

# Vitafol®-OB+DHA

Prenatal Multivitamin/Mineral with DHA

By Prescription Only

## SEE ORDERING INFORMATION BELOW

Everett Laboratories has a long history of successfully producing quality prenatal nutritional supplements manufactured to the highest quality of cGMP.

This tradition continues with VITAFOL-OB+DHA Caplets

If you are having difficulties obtaining a specific brand or generic prenatal vitamin no longer available please consider recommending VITAFOL-OB+DHA to the prescribing physician for your patient.

### GLUTEN • SUGAR • LACTOSE FREE

Pleasant orange flavor • No fish taste, smell or after taste • No Fish byproducts

Available in Unit-Dose Boxes of 30 (6 child resistant blister cards of 5 caplets and 5 capsules each).

PRODUCT	NDC	CARDINAL HEALTH
VITAFOL-OB+DHA Caplets 30's	0642-0076-30	3933827
PRODUCT	NDC	MCKESSON
VITAFOL-OB+DHA Caplets 30's	0642-0076-30	1700350
PRODUCT	NDC	ABC
VITAFOL-OB+DHA Caplets 30's	0642-0076-30	837935

**VITAFOL®-OB+DHA    NDC 0642-0076-30    Vitamin & Mineral Caplets +DHA Capsule For Use Before, During and After Pregnancy    Rx Only**

**Each VITAFOL®-OB caplet provides:**

**VITAMINS:**

A (beta carotene)..... 2700 IU  
 D (cholecalciferol)..... 400 IU  
 C (ascorbic acid)......70 mg  
 E (dl-alpha tocopheryl acetate).....30 IU

Folic Acid..... 1 mg  
 B1 (thiamine mononitrate) .....1.6 mg  
 B2 (riboflavin).....1.8 mg  
 B6 (pyridoxine hydrochloride).....2.5 mg  
 B12 (cyanocobalamin)..... 12 mcg  
 Niacin (niacinamide).....18 mg

**MINERALS:**

Calcium (calcium carbonate).....100 mg  
 Elemental Iron (ferrous fumarate) 65 mg  
 Magnesium (magnesium oxide).....25 mg  
 Zinc (zinc oxide) .....25 mg  
 Copper (copper oxide) ..... 2 mg

**Each DHA gelatin capsule provides:** Docosahexaenoic Acid (DHA).....250 mg

DHA is contained in the oil derived from microalgae. Other ingredients in DHA gelatin capsule: gelatin, Glycerin USP, water, orange flavor.

**INACTIVE INGREDIENTS** Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid, Hydroxypropyl Methylcellulose, Titanium Dioxide, Polydextrose, Magnesium Stearate, Colloidal Silicon Dioxide, Hydroxypropyl Cellulose, Triacetin, Dicalcium Phosphate, FD&C Blue #1 Aluminum Lake, Polyethylene Glycol, FD&C Blue #2 Aluminum Lake, D&C Yellow #10 Aluminum Lake.

**INDICATIONS AND USAGE** VITAFOL®-OB+DHA is indicated to provide vitamin and mineral supplementation 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. It is also useful for improving the nutritional status prior to conception. VITAFOL®-OB+DHA: Contains 1 mg folic acid, which is very important in the development of the baby's spinal column during a specific period of time. Women are advised to start taking folate supplementation several weeks before conception and to continue taking them through the first 12 weeks of pregnancy, or longer. It is recommended that all women of childbearing years take folic acid supplementation.

**CONTRAINDICATIONS** Folic acid (pteroylglutamic 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).

**WARNINGS** Pernicious anemia should be ruled out before starting treatment. While folic acid corrects the blood picture of pernicious anemia, it does not ameliorate the attendant neurologic involvement. Resistance to treatment may be due to depressed hematopoiesis, alcoholism, the present of anti-metabolic drugs, and to deficiencies of vitamins. Prolonged use of iron salts may produce iron storage disease.

**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.**

Ingestion of more than 3 grams of omega-3 fatty acids per day has been shown to have potential antithrombotic effects, including an increased bleeding time and INR. Administration of omega-3 fatty acids should be avoided in patients on anticoagulants and in those known to have an inherited or acquired bleeding diathesis.

**PRECAUTIONS** Folic acid (pteroylglutamic acid) and Vitamin B-12 microbiological blood assays are invalidated by the administration of most antibiotics, methotrexate, and pyrimethamine. Folic acid (pteroylglutamic acid) is not effective reversing the toxic effects of methotrexate. Folic acid (5-formyltetrahydrofolic acid) must be used in that situation. Black tarry stools may be due to either occult GI bleeding or iron therapy or both. Folic acid may partially correct the hematological damage due to Vitamin B-12 deficiency of pernicious anemia, while the associated neurological damage progresses. In rare instances, allergic sensitization has been reported following both oral and parenteral administration of folic acid. Supplementation of the diet by milk or other dietary sources of Calcium may be advisable. Exercise caution to ensure that the prescribed dosage of DHA does not exceed 1 gram (1000 mg) per day.

**ADVERSE REACTIONS** Allergic sensitivity reactions and gastrointestinal disturbances may occur.

**DOSAGE AND ADMINISTRATION** Before, during and after pregnancy, one caplet and one gel capsule daily, or as directed by a physician.

**HOW SUPPLIED** VITAFOL®-OB+DHA is available as a light blue, capsule shaped caplet imprinted "EV 0079" and one DHA Capsule. Available in Box of Unit-Dose pack of 30 (6 child resistant blister cards of 5 caplets and 5 capsules each), NDC 0642-0076-30

**KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN** Store at room temperature, approximately 15°-30°C (59°-86°F), avoid excessive heat.

U.S. Patent No. 6,814,983; 6,977,167; 5,407,957; 5,492,938 and other patents pending

Manu. for EVERETT LABORATORIES, INC. West Orange, NJ 07052