**Vitafol® Ultra**
**Prenatal Supplement with DHA**
**Rx**

**COMPOSITION:**

Amount per Capsule:

| **VITAMINS AND MINERALS:** | |
|---|---|
| Vitamin A (as beta carotene) | 330 mcg RAE |
| Vitamin C (as ascorbic acid) | 30 mg |
| Vitamin D (as cholecalciferol) | 25 mcg |
| Vitamin E (as dl-alpha tocopheryl acetate) | 9 mg |
| Thiamin (Vitamin B1 as thiamine mononitrate) | 1.6 mg |
| Riboflavin (Vitamin B2) | 1.8 mg |
| Niacin (as niacinamide) | 15 mg NE |
| Vitamin B6 (as pyridoxine hydrochloride) | 2.5 mg |
| Folate (680 mcg DFE from folic acid & 1020 mcg DFE from l-methylfolate calcium) | 1700 mcg DFE |
| Vitamin B12 (as cyanocobalamin) | 12 mcg |
| Iron (as polysaccharide iron complex) | 29 mg |
| Iodine (as potassium iodide) | 150 mcg |
| Magnesium (as magnesium oxide) | 20 mg |
| Zinc (as zinc oxide) | 25 mg |
| Copper (as copper oxide) | 2 mg |
| Docosahexaenoic acid (DHA) (from natural algal oil) | 200 mg |

**Other Ingredients:** Gelatin (Bovine), Glycerin, Soybean Oil, Yellow Beeswax, Sorbitol, Purified Water, Soy Lecithin, Microcrystalline Cellulose, Mannitol, FD&C Blue #1, Ethyl Vanillin. Titanium Dioxide (color). May contain: Sunflower Oil, Olive Oil. **Contains: Soy.**

**USAGE:** Vitafol® Ultra provides vitamin, mineral, and DHA supplementation prior to conception, throughout pregnancy, and during the postnatal period for the lactating and non-lactating mother.*
Vitafol® Ultra does not contain fish, fish oils, fish proteins or fish byproducts.

**CONTRAINDICATIONS:** Vitafol® Ultra 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:** Vitafol® Ultra contains soy and should be used with caution in patients with known sensitivity or allergy to soy.

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.

Iodine should be used with caution in patients with an overactive thyroid.

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:** Medications for an overactive thyroid (anti-thyroid drugs) used in conjunction with iodine supplementation may lead to hypothyroidism.

Medications for hypertension used in conjunction with iodine supplementation may increase potassium.

High doses of folic acid may result in decreased serum levels of the anticonvulsant drugs; carbamazepine, fosphenytoin, phenytoin, phenobarbitol, valproic acid. Folic acid may decrease a patient's response to methotrexate.

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.

**ADVERSE REACTIONS:** Adverse reactions have been reported with specific vitamins and minerals, but generally at doses substantially higher than those in Vitafol® Ultra. However, allergic and idiosyncratic reactions are possible at any dose. Reported adverse events include skin ailments, gastrointestinal complaints, glucose abnormalities, and visual problems.

You should call your doctor for medical advice about serious adverse events. To report a serious adverse event or obtain product information, contact 1-877-324-9349.

**DOSAGE AND ADMINISTRATION:** Before, during and after pregnancy, take one softgel capsule by mouth daily, or as directed by a physician.

**HOW SUPPLIED:** Vitafol® Ultra is available as a dark blue, oval shaped softgel capsule imprinted "EV0093". Available in Box of Unit Dose pack of 30 (5 child resistant blister cards of 6 softgel capsules) (0642-0093-30) and as professional samples (0642- 0093-03).

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.

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