 mg	200%
Lauric Acid	60 mg	†
Omega-3 Fatty Acid: DHA from Algal (crypthecodinium) Oil	200 mg	†

† Daily Value not established

Other Ingredients: Gelatin, Sorbitol, Glycerin, Soybean Oil, USP Purified Water, Yellow Beeswax, Soy Lecithin, FD&C Blue #1, Titanium Dioxide (color), High Oleic Sunflower Oil, Tocopherols, Ascorbyl Palmitate, FD&C Yellow #5, FD&C Red #40.

N 3 0642-0092-30 5

Rx only

Patent Pending

life's DHA

DOES NOT CONTAIN FISH OIL

Unit Dose Pack
30 Softgel Capsules

Small, All-In-One,
Once Daily
Softgel Capsule

Vitafol-Plus

Prenatal Supplement with DHA

NDC 0642-0092-30

INDICATIONS AND USAGE: Vitafol®-Plus is indicated to provide vitamin, mineral and omega-3 fatty acid supplementation prior to conception, throughout pregnancy, and during the postnatal period for the lactating and non-lactating mother, including individuals with known allergies to fish. Vitafol®-Plus does not contain fish, fish oils, fish proteins or fish byproducts.

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Store at room temperature, approximately 15°-30°C (59°-86°F), avoid excessive heat, moisture and protect from light.

Rx only.

See package insert for full prescribing information

Manufactured for
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U.S. Patent No. 5,492,938; 7,163,811

(Rev. 08/12)

Vitafol-Plus

Prenatal Supplement with DHA

Small, All-In-One,
Once Daily Softgel Capsule

- 200 mcg Iodine
- 1000 IU Vitamin D
- 200 mg Plant source DHA
- 60 mg Lauric Acid
- 1 mg Folic Acid
- Gluten, Lactose and Sugar Free

Lot No.

Exp. Date:

VITAFOL PLUS

omega-3 fatty acids, niacin, .alpha.-tocopherol, vitamin d, lauric acid, vitamin a, ascorbic acid, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamin, iron, zinc, copper, iodine, magnesium, and folic acid capsule, liquid filled

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0642-0092
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Omega-3 Fatty Acids (UNII: 71M78END5S) (Doconexent - UNII:ZAD9OKH9JC)	Omega-3 Fatty Acids	200 mg
Niacin (UNII: 2679MF687A) (Niacinamide - UNII:25X51I8RD4)	Niacin	15 mg
.Alpha.-Tocopherol (UNII: H4N855PNZ1) (.Alpha.-Tocopherol - UNII:H4N855PNZ1)	.Alpha.-Tocopherol	10 [iU]
Vitamin D (UNII: 9VU1KI44GP) (Cholecalciferol - UNII:1C6V77QF41)	Vitamin D	1000 [iU]
Lauric Acid (UNII: 1160N9NU9U) (Lauric Acid - UNII:1160N9NU9U)	Lauric Acid	60 mg
Vitamin A (UNII: 81G40H8B0T) (.Beta.-Carotene - UNII:01YAE03M7J)	Vitamin A	1100 [iU]
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	12 mg
Thiamine Mononitrate (UNII: 8K0I04919X) (Thiamine - UNII:X66NSO3N35)	Thiamine Mononitrate	1.6 mg
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	1.8 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	2.5 mg
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	12 ug
Iron (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7)	Iron	27 mg
Zinc (UNII: J41CSQ7QDS) (Zinc Oxide - UNII:SOI2LOH54Z)	Zinc	15 mg
Copper (UNII: 789U1901C5) (Cupric Oxide - UNII:V1XJQ704R4)	Copper	2 mg
Iodine (UNII: 9679TC07X4) (Iodine - UNII:9679TC07X4)	Iodine	200 ug
Magnesium (UNII: I38ZP9992A) (Magnesium Oxide - UNII:3A3U0GI71G)	Magnesium	5 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1 mg

Inactive Ingredients

Ingredient Name	Strength
Gelatin (UNII: 2G86QN327L)	
Sorbitol (UNII: 506T60A25R)	
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Soybean Oil (UNII: 241ATL177A)	
Lecithin, Soybean (UNII: 1DI56QDM62)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
FD&C Yellow No. 5 (UNII: I753WB2F1M)	

FD&C Red No. 40 (UNII: WZB9127XOA)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
Sunflower Oil (UNII: 3W1JG795YI)	
Tocopherol (UNII: R0ZB2556P8)	
Ascorbyl Palmitate (UNII: QN83US2B0N)	

Product Characteristics

Color	PURPLE	**Score**	no score
Shape	OVAL	**Size**	12mm
Flavor		**Imprint Code**	EV0092
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0642-0092-30	5 in 1 BOX		
1		6 in 1 BLISTER PACK		
2	NDC:0642-0092-01	1 in 1 BOX		
2		4 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		04/23/2012	

Labeler - Everett Laboratories, Inc. (071170534)

Establishment

Name	Address	ID/FEI	Business Operations
Interge Pharmaceutical, Inc,		964464114	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Blispak Acquisition Corporation		194902235	PACK

Establishment

Name	Address	ID/FEI	Business Operations
Nutra-Med Packaging, Inc		022004902	PACK

Revised: 4/2012 Everett Laboratories, Inc.