VITAFOL GUMMIES- vitamin a, ascorbic acid, vitamin d, .alpha.-tocopherol, niacin, pyridoxine hydrochloride, folic acid, cyanocobalamin, iron, iodine, choline, doconexent, icosapent, and omega-3 fatty acids tablet, chewable
Exeltis USA, Inc.

Vitafol® gummies
Prenatal Supplement with Iron

Rx

COMPOSITION

Amount per daily dose (3 gummies)

VITAMINS AND MINERALS:	
Calories	24
Total Carbohydrates	5 g
Sugars	5 g
Vitamin A (as Vitamin A palmitate)	330 mcg RAE
Vitamin C (as ascorbic acid)	30 mg
Vitamin D (as cholecalciferol)	25 mcg
Vitamin E (as d-alpha tocopheryl acetate)	6.75 mg
Niacin (as niacinamide)	15 mg NE
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg
Folate (as folic acid)	1700 mcg DFE
Vitamin B12 (as cyanocobalamin)	8 mcg
Iron (as ferric orthophosphate)	10 mg
Iodine (as potassium iodide)	150 mcg
Choline (as choline bitartrate)	10 mg
Omega 3 fatty acid	104.5 mg
Docosahexaenoic acid (DHA)	75 mg
Eicosapentaenoic acid (EPA)	15.3 mg
Other Omega 3 fatty acid	14.2 mg

Other Ingredients: Sugar, glucose syrup, water, gelatin, lactic acid, citric acid, mixed berry flavor, Certicoat 580 (contains mineral oil and Carnauba wax), Natural Color and Masking flavor.

Contains soybean an**d fish oil (cod).**

USAGE

Vitafol® Gummies is indicated to provide vitamin, mineral, and DHA supplementation throughout pregnancy.

CONTRAINDICATIONS

Vitafol® Gummies 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

This product is intended for use as directed by your healthcare provider. Please do not share with others. Contains soybean and fish oil (cod).

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.

Do not use if inner seal is broken or missing.

Do not exceed recommended dose.

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.

Pediatric Use

Not for pediatric use.

ADVERSE REACTIONS

Adverse reactions have been reported with specific vitamins and minerals, but generally at doses higher than those in Vitafol® Gummies. 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

During pregnancy, take 3 gummies once daily, or as directed by a physician.

HOW SUPPLIED

Vitafol® Gummies is available as a coated berry shaped gummy. Available in bottle of 90, Item No. 0642-0125-90 and as professional samples, in bottle with 3 gummies, Item No. 0642-0125-04.

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

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

Made in Colombia.
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 USA, Inc.
U.S. Patent Pending

Rev. April 2021
1250301-04

PRINCIPAL DISPLAY PANEL - 90 Tablet Bottle Label

0642-0125-90

VITAFOL
gummies

Prenatal Vital Nutrition with iron

90 gummies (30 Days Supply)

R_X
DIETARY SUPPLEMENT

0642-0125-90

VITAFOL gummies

Prenatal Vital Nutrition with iron

90 gummies (30 Days Supply)

R_x DIETARY SUPPLEMENT

Supplement Facts

Serving Size 3 Gummies

Amount Per Serving		% Daily Value in Pregnancy
Calories	24	
Total Carbohydrates	5 g	†*
Sugars	5 g	†*
Vitamin A (as Vitamin A palmitate)	330 mcg RAE	14%
Vitamin C (as ascorbic acid)	30 mg	50%
Vitamin D (as cholecalciferol)	25 mcg	250%
Vitamin E (as d-alpha tocopheryl acetate)	6.75 mg	50%
Niacin (as niacinamide)	15 mg NE	75%
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg	100%
Folate (as folic acid)	1700 mcg DFE	125%
Vitamin B12 (as cyanocobalamin)	8 mcg	100%
Iron (as ferric orthophosphate)	10 mg	56%
Iodine (as potassium iodide)	150 mcg	100%
Choline (as choline bitartrate)	10 mg	†
Omega 3 fatty acid	104.5 mg	†
Docosahexaenoic acid (DHA)	75 mg	†
Eicosapentaenoic acid (EPA)	15.3 mg	†
Other Omega 3 fatty acid	14.2 mg	†

† Daily Value not established
* Percent Daily Values based on 2,000 calorie diet.

