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.

Vitafol®-Ultra
Prenatal Supplement with DHA

0642-0093-30

Rx

COMPOSITION

Amount per Capsule:

VITAMINS AND MINERALS:

Vitamin A (as beta carotene)	1100 IU
Vitamin C (as ascorbic acid)	30 mg
Vitamin D (as cholecalciferol)	1000 IU
Vitamin E (as dl-alpha tocopheryl acetate)	20 IU
Thiamin (Vitamin B1)	1.6 mg
Riboflavin (Vitamin B2)	1.8 mg
Niacin (as niacinamide)	15 mg
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg
Folate (as Folic acid USP 0.4 mg and L-methylfolate Calcium 0.6 mg, as Metafolin® CAS# 151533-22-1)	1 mg
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
Algal oil blend (derived from Natural Algal Oil)	415 mg*

* (providing 200 mg DHA (docosahexaenoic acid))

Other Ingredients:

Gelatin (bovine BSE-free), Sorbitol, Glycerin, Soybean Oil, Yellow Beeswax, USP Purified Water, Lecithin, FD&C Blue #1, Titanium Dioxide (color), Ethyl Vanillin. May contain: Corn Oil, dl-alpha tocopherol, High Oleic Sunflower Oil, Tocopherols, Ascorbyl Palmitate.

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, including individuals with known allergies to fish. 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.

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.

Rx

Distributed by:
Exeltis USA, Inc.
Florham Park, NJ 07932
1-877-324-9349
www.exeltisusa.com

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

Rev. November 2018

0933001-01

PRINCIPAL DISPLAY PANEL - 30 Capsule Blister Pack Box

0642-0093-30

VITAFOL
ULTRA

Prenatal Supplement with 200mg DHA

Unit Dose Pack
30 Softgel Capsules

R_x
DIETARY SUPPLEMENT
U.S. PATENTED

0642-0093-30

VITAFOL ULTRA

Prenatal Supplement with 200mg DHA

Unit Dose Pack
30 Softgel Capsules

Rx DIETARY SUPPLEMENT U.S. PATENTED

Lot No.

Exp. Date:

