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

Prenatal Supplement

Rx only

COMPOSITION

Each Caplet contains:

VITAMINS AND MINERALS:

Vitamin A (as beta carotene)	810	mcg RAE
Vitamin C (as ascorbic acid)	70	mg
Vitamin D (as cholecalciferol)	10	mcg
Vitamin E (as dl-alpha tocopheryl acetate)	13.5	mg
Thiamin (Vitamin B1 as thiamine mononitrate)	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	mg 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

Other Ingredients: microcrystalline cellulose, croscarmellose sodium, silicon dioxide, maltodextrin, copovidone, stearic acid, hydroxypropyl methylcellulose, dicalcium phosphate, acacia gum, titanium dioxide, polydextrose, starch, magnesium stearate, triacetin, modified food starch, mannitol, vitamin E alcohol, polyethylene glycol, talc, FD&C Blue #1, FD&C Blue #2.

INDICATIONS AND USAGE

Vitafol ®-OB is indicated to provide vitamin, mineral, supplementation prior to conception, throughout pregnancy, and during the postnatal period for the lactating and non-lactating mother.*

CONTRAINDICATIONS

Vitafol ®-OB 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.

WARNINGS/PRECAUTIONS

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.

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.

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. 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 daily, or as directed by a physician.

HOW SUPPLIED

Vitafol ®-OB is available as a light blue caplet, debossed EV0079. Available in Box of Unit-Dose pack of 100 (NDC 0642-0079-12) and as professional samples (0642-0079-03).

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

*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.

Rx

Disributed 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 Healthcare S.L.

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PRINCIPAL DISPLAY PANEL - 100 Caplet Carton

0642-0079-12

Vitafol ®-OB

Prenatal Supplement

10 X 10 UNIT DOSE PACK

100 CAPLETS

R x

VITAFOL OB CAPLET

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

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0642-0079
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
VITAMIN A (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	2700 [iU]
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	70 mg
VITAMIN D (UNII: 9VU1KI44GP) (CHOLECALCIFEROL - UNII:1C6V77QF41)	VITAMIN D	400 [iU]
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) (.ALPHA.-TOCOPHEROL - UNII:H4N855PNZ1)	.ALPHA.-TOCOPHEROL	30 [iU]
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	1 mg
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)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
TRIACETIN (UNII: XHX3C3X673)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	EV0079
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0642-0079-03	3 in 1 CARTON; Type 0: Not a Combination Product	11/09/2015	
2	NDC:0642-0079-12	100 in 1 CARTON; Type 0: Not a Combination Product	12/02/2002	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/02/2002	

Labeler - Exeltis USA, Inc. (071170534)

Registrant - Exeltis USA, Inc. (071170534)

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