VITAFOL-OB PLUS DHA PRENATAL SUPPLEMENT PLUS DHA- vitamin a, ascorbic acid, vitamin d, .alpha.-tocopherol, thiamine mononitrate, riboflavin, niacin, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium, iron, magnesium, zinc, copper, and doconexent
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®-OB+DHA

0642-0076-30

Prenatal Supplement with DHA

Rx

COMPOSITION

Each Vitafol®-OB caplet contains:

Vitamin A (as beta carotene)	810 mcg RAE
Vitamin C (as ascorbic acid)	70 mg
Vitamin D3 (as cholecalciferol)	10 mcg
Vitamin E (as dl-alpha tocopheryl acetate)	13.5 mg
Thiamine mononitrate (Vitamin B1)	1.6 mg
Riboflavin (Vitamin B2)	1.8 mg
Niacin (as niacinamide)	18 mg NE
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg
Folate (as folic acid)	1700 mcg DFE
Vitamin B12 (as cyanocobalamin)	12 mcg
Calcium (as calcium carbonate)	100 mg
Iron (as ferrous fumarate)	65 mg
Magnesium (as magnesium oxide)	25 mg
Zinc (as zinc oxide)	25 mg
Copper (as copper oxide)	2 mg
Each DHA softgel capsule contains:	486 mg*
Algal oil blend (derived from Natural Algal Oil)	

* (providing 250 mg DHA (docosahexaenoic acid))

Other Ingredients in Vitafol®-OB caplet: Microcrystalline Cellulose, hydrolyzed gelatin (pig skin), modified cellulose gum, stearic acid, hydroxypropylmethylcellulose, titanium dioxide (as color), polydextrose, silicon dioxide, gelatin, magnesium stearate, modified food starch, sucrose, maize starch, triacetin, dibasic calcium phosphate, hydroxypropylcellulose, FD&C Blue #1 Aluminum Lake, polyethylene glycol, sodium

ascorbate, tocopherol concentrate, FD&C Blue #2 Aluminum Lake, medium chain trglycerides, sorbic acid, tribasic calcium phosphate, sodium benzoate, dl-alpha-tocopherol. **Contains: Soy**

Other Ingredients in DHA softgel capsule: Gelatin, Glycerin USP, Water.

INDICATIONS AND USAGE

Vitafol®-OB+DHA 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®-OB+DHA does not contain fish, fish oils, fish proteins or fish byproducts.

CONTRAINDICATIONS

Vitafol®-OB+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 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

Vitamin D supplementation should be used with caution in those with hypercalcemia or conditions that may lead to hypercalcemia such as hyperparathryroidism 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.

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

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 Vitafol®-OB+DHA. Allergic reactions have been reported with some forms of gum acacia to include respiratory problems and skin lesions.

DOSAGE AND ADMINISTRATION

Before, during and after pregnancy, one caplet and one soft-gel capsule daily, or as directed by a physician.

HOW SUPPLIED

VITAFOL®-OB+DHA is available as a light blue caplet debossed EV0079 and one amber-colored DHA softgel capsule. Available in Box of Unit-Dose pack of 30 (6 child resistant blister cards of 5 caplets and 5 softgel capsules each), (0642-0076-30) and as professional samples (0642-0076-03).

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. 6,814,983; 7,390,509
Vitafol® is a trademark of Exeltis USA, Inc.

