**VITAFOL ULTRA- doconexent, niacinamide, .alpha.-tocopherol acetate, dl-, cholecalciferol, .beta.-carotene, ascorbic acid, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamin, iron, zinc oxide, cupric oxide, potassium iodide, magnesium oxide, folic acid, and levomefolate calcium capsule, liquid filled**
**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.*

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**0642-0093-30**

**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 |
| | 150 |

| | |
|---|---|
| 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 B12).

**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 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.

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.

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

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.

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

## DIRECTIONS FOR USE

Before, during and after pregnancy, one softgel capsule 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.

Rx

**Distributed by:**

**Exeltis USA, Inc.**

**Florham Park, NJ 07932**

1-877-324-9349

www.exeltisusa.com



Vitafol ® is a trademark of Exeltis Healthcare S.L.

U.S. Patent No. 8,183,227

Rev. January 2023

0933001-03

## PRINCIPAL DISPLAY PANEL - 30 Capsule Blister Pack Box

0642-0093-30

V ®

VITAFOL

ULTRA

Prenatal Supplement with 200mg DHA

Unit Dose Pack

30 Softgel Capsules

R x

DIETARY SUPPLEMENT

U.S. PATENTED


**VITAFOL ULTRA**

doconexent, niacinamide, .alpha.-tocopherol acetate, dl-, cholecalciferol, .beta.-carotene, ascorbic

acid, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, cyanocobalamin, iron, zinc oxide, cupric oxide, potassium iodide, magnesium oxide, folic acid, and levomefolate calcium capsule, liquid filled

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:0642-0093 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **DOCONEXENT** (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC) | DOCONEXENT | 200 mg |
| **NIACINAMIDE** (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4) | NIACINAMIDE | 15 mg |
| **.ALPHA.-TOCOPHEROL ACETATE, DL-** (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01) | .ALPHA.-TOCOPHEROL, DL- | 9 mg |
| **CHOLECALCIFEROL** (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41) | CHOLECALCIFEROL | 25 ug |
| **BETA CAROTENE** (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J) | BETA CAROTENE | 330 ug |
| **ASCORBIC ACID** (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R) | ASCORBIC ACID | 30 mg |
| **THIAMINE MONONITRATE** (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J) | THIAMINE | 1.6 mg |
| **RIBOFLAVIN** (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR) | RIBOFLAVIN | 1.8 mg |
| **PYRIDOXINE HYDROCHLORIDE** (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z) | PYRIDOXINE HYDROCHLORIDE | 2.5 mg |
| **CYANOCOBALAMIN** (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204) | CYANOCOBALAMIN | 12 ug |
| **IRON** (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7) | IRON | 29 mg |
| **ZINC OXIDE** (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 25 mg |
| **CUPRIC OXIDE** (UNII: V1XJQ704R4) (CUPRIC CATION - UNII:8CBV67279L) | CUPRIC CATION | 2 mg |
| **POTASSIUM IODIDE** (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q) | IODIDE ION | 150 ug |
| **MAGNESIUM OXIDE** (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838) | MAGNESIUM OXIDE | 20 mg |
| **FOLIC ACID** (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8) | FOLIC ACID | 680 ug |
| **LEVOMEFOLATE CALCIUM** (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC) | LEVOMEFOLATE CALCIUM | 1020 ug |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **MANNITOL** (UNII: 3OWL53L36A) | |
| **GELATIN, UNSPECIFIED** (UNII: 2G86QN327L) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **YELLOW WAX** (UNII: 2ZA36H0S2V) | |
| **SOYBEAN OIL** (UNII: 241ATL177A) | |
| **LECITHIN, SOYBEAN** (UNII: 1DI56QDM62) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **ETHYL VANILLIN** (UNII: YC9ST449YJ) | |
| **SUNFLOWER OIL** (UNII: 3W1JG795YI) | |
| **OLIVE OIL** (UNII: 6UYK2W1W1E) | |
| **CELLULOSE, MICROCRYSTALLINE** (UNII: OP1R32D61U) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | blue | **Score** | no score |
| **Shape** | OVAL | **Size** | 12mm |
| **Flavor** | | **Imprint Code** | EV0093 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:0642-0093-30 | 5 in 1 BOX | 09/23/2013 | |
| **1** | | 6 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| **2** | NDC:0642-0093-03 | 1 in 1 BOX | 09/23/2013 | |
| **2** | | 4 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 09/23/2013 | |

## Labeler - Exeltis USA, Inc. (071170534)

Revised: 3/2023 Exeltis USA, Inc.