Other Ingredients: Sugar, glucose syrup, water, gelatin, lactic acid, citric acid, mixed berry flavor, Certicoat 580 (contains mineral oil and Carnauba wax), Natural Color and Masking flavor. **Contains soybean and fish oil (cod).**

USAGE: Vitafol® Gummies is indicated to provide vitamin, mineral, and DHA supplementation throughout pregnancy.
CONTRAINDICATIONS: Vitafol® Gummies 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).

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WARNINGS/PRECAUTIONS: This product is intended for use as directed by your healthcare provider. Please do not share with others. **Contains soybean and fish oil (cod).** 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.
Do not use if inner seal is broken or missing. Do not exceed recommended dose. 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. **Pediatric Use:** Not for pediatric use.
ADVERSE REACTIONS: Adverse reactions have been reported with specific vitamins and minerals, but generally at doses higher than those in Vitafol® Gummies. 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: During pregnancy, take 3 gummies once daily, or as directed by a physician.
HOW SUPPLIED: Vitafol® Gummies is available as a coated berry shaped gummy. Available in bottle of 90, 0642-0125-90 and as professional samples in bottle, 0642-0125-04.
Store at room temperature, approximately 15°-30°C (59°-86°F), avoid excessive heat and moisture.
Rx

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1259002-04

VITAFOL GUMMIES

vitamin a, ascorbic acid, vitamin d, .alpha.-tocopherol, niacin, pyridoxine hydrochloride, folic acid, cyanocobalamin, iron, iodine, choline, doconexent, icosapent, and omega-3 fatty acids tablet, chewable

Product Information

Product Type	DIETARY SUPPLEMENT	**Item Code (Source)**	NHRIC:0642-0125
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Vitamin A (UNII: 81G40H8B0T) (Vitamin A - UNII:81G40H8B0T)	Vitamin A	330 ug
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	30 mg
Vitamin D (UNII: 9VU1KI44GP) (Cholecalciferol - UNII:1C6V77QF41)	Vitamin D	25 ug
.Alpha.-Tocopherol (UNII: H4N855PNZ1) (.Alpha.-Tocopherol - UNII:H4N855PNZ1)	.Alpha.-Tocopherol	6.75 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	1700 ug
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	8 ug
Iron (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7)	Iron	10 mg
Iodine (UNII: 9679TC07X4) (Iodine - UNII:9679TC07X4)	Iodine	150 ug
Choline (UNII: N91BDP6H0X) (Choline - UNII:N91BDP6H0X)	Choline	10 mg
DOCONEXENT (UNII: ZAD9OKH9JC) (DOCONEXENT - UNII:ZAD9OKH9JC)	DOCONEXENT	75 mg
Icosapent (UNII: AAN7QOV9EA) (Icosapent - UNII:AAN7QOV9EA)	Icosapent	15.3 mg
Omega-3 Fatty Acids (UNII: 71M78END5S) (Omega-3 Fatty Acids - UNII:71M78END5S)	Omega-3 Fatty Acids	14.2 mg

Inactive Ingredients

Ingredient Name	Strength
Sucrose (UNII: C151H8M554)	
Corn Syrup (UNII: 9G5L16BK6N)	
Water (UNII: 059QF0KO0R)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
Lactic Acid, Unspecified Form (UNII: 33X04XA5AT)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Keracyanin (UNII: V0N2VMB4FV)	
Propylene Glycol (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:0642-0125-90	90 in 1 BOTTLE, PLASTIC		
2	NHRIC:0642-0125-04	3 in 1 BOX, UNIT-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		05/01/2016	

Supplement Facts

Serving Size : **Serving per Container :**

Amount Per Serving	% Daily Value
color	
scoring 1	
shape	
size (solid drugs) 20 mm	
flavor	

Labeler - Exeltis USA, Inc. (071170534)

Revised: 6/2021 Exeltis USA, Inc.