

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)	2700 IU
Vitamin C (as ascorbic acid)	70 mg
Vitamin D3 (as cholecalciferol)	400 IU
Vitamin E (as dl-alpha tocopheryl acetate)	30 IU
Thiamine mononitrate (Vitamin B1)	1.6 mg
Riboflavin (Vitamin B2)	1.8 mg
Niacin (as niacinamide)	18 mg
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg
Folic acid	1.0 mg
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, Gelatin, Sodium Croscarmellose, Stearic Acid, Gum Acacia, Silicon Dioxide, Magnesium Stearate, Modified Food Starch, Sucrose, Silicon Dioxide, Maize Starch, Dicalcium Phosphate, Sodium Ascorbate, Tocopherol Concentrate, Medium Chain Triglycerides, Sorbic Acid, Tricalcium Phosphate, dl-Alpha-Tocopherol. Coating: Hypromellose, Titanium Dioxide, Polydextrose, Triacetin, Hydroxypropyl Cellulose, FD&C Blue #1 / Aluminum Lake, Polyethylene Glycol, FD&C Blue #2 / Aluminum Lake, FD&C Yellow #10 Aluminum Lake.

Contains: Soy

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.

Rx

Distributed by:
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www.exeltisusa.com

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REV. October 2015

PRINCIPAL DISPLAY PANEL - 100 Caplet Carton

0642-0079-12

Vitafol[®]-OB

Prenatal Supplement

10 X 10 UNIT DOSE PACK

100 CAPLETS

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0642-0079-12

Vitafol-OB

Prenatal Supplement

10 X 10 UNIT DOSE PACK
100 CAPLETS

Supplement Facts

Serving Size 1 Caplet

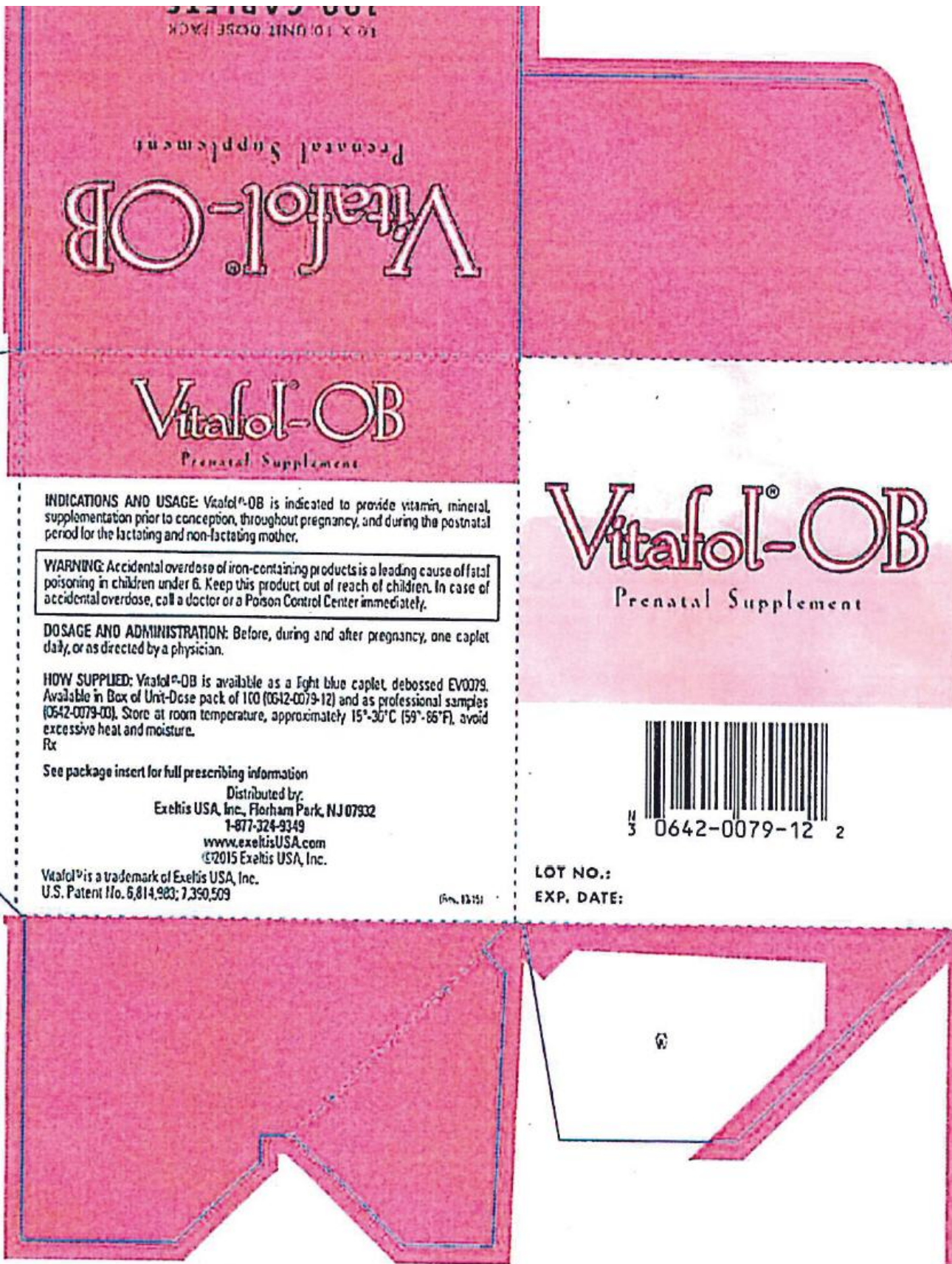
Each Caplet contains		% Daily Value in Pregnancy
Vitamin A (as beta carotene)	2700 IU	34%
Vitamin C (as ascorbic acid)	70 mg	117%
Vitamin D3 (as cholecalciferol)	400 IU	100%
Vitamin E (as d-alpha tocopheryl acetate)	30 IU	100%
Thiamine mononitrate (Vitamin B1)	1.6 mg	94%
Riboflavin (Vitamin B2)	1.8 mg	90%
Niacin (as niacinamide)	18 mg	90%
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg	100%
Folic acid	1 mg	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%

Other Ingredients: 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, xanthan gum, FD&C Blue #2 Aluminum Lake, medium chain triglycerides, sorbic acid, tribasic calcium phosphate, sodium benzoate, d-alpha-tocopherol.
Contains Soy.

Rx

1

100 CAPLETS



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:KV2JZ1B16Z)	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: 3WJQ0SDW1A)	
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 (160000 WAMW) (UNII: RFW2ET671P)	

FD&C Blue No. 1 (UNII: H3R47K3TBD)	
Aluminum Oxide (UNII: LM26O6933)	
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:0642-0079-08	4 in 1 CARTON; Type 0: Not a Combination Product	12/02/2002	
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)

Revised: 1/2021

Exeltis USA, Inc.