VITAFOL FE PLUS- vitamin a, ascorbic acid, vitamin d, .alpha.-tocopherol, thiamine mononitrate, riboflavin, niacin, pyridoxine hydrochloride, folic acid, cyanocobalamin, iodine, iron, magnesium, zinc, copper, doconexent, and docusate sodium
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® Fe+ Supplement
Prenatal Supplement with 90 mg Iron, and Optional Stool Softener

Rx

Prenatal Supplement

COMPOSITION

Each PURPLE softgel capsule contains:

Vitamin A (as beta carotene)	1100	IU
Vitamin C (as ascorbic acid)	60	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; as L-methylfolate calcium 0.6 mg)	1	mg
Vitamin B12 (as cyanocobalamin)	25	mcg
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
Algal oil (from crypthecodinium cohnii) providing 200 mg DHA (docosahexaenoic acid)	415	mg

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 also contain: Corn Oil, DL alpha-tocopherol, Medium Chain Triglycerides.

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, 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.

Stool Softener Supplement

COMPOSITION

Each WHITE softgel capsule contains: Docusate sodium, 50 mg

Other Ingredients: Gelatin, Sorbitol, Polyethylene Glycol, Glycerin, Purified Water, Propylene Glycol, Titanium Dioxide, Citric Acid, Black Edible Ink.

USAGE

Helps maintain bowel regularity and to provide relief from occasional constipation which may occur during pregnancy or associated with use of supplements containing iron.

WARNINGS/PRECAUTIONS

Ask a doctor before use if you have stomach pain, nausea, or vomiting; or a sudden change in bowel habits that lasts over 14 days.

Ask your doctor before use if you are breastfeeding.

Ask a doctor or pharmacist before use if you are presently taking mineral oil, or other laxative products.

Stop use and ask a doctor if you have rectal bleeding or no bowel movement after using this product, as these could be signs of a serious condition.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS FOR USE

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

Take one **white softgel** capsule daily, or as needed to help relieve occasional constipation. Take with water. May be taken at the same time as the prenatal supplement or separately.

HOW SUPPLIED

Vitafol® Fe+ is available as a purple, oval shaped softgel capsule imprinted "EX0096" and one white, oval shaped softgel capsule imprinted "50". Available in box of Unit-Dose pack of 30 (6 child resistant blister cards of 5+5 softgel capsules), Item No. 0642-0096-30 and as professional samples Item No. 0642-0096-01.

Store at room temperature, approximately 15°-30°C (59°-86°F), avoid excessive heat 40°C (104°F), light and moisture.

Please dispose of any unused capsules promptly, and properly.

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.

Manufactured in the USA.

Distributed by:
Exeltis USA, Inc.
Florham Park, NJ 07932

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.

(Rev.08/15)

PRINCIPAL DISPLAY PANEL - Kit Carton

SAMPLE NOT FOR SALE
0642-0096-01

Vitafol® Fe+
COMPLETE PRENATAL SUPPLEMENT WITH 90 mg IRON

Small, Once Daily Softgel
with 16 Key Nutrients

- 90 mg Iron
- Gluten, Lactose and Sugar Free

+ Optional stool softener softgel

3-Day
Starter Pack

R_x
U.S. Patent Pending

Supplement Facts

Serving Size 1 Purple Softgel Capsule

Each Purple Softgel Capsule contains		% Daily Value in Pregnancy
Vitamin A (as beta carotene)	1100 IU	14%
Vitamin C (as ascorbic acid)	60 mg	100%
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 0.4 mg and L-methylfolate calcium 0.6 mg)	1 mg	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 *Crypthecodinium cohnii*) (*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 cobrant), FD&C Red #40, FD&C Blue #1, White Edible Ink. **Contains: Soy.**
May Contain: Corn Oil, Medium Chain Triglycerides.

Supplement Facts

Serving Size 1 White Softgel Capsule

Each White Softgel Capsule contains		% Daily Value in Pregnancy
Docusate sodium	50 mg	†

† Daily Value not established

Other Ingredients: Gelatin, sorbitol, polyethylene glycol, glycerin, purified water, propylene glycol, titanium dioxide, citric acid, black edible ink.

WARNINGS/PRECAUTIONS: Ask a doctor before use if you have stomach pain, nausea, or vomiting; or a sudden change in bowel habits that lasts over 14 days. Ask your doctor before use if you are breastfeeding. Ask a doctor or pharmacist before use if you are presently taking mineral oil, or other laxative products. Stop use and ask a doctor if you have rectal bleeding or no bowel movement after using this product, as these could be signs of a serious condition.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

USAGE: Vitafol®-Fe+ is indicated to provide vitamin, mineral, and DHA supplementation throughout pregnancy, including individuals with known allergies to fish. Vitafol®-Fe+ does not contain fish, fish oils, fish proteins or fish byproducts. A separate (white) softgel capsule containing docusate sodium is provided to help maintain bowel regularity and to relieve occasional constipation associated with pregnancy or iron supplementation.

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 purple softgel capsule daily, or as directed by a physician. Take one white softgel daily to help maintain bowel regularity, or as needed to relieve occasional constipation.

HOW SUPPLIED: Vitafol®-Fe+ is available as a purple, oval shaped softgel capsule imprinted "EX0096" and one white, oval shaped softgel capsule imprinted "50". Available in Box of Unit-Dose pack of 30 (6 child resistant blister cards of 5+5 softgel capsules), NDC 0642-0096-30 and as professional samples, NDC 0642-0096-01.

