VITAFOL NANO- cholecalciferol, pyridoxine hydrochloride, folic acid, levomefolate calcium, cyanocobalamin, iron, and iodine tablet, coated
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®-Nano
Preconception and Prenatal Supplement

COMPOSITION

Amount per Tablet:

VITAMINS AND MINERALS

Vitamin D (as cholecalciferol)	25 mcg
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg
Folate (as Folic acid USP 680 mcg DFE and L-methylfolate calcium 1020 mcg DFE, as Metafolin® CAS# 151533-22-1)	1700 mcg DFE
Vitamin B12 (as cyanocobalamin)	12 mcg
Iron (as ferrous fumarate)	18 mg
Iodine (as potassium iodide)	150 mcg

Other Ingredients

Microcrystalline cellulose, hydroxypropylcellulose, modified food starch, croscarmellose sodium, magnesium stearate, sucrose, silicon dioxide, dibasic calcium phosphate, polyvinyl alcohol, titanium dioxide (as color), polyethylene glycol, talc, sodium ascorbate, medium chain triglycerides, dl-alpha-tocopherol, sucralose, FD&C Blue #2 Aluminum Lake.

USAGE

Vitafol®-Nano provides vitamin and mineral supplementation prior to conception, throughout pregnancy, and during the postnatal period for the lactating and non-lactating mother.

CONTRAINDICATIONS

Vitafol®-Nano 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

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.

Prolonged use of iron salts may produce iron storage disease.

Folate, especially in doses above 1700 mcg DFE (1000 mcg folic acid) 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.

Avoid Overdosage. Keep out of the reach of children.

DRUG INTERACTIONS

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.

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 substantially higher than those in Vitafol®-Nano. 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 tablet daily, or as directed by a physician.

HOW SUPPLIED

Vitafol®-Nano is available as a light blue, round tablet imprinted with "94" on one side. Available in 30 cts in HDPE bottle, 0642-0094-01.

Store at room temperature approximately 20°-25°C (68°-77°F). Avoid excessive heat, light, moisture and humidity.

Rx

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

www.exeltisusa.com

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

Rev. January 2021
0940101-01

PRINCIPAL DISPLAY PANEL - 30 Tablet Bottle Label

0642-0094-01

VITAFOL
Nano

Smallest Prenatal Supplement with essential nutrients

30 Tablets

R_x
DIETARY SUPPLEMENT

VITAFOL NANO

cholecalciferol, pyridoxine hydrochloride, folic acid, levomefolate calcium, cyanocobalamin, iron, and iodine tablet, coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0642-0094
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHOLECALCIFEROL (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	CHOLECALCIFEROL	25 ug
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (Pyridoxine - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	2.5 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
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	12 ug
Iron (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7)	Iron	18 mg
Iodine (UNII: 9679TC07X4) (Iodine - UNII:9679TC07X4)	Iodine	150 ug

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SUCROSE (UNII: C151H8M554)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	

TALC (UNII: 7SEV7J4R1U)	
SODIUM ASCORBATE (UNII: S033EH8359)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	

Product Characteristics

Color	BLUE	**Score**	no score
Shape	ROUND	**Size**	6mm
Flavor		**Imprint Code**	EV0094
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0642-0094-01	30 in 1 BOTTLE; Type 0: Not a Combination Product	07/14/2014	
2	NDC:0642-0094-03	3 in 1 BLISTER PACK; Type 0: Not a Combination Product	07/14/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		07/14/2014	

Labeler - Exeltis USA, Inc. (071170534)

Revised: 6/2021 Exeltis USA, Inc.