VITAFOL- cholecalciferol, pyridoxine hydrochloride, cyanocobalamin, and folic acid strip
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® Strips
Prenatal Supplement

0642-7468-30

Rx Only

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.

COMPOSITION

Amount per daily dose (1 strip)

VITAMINS AND MINERALS:

Calories	1
Total Carbohydrates	0