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

Rx

See package insert for full prescribing information

Manufactured in USA. Distributed by:
Exeltis USA, Inc., Florham Park, NJ 07932
You should call your doctor for medical advice about adverse events. To report an adverse event or obtain product information, contact
1-877-324-9349

Vitafol® is a trademark of Exeltis USA, Inc. U.S Patent Pending
life'sDHA is a trademark of DSM. U.S. Patent No. 7,163,811 and 7,824,892
Metafolin® is a trademark of Merck KGaA, Darmstadt, Germany.
U.S. Patent No. 6,441,168 B1; 5,997,915; 6,254,904; 6,808,725; 7,172,778 and 7,674,490
(Rev. 08/15)

Vitafol® Fe+
COMPLETE PRENATAL SUPPLEMENT WITH 90 mg IRON
Small, Once Daily Softgel with 16 Key Nutrients

SAMPLE NOT FOR SALE
0642-0096-01

Vitafol® Fe+

COMPLETE PRENATAL SUPPLEMENT WITH 90 mg IRON

Small, Once Daily Softgel with 16 Key Nutrients

- 90 mg Iron
- Gluten, Lactose and Sugar Free

+ Optional stool softener softgel

3-Day
Starter Pack

Rx

U.S. Patent Pending

Vitafol® Fe+
COMPLETE PRENATAL SUPPLEMENT WITH 90 mg IRON
Small, Once Daily Softgel with 16 Key Nutrients

Vitafol® Fe+
COMPLETE PRENATAL SUPPLEMENT WITH 90 mg IRON

Small, Once Daily Softgel with 16 Key Nutrients

Vitafol® Fe+
COMPLETE PRENATAL SUPPLEMENT WITH 90 mg IRON

VITAFOL FE PLUS

vitamin a, ascorbic acid, vitamin d, .alpha.-tocopherol, thiamine mononitrate, riboflavin, niacin, pyridoxine hydrochloride, folic acid, cyanocobalamin, iodine, iron, magnesium, zinc, copper, doconexent, and docusate sodium kit

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0642-0096

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0642-0096-01	1 in 1 CARTON		

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	5
Part 2	1 BLISTER PACK	5

Part 1 of 2

VITAFOL FE PLUS PRENATAL SUPPLEMENT

vitamin a, ascorbic acid, vitamin d, .alpha.-tocopherol, thiamine mononitrate, riboflavin, niacin, pyridoxine hydrochloride, folic acid, cyanocobalamin, iodine, iron, magnesium, zinc, copper, and doconexent capsule, liquid filled

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Vitamin A (UNII: 81G40H8B0T) (Vitamin A - UNII:81G40H8B0T)	Vitamin A	1100 [iU]
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg
Vitamin D (UNII: 9VU1KI44GP) (Cholecalciferol - UNII:1C6V77QF41)	Vitamin D	1000 [iU]
.Alpha.-Tocopherol (UNII: H4N855PNZ1) (.Alpha.-Tocopherol - UNII:H4N855PNZ1)	.Alpha.-Tocopherol	20 [iU]
Thiamine Mononitrate (UNII: 8K0I04919X) (Thiamine Ion - UNII:4ABT0J945J)	Thiamine	1.6 mg
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	1.8 mg
Niacin (UNII: 2679MF687A) (Niacin - UNII:2679MF687A)	Niacin	15 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	2.5 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1 mg
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	25 ug
Iodine (UNII: 9679TC07X4) (Iodine - UNII:9679TC07X4)	Iodine	150 ug
Iron (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7)	Iron	90 mg
Magnesium (UNII: I38ZP9992A) (Magnesium - UNII:I38ZP9992A)	Magnesium	20 mg

Zinc (UNII: J41CSQ7QDS) (Zinc - UNII:J41CSQ7QDS)	Zinc	25 mg
Copper (UNII: 789U1901C5) (Copper - UNII:789U1901C5)	Copper	2 mg
Doconexent (UNII: ZAD9OKH9JC) (Doconexent - UNII:ZAD9OKH9JC)	Doconexent	200 mg

Inactive Ingredients

Ingredient Name	Strength
Gelatin (UNII: 2G86QN327L)	
Soybean Oil (UNII: 241ATL177A)	
Sorbitol (UNII: 506T60A25R)	
Glycerin (UNII: PDC6A3C0OX)	
Yellow Wax (UNII: 2ZA36H0S2V)	
Water (UNII: 059QF0KO0R)	
Lecithin, Soybean (UNII: 1DI56QDM62)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
Corn Oil (UNII: 8470G57WFM)	
Medium-Chain Triglycerides (UNII: C9H2L21V7U)	

Product Characteristics

Color	PURPLE	**Score**	no score
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	EX0096
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5 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		10/01/2015	

Part 2 of 2

VITAFOL FE PLUS STOOL SOFTENER SUPPLEMENT

docusate sodium capsule, liquid filled

Product Information

Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Docusate Sodium (UNII: F05Q2T2JA0) (Docusate - UNII:M7P27195AG)	Docusate Sodium	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Gelatin (UNII: 2G86QN327L)	
Polyethylene Glycols (UNII: 3WJQ0SDW1A)	
Sorbitol (UNII: 506T60A25R)	
Glycerin (UNII: PDC6A3C0OX)	
Water (UNII: 059QF0KO0R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	

Product Characteristics			
Color	WHITE	**Score**	no score
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	50
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		5 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
DIETARY SUPPLEMENT		10/01/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		10/01/2015	

Labeler - Exeltis USA, Inc. (071170534)

Revised: 9/2015 Exeltis USA, Inc.