**0642-0076-30**
**Vitafol®-OB+DHA**
**Prenatal Supplement with DHA**
**Rx**

**COMPOSITION:**

| Each Vitafol®-OB caplet contains: | |
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| 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 |

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| Each DHA softgel capsule contains:<br>Algal oil blend (derived from Natural Algal Oil)<br>(*providing 250 mg DHA (docosahexaenoic acid)) | 486 mg* |

**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 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

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