3 06420 09330 2

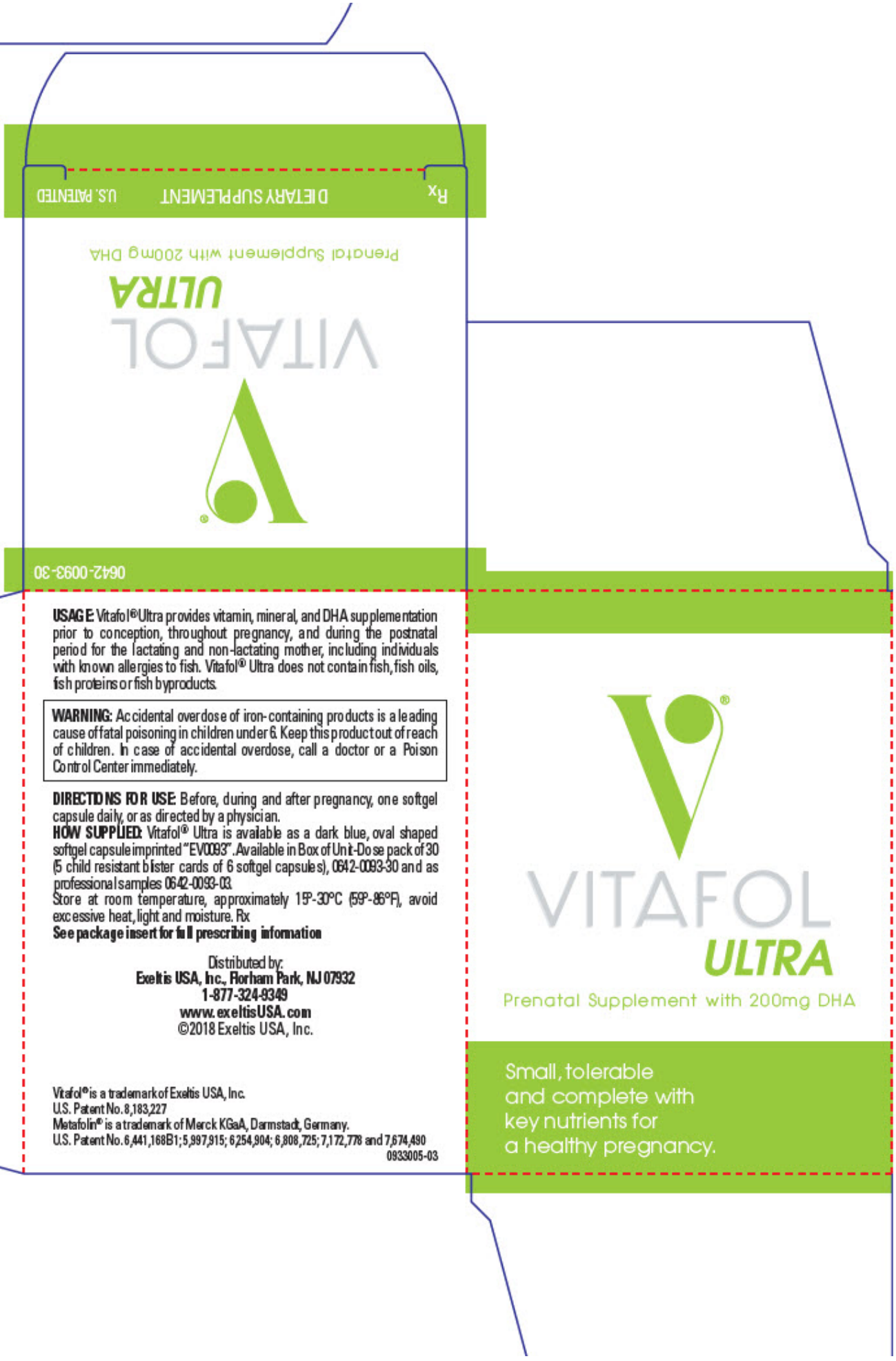
Supplement Facts

Serving Size 1 Softgel Capsule

Each Softgel Capsule contains		% Daily Value in Pregnancy
Vitamin A (as beta carotene)	1100 IU	14%
Vitamin C (as ascorbic acid)	30 mg	50%
Vitamin D (as cholecalciferol)	1000 IU	250%
Vitamin E (as dl-alpha tocopheryl acetate)	20 IU	67%
Thiamin (Vitamin B1)	1.6 mg	94%
Riboflavin (Vitamin B2)	1.8 mg	90%
Niacin (as niacinamide)	15 mg	75%
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg	100%
Folate (as Folic acid USP 0.4 mg and L-methylfolate calcium 0.6 mg)	1 mg	125%
Vitamin B12 (as cyanocobalamin)	12 mcg	150%
Iron (as polysaccharide iron complex)	29 mg	161%
Iodine (as potassium iodide)	150 mcg	100%
Magnesium (as magnesium oxide)	20 mg	4%
Zinc (as zinc oxide)	25 mg	167%
Copper (as copper oxide)	2 mg	100%
Algal oil blend (from natural algal oil) (*providing 200 mg DHA (docosahexaenoic acid))	415 mg*	†

† Daily Value not established

Other Ingredients: Gelatin, Sorbitol, Glycerin, Soybean Oil, Yellow Beeswax, USP Purified Water, Lecithin, FD&C Blue #1, Titanium Dioxide (color), Ethyl Vanillin. May contain: Corn Oil, dl-alpha tocopherol, High Oleic Sunflower Oil, Tocopherols, Ascorbyl Palmitate. **Contains: Soy.**


Rx
DIETARY SUPPLEMENT
U.S. PATENTED
Prenatal Supplement with 200mg DHA
ULTRA
VITAFOL
0642-0093-30
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, including individuals with known allergies to fish. Vitafol® Ultra does not contain fish, fish oils, fish proteins or fish byproducts.
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.
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, light and moisture. Rx
See package insert for full prescribing information
Distributed by:
Exeltis USA, Inc., Florham Park, NJ 07932
1-877-324-9349
www.exeltisUSA.com
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Vitafol® is a trademark of Exeltis USA, Inc.
U.S. Patent No. 8,183,227
Metafolin® is a trademark of Merck KGaA, Darmstadt, Germany.
U.S. Patent No. 6,441,168B1; 5,997,915; 6,254,904; 6,808,725; 7,172,778 and 7,674,490
0933005-03
VITAFOL
ULTRA
Prenatal Supplement with 200mg DHA
Small, tolerable
and complete with
key nutrients for
a healthy pregnancy.

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-	20 [iU]
Cholecalciferol (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	Cholecalciferol	1000 [iU]
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	1100 [iU]
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	0.4 mg
Levomefolate Calcium (UNII: A9R10K3F2F) (Levomefolic Acid - UNII:8S95DH25XC)	Levomefolate Calcium	0.6 mg

Inactive Ingredients

Ingredient Name	Strength
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)	
Tocopherol (UNII: R0ZB2556P8)	
Ascorbyl Palmitate (UNII: QN83US2B0N)	
Corn Oil (UNII: 8470G57WFM)	
.Alpha.-Tocopherol, DL- (UNII: 7QWA1RIO01)	

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:0642-0093-01	1 in 1 BOX	09/23/2013	09/23/2013
2		4 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0642-0093-03	1 in 1 BOX	09/23/2013	
3		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: 4/2019 Exeltis USA, Inc.