VITAFOL ONE- prenatal supplement with dha 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.

V™
Vitafol-One
Prenatal Supplement with DHA

Rx

0642-0070-30

COMPOSITION:
Each Softgel Capsule Contains:
VITAMINS AND MINERALS:

Vitamin A (as Vitamin A palmitate)	330 mcg RAE
Vitamin C (as ascorbic acid)	30 mg
Vitamin D3 (as cholecalciferol)	25 mcg
Vitamin E (as dl-alpha tocopheryl acetate)	9 mg
Thiamine mononitrate (Vitamin B1)	1.6 mg
Riboflavin (Vitamin B2)	1.8 mg
Niacin (as niacinamide)	15 mg NE
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg
Folate (as folic acid)	1700 mcg DFE
Vitamin B12 (as cyanocobalamin)	12 mcg
Elemental Iron (as polysaccharide iron complex)	29 mg
Iodine (as potassium iodide)	150 mcg
Magnesium (as magnesium oxide)	20 mg
Zinc (as zinc oxide)	25 mg
Copper (as copper oxide)	2 mg
Algal oil blend (derived from natural algal oil)	415 mg*

* providing 200DHA (docosahexaenoic acid)

Other Ingredients:

Gelatin (Bovine BSE-free), Sorbitol, Glycerin, Soybean Oil, USP Purified Water, Yellow Beeswax, Dicalcium Phosphate, Soy Lecithin, Vegetable Oil, FD&C Blue #1, Titanium Dioxide (color), Sodium Thiosulfate, Caramel (color), High Oleic Sunflower Oil, Tocopherols, Ascorbyl Palmitate. **Contains: Soy.**

INDICATIONS AND USAGE

Vitafol-One 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-One does not contain fish, fish oils, fish proteins or fish byproducts.

CONTRAINDICATIONS

Vitafol-One 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 reach of children. In case of accidental overdose, call a doctor or a Poison Control Center immediately.

WARNINGS/PRECAUTIONS

Vitafol-One 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, 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; taken 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 recommended 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-One. 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-One is available as a dark blue, oval shaped softgel capsule imprinted "EV0070". Available in Box of Unit-Dose pack of 30 (5 child resistant blister cards of 6 softgel capsules), (0642-0070-30) and as professional samples (0642-0070-03).

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

Rx

Distributed by:
Exeltis USA, Inc.
Florham Park, NJ 07932
1-877-324-9349
www.exeltisusa.com

U.S. Patent No. 8,183,227

Rev. April 2021
0703001-02

PRINCIPAL DISPLAY PANEL - 30 Capsule Blister Pack Carton

0642-0070-30

VITAFOL
One

Prenatal Supplement with DHA

Unit Dose Pack
30 Softgel Capsules

R_X
DIETARY SUPPLEMENT
U.S. PATENTED

0642-0070-30

VITAFOL One

Prenatal Supplement with DHA

Unit Dose Pack
30 Softgel Capsules

Rx DIETARY SUPPLEMENT U.S. PATENTED

Lot No.

Exp. Date:

N 3 0642-0070-30 3

Supplement Facts

Serving Size 1 Softgel Capsule

Each Softgel Capsule contains		% Daily Value in Pregnancy
Vitamin A (as beta carotene)	330 mcg RAE	14%
Vitamin C (as ascorbic acid)	30 mg	50%
Vitamin D3 (as cholecalciferol)	25 mcg	250%
Vitamin E (as dl-alpha tocopheryl acetate)	9 mg	67%
Thiamine mononitrate (Vitamin B1)	1.6 mg	94%
Riboflavin (Vitamin B2)	1.8 mg	90%
Niacin (as niacinamide)	15 mg NE	75%
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg	100%
Folate (as folic acid)	1700 mcg DFE	125%
Vitamin B12 (as cyanocobalamin)	12 mcg	150%
Elemental Iron (as polysaccharide iron complex)	29 mg	161%
Iodine (as potassium iodide)	150 mcg	100%
Magnesium (as magnesium oxide)	20 mg	4%
Zinc (as zinc oxide)	25 mg	167%
Copper (as copper oxide)	2 mg	100%
Algal oil blend (derived from natural algal oil) (*providing 200 mg DHA (docosahexaenoic acid))	415 mg*	†

† Daily Value not established

Other Ingredients: Gelatin (bovine BSE-free), Sorbitol, Glycerin, Soybean Oil, USP Purified Water, Yellow Beeswax, Dicalcium Phosphate, Soy Lecithin, Vegetable Oil, FD&C Blue #1, Titanium Dioxide (color), Sodium Thiosulfate, Caramel (color), High Oleic Sunflower Oil, Tocopherols, Ascorbyl Palmitate.
Contains: Soy.


