VITAFOL FE PLUS- 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.

0642-7473-30

Vitafol ® Fe + Supplement

Prenatal Supplement with 90 mg Iron

Rx

COMPOSITION:

Each Vitafol ® Fe+ softgel capsule contains:

Vitamin A (as beta carotene)	330 mcg RAE
Vitamin C (as ascorbic acid)	60 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	1700 mcg DFE
(680 mcg DFE from folic acid & 1020 mcg DFE from l-methylfolate calcium)	
Vitamin B12 (as cyanocobalamin)	25 mg
Iron (as polysaccharide iron complex)	90 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), Soybean Oil, Glycerin, Yellow Beeswax, Sorbitol, Soy Lecithin, Titanium Dioxide (color), FD&C Red #40, FD&C Blue #1

Contains: Soy

USAGE:

Vitafol ® Fe + prenatal supplement provides vitamin, mineral and omega-3 fatty acid supplementation throughout pregnancy, including individuals with known allergies to fish.* Vitafol ® Fe + does not contain fish oils, fish proteins, or fish by-products.

CONTRAINDICATIONS:

Vitafol ® Fe + prenatal supplement 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 supplementation 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:

This product is intended for use as directed by your healthcare provider. Do not share with others. Vitafol ® Fe + must 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 levels in blood.

High doses of folic acid may result in decreased serum levels of the anticonvulsant drugs; carbamazepine, fosphenytoin, phenytoin, phenobarbital, 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.

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 ® Fe $^{+}$. 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 adverse or unexpected reactions. To report to the company an
adverse event or obtain product information, call 1-877-324-9349.

DIRECTIONS FOR USE:

Take one **purple softgel** capsule daily during pregnancy, or as directed by a physician.

HOW SUPPLIED:

Vitafol ® Fe + is available as a purple, oval shaped softgel capsule imprinted "EX0096". Available in box of Unit-Dose pack of 30 (5 child resistant blister cards containing 6 softgel capsules) (0642-7473-30) and as professional samples (0642-7473-01).

Store at room temperature, approximately 15°-30°C (59°-86°F), avoid excessive heat above 30°C (86°F), light and moisture.

Please dispose of any unused capsules promptly, and properly.

Distributed by:

Exeltis USA, Inc.

Florham Park, NJ 07932

1-877-324-9349

www.exeltisusa.com

*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.

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

4733001-03 Rev. February 2023

PRINCIPAL DISPLAY PANEL - 30 Capsule Dose Pack Box

0642-7473-30

VITAFOL
Fe+

Complete Prenatal Supplement
with 90mg iron

Unit Dose Pack
30 Softgel Capsules

R X
DIETARY SUPPLEMENT
U.S. Patent Pending

0642-7473-30

VITAFOL

Fe+

Complete Prenatal Supplement
with 90mg iron

Unit Dose Pack
30 Softgel Capsules

Rx DIETARY SUPPLEMENT U.S. Patent Pending

Lot No.

Exp. Date:

3 06427 47330 5

Supplement Facts

Serving Size 1 Softgel Capsule

Each Softgel Capsule contains		% Daily Value in Pregnancy
Vitamin A (as beta carotene)	330 mcg RAE	14%
Vitamin C (as ascorbic acid)	60 mg	100%
Vitamin D (as cholecalciferol)	25 mcg	250%
Vitamin E (as dl-alpha tocopheryl acetate)	9 mg	67%
Thiamin (Vitamin B1)	1.6 mg	94%
Riboflavin (Vitamin B2)	1.8 mg	90%
Niacin (as niacinamide)	15 mg NE	75%
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg	100%
Folate (as folic acid 680 mcg DFE and L-methylfolate calcium 1020 mcg DFE)	1700 mcg DFE	125%
Vitamin B12 (as cyanocobalamin)	25 mcg	313%
Iron (as polysaccharide iron complex)	90 mg	500%
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, Soybean Oil, Sorbitol, Glycerin, Yellow Beeswax, USP Purified Water, Lecithin, Titanium Dioxide (as colorant), FD&C Red #40, FD&C Blue #1, White Edible Ink. **Contains: Soy.**
May contain: Corn Oil, Medium Chain Triglycerides.

Rx DIETARY SUPPLEMENT U.S. Patent Pending

Complete Prenatal Supplement
with 90mg iron

VITAFOL Fe+

0642-7473-30

USAGE: Vitafol® Fe+ prenatal supplement provides vitamin, mineral, and omega-3 fatty acid supplementation throughout pregnancy, including individuals with known allergies to fish. Vitafol® Fe+ does not contain fish oil, 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: During pregnancy, take one softgel capsule daily, or as directed by a physician.

HOW SUPPLIED: Vitafol® Fe+ is available as a purple, oval shaped softgel capsule imprinted "EX0096". Available in Box of Unit-Dose pack of 30 count (5 child resistant blister cards containing 6 softgel capsules), 0642-7473-30 and as professional samples 0642-7473-01.

Store at room temperature, approximately 15°-30°C (59°-86°F), avoid excessive heat above 30°C (86°F), 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

4733005-02

VITAFOL
Fe+

Complete Prenatal Supplement
with 90mg iron

Vital nutrition
for women who need
more iron.

VITAFOL FE PLUS

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:0642-7473
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 mg
BETA CAROTENE (UNII: 01YAE03M7J) (BETA CAROTENE - UNII:01YAE03M7J)	BETA CAROTENE	330 ug
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	60 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	25 ug
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	90 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)	POTASSIUM IODIDE	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 mg
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	1020 ug

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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
TOCOPHEROL (UNII: R0ZB2556P8)	
ASCORBYL PALMITATE (UNII: QN83US2B0N)	
CORN OIL (UNII: 8470G57WFM)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

Product Characteristics

Color	purple	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	EV0096
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0642-7473-30	5 in 1 BOX, UNIT-DOSE	03/15/2020	
1		6 in 1 BLISTER PACK; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/15/2020	

Labeler - Exeltis USA, Inc. (071170534)

Revised: 2/2023 Exeltis USA, Inc.