Rev. May 2021

0763001-02

PRINCIPAL DISPLAY PANEL - Kit Carton

0642-0076-30

Vitafol®-OB+DHA

Prenatal Supplement with DHA

SUGAR, LACTOSE, GLUTEN AND IODINE FREE

New
Smaller DHA Softgel

DOES NOT CONTAIN
FISH OIL

R_X
Unit Dose Pack
30 Caplets and 30 Softgel Capsules
U.S. Patented

0642-0076-30

Vitafol®-OB+DHA

Prenatal Supplement with DHA

SUGAR, LACTOSE, GLUTEN AND IODINE FREE

Unit Dose Pack

Rx 30 Caplets and 30 Softgel Capsules U.S. Patented

N 3 0642-0076-30 5

Vitafol®-OB+DHA

Prenatal Supplement with DHA

Supplement Facts

Serving Size 1 Caplet and 1 Softgel Capsule

Each Caplet contains		% Daily Value In Pregnancy
Vitamin A (as beta carotene)	810 mcg RAE	34%
Vitamin C (as ascorbic acid)	70 mg	117%
Vitamin D3 (as cholecalciferol)	10 mcg	100%
Vitamin E (as dl-alpha tocopheryl acetate)	13.5 mg	100%
Thiamine Mononitrate (Vitamin B1)	1.6 mg	94%
Riboflavin (Vitamin B2)	1.8 mg	90%
Niacin (as niacinamide)	18 mg NE	90%
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg	100%
Folate (as folic acid)	1700 mcg DFE	125%
Vitamin B12 (as cyanocobalamin)	12 mcg	150%
Calcium (as calcium carbonate)	100 mg	8%
Elemental Iron (as ferrous fumarate)	65 mg	361%
Magnesium (as magnesium oxide)	25 mg	6%
Zinc (as zinc oxide)	25 mg	167%
Copper (as copper oxide)	2 mg	100%
Each Softgel Capsule contains		
Algal oil blend (derived from natural algal oil) (*providing 250mg DHA (docosahexaenoic acid))	486 mg*	†

† Daily Value not established

Other Ingredients in Vitafol®-OB Caplet: Microcrystalline cellulose, hydrolyzed gelatin (pig skin), modified cellulose gum, stearic acid, hydroxypropylmethylcellulose, titanium dioxide (as color), polydextrose, silicon dioxide, gelatin, magnesium stearate, modified food starch, sucrose, maize starch, triacetin, dibasic calcium phosphate, hydroxypropylcellulose, FD&C Blue #1 Aluminum Lake, polyethylene glycol, sodium ascorbate, tocopherol concentrate, FD&C Blue #2 Aluminum Lake, medium chain triglycerides, sorbic acid, tribasic calcium phosphate, sodium benzoate, dl-alpha-tocopherol. **Contains: Soy.**
Other Ingredients in DHA Softgel Capsule: Gelatin, Glycerin USP, Water.

Unit Dose Pack
30 Caplets and 30 Softgel Capsules
U.S. Patented
Rx

FISH OIL DOES NOT CONTAIN

Prenatal Supplement with DHA

Vitafol®-OB+DHA

0642-0076-30

INDICATIONS AND USAGE: Vitafol®-OB+DHA 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®-OB+DHA 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 caplet and one softgel capsule daily, or as directed by a physician.

HOW SUPPLIED: Vitafol®-OB+DHA is available as a light blue caplet debossed EV0079 and one amber-colored DHA softgel capsule. Available in Box of Unit-Dose pack of 30 (6 child resistant blister cards of 5 caplets and 5 softgel capsules each), (0642-0076-30) and as professional samples (0642-0076-03).

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

Rx

See package insert for full prescribing information

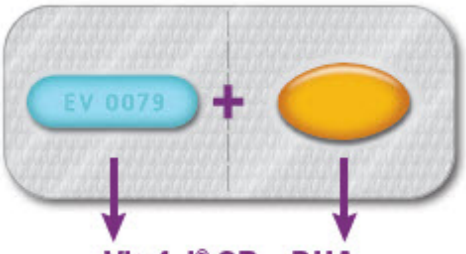
Distributed by:
Exeltis USA, Inc. Florham Park, NJ 07932
1-877-324-9349
www.exeltisUSA.com