Rx
DIETARY SUPPLEMENT
U.S. PATENTED
Prenatal Supplement with DHA
One
VITAFOL
0642-0070-30
INDICATIONS AND USAGE: Vitafol® One 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® One does not contain fish, fish oils, fish proteins or fish byproducts.
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 a Poison Control Center immediately.
DOSAGE AND ADMINISTRATION: Before, during and after pregnancy, one softgel capsule daily, or as directed by a physician.
HOW SUPPLIED: Vitafol® One is available as a dark blue, oval shaped softgel capsule imprinted "EV 0070". Available in Box of Unit-Dose pack of 30 (5 child resistant blister cards of 6 softgel capsules), 0642-0070-30 and as professional samples 0642-0070-03.
Store at room temperature, approximately 15°-30°C (59°-86°F), avoid excessive heat. Rx
See package insert for full prescribing information
Distributed by:
Exeltis USA, Inc., Florham Park, NJ 07932
1-877-324-9349
www.exeltisUSA.com
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Vitafol® is a trademark of Exeltis USA, Inc.
U.S. Patent No. 8,183,227
0703005-03
VITAFOL
One
Prenatal Supplement with DHA
Small, all-in-one, once daily softgel capsule with DHA

VITAFOL ONE

prenatal supplement with dha capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0642-0070
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Vitamin A (UNII: 81G40H8B0T) (Vitamin A - UNII:81G40H8B0T)	Vitamin A	330 ug
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	30 mg
Thiamine Mononitrate (UNII: 8K0I04919X) (Thiamine Ion - UNII:4ABT0J945J)	Thiamine	1.6 mg
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	1.8 mg
Niacin (UNII: 2679MF687A) (Niacin - UNII:2679MF687A)	Niacin	15 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine	2.5 mg
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	.012 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1700 ug
Iodine (UNII: 9679TC07X4) (Iodine - UNII:9679TC07X4)	Iodine	0.150 mg
Magnesium (UNII: I38ZP9992A) (Magnesium - UNII:I38ZP9992A)	Magnesium	20 mg
Zinc (UNII: J41CSQ7QDS) (Zinc - UNII:J41CSQ7QDS)	Zinc	25 mg
Copper (UNII: 789U1901C5) (Copper - UNII:789U1901C5)	Copper	2 mg
Vitamin D (UNII: 9VU1KI44GP) (Cholecalciferol - UNII:1C6V77QF41)	Vitamin D	25 ug
Omega-3 Fatty Acids (UNII: 71M78END5S) (Omega-3 Fatty Acids - UNII:71M78END5S)	Omega-3 Fatty Acids	200 mg
.Alpha.-Tocopherol (UNII: H4N855PNZ1) (.Alpha.-Tocopherol - UNII:H4N855PNZ1)	.Alpha.-Tocopherol	9 mg
Iron (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7)	Iron	29 mg

Inactive Ingredients

Ingredient Name	Strength
Gelatin, Unspecified (UNII: 2G86QN327L)	
Sorbitol (UNII: 506T60A25R)	
Glycerin (UNII: PDC6A3C0OX)	
Soybean Oil (UNII: 241ATL177A)	
Water (UNII: 059QF0KO0R)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Anhydrous Dibasic Calcium Phosphate (UNII: L11K75P92J)	
Lecithin, Soybean (UNII: 1DI56QDM62)	

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**	EV0070
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0642-0070-30	5 in 1 BOX	06/13/2011	
1		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0642-0070-01	1 in 1 BOX	06/13/2011	
2		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/13/2011	

Labeler - Everett Laboratories, Inc. (071170534)

Revised: 8/2021 Everett Laboratories, Inc.