

0642-0079-12

# Vitafo<sup>l</sup>-OB

## Prenatal Supplement

Rx

### 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, 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**

#### INDICATIONS AND USAGE:

Vitafo<sup>l</sup>-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:

Vitafo<sup>l</sup>-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 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 anti-convulsant 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 Vitafo<sup>l</sup>-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:

Vitafo<sup>l</sup>-OB is available as a light blue caplet, debossed EV0079. Available in Box of Unit-Dose pack of 100 (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

#### Disbuted by:

**Exeltis USA, Inc.**

**Florham Park, NJ 07932**

1-877-324-9349

www.exeltisusa.com

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