Vitafol®-OB+DHA

Prenatal Supplement with DHA

SUGAR, LACTOSE, GLUTEN AND IODINE FREE

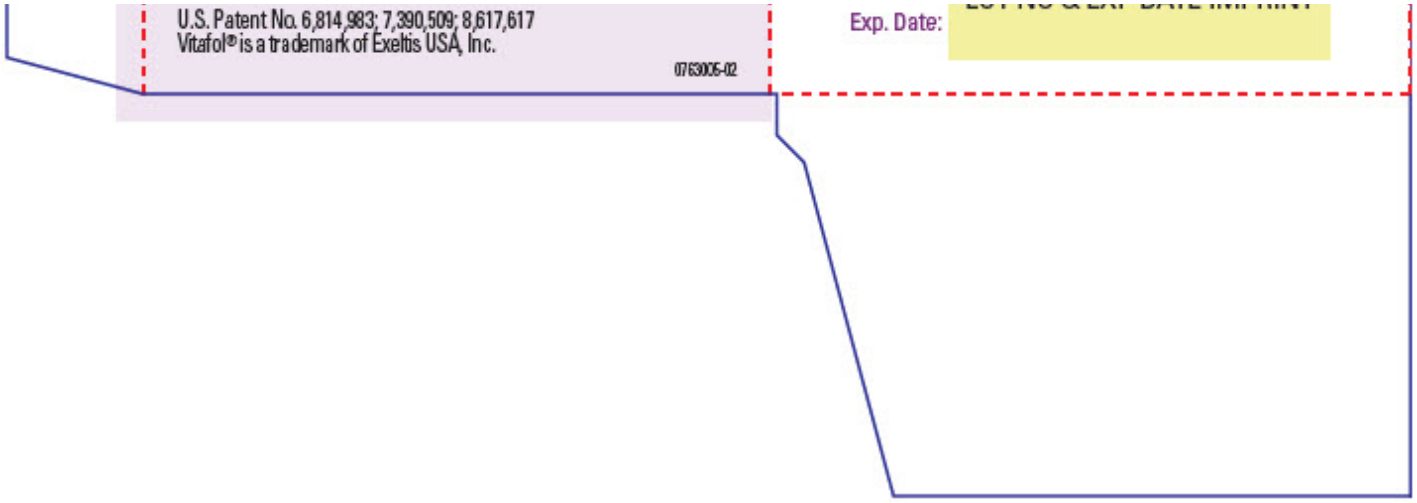
• Natural source DHA



Vitafol®-OB + DHA
(DAILY DOSE)

Lot No.

NO VARNISH AREA FOR
LOT NO & EXP DATE IMPRINT



VITAFOL-OB PLUS DHA PRENATAL SUPPLEMENT PLUS DHA

vitamin a, ascorbic acid, vitamin d, .alpha.-tocopherol, thiamine mononitrate, riboflavin, niacin, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium, iron, magnesium, zinc, copper, and doconexent kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0642-0076

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0642-0076-30	1 in 1 CARTON	02/16/2007	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOX	30
Part 2	1 BOX	30

Part 1 of 2

VITAFOL-OB

vitamin a, ascorbic acid, vitamin d, .alpha.-tocopherol, thiamine mononitrate, riboflavin, niacin, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium, iron, magnesium, zinc, and copper tablet, coated

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Vitamin A (UNII: 81G40H8B0T) (Vitamin A - UNII:81G40H8B0T)	Vitamin A	810 ug
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	70 mg
Vitamin D (UNII: 9VU1KI44GP) (Cholecalciferol - UNII:1C6V77QF41)	Vitamin D	10 ug
.Alpha.-Tocopherol (UNII: H4N855PNZ1) (.Alpha.-Tocopherol - UNII:H4N855PNZ1)	.Alpha.-Tocopherol	13.5 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	18 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	2.5 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1700 ug
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	12 ug
Calcium (UNII: SY7Q814VUP) (Calcium - UNII:SY7Q814VUP)	Calcium	100 mg
Iron (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7)	Iron	65 mg
Magnesium (UNII: I38ZP9992A) (Magnesium - UNII:I38ZP9992A)	Magnesium	25 mg
Zinc (UNII: J41CSQ7QDS) (Zinc - UNII:J41CSQ7QDS)	Zinc	25 mg
Copper (UNII: 789U1901C5) (Copper - UNII:789U1901C5)	Copper	2 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Modified Corn Starch (1-Octenyl Succinic Anhydride) (UNII: 461P5CJN6T)	
Sucrose (UNII: C151H8M554)	
Starch, Corn (UNII: O8232NY3SJ)	
Sodium Ascorbate (UNII: S033EH8359)	
Tocopherol (UNII: R0ZB2556P8)	
Magnesium Stearate (UNII: 70097M6I30)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Acacia (UNII: 5C5403N26O)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	
Sorbic Acid (UNII: X045WJ989B)	
Tricalcium Phosphate (UNII: K4C08XP666)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
Polydextrose (UNII: VH2XOU12IE)	
Triacetin (UNII: XHX3C3X673)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
FD&C Blue No. 2 (UNII: L06K8R7DQK)	
D&C Yellow No. 10 (UNII: 35SW5USQ3G)	
Aluminum Oxide (UNII: LMI26O6933)	

Product Characteristics			
Color	BLUE	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	EV;0079
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		30 in 1 BOX; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/16/2007	

Part 2 of 2

DHA

doconexent capsule

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	250 mg

Inactive Ingredients	
Ingredient Name	**Strength**
GLYCERIN (UNII: PDC6A3C0OX)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color	YELLOW (Amber)	**Score**	no score
Shape	OVAL	**Size**	15mm

Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		30 in 1 BOX; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		02/16/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		02/16/2007	

Labeler - Everett Laboratories, Inc. (071170534)

Revised: 8/2021 Everett Laboratories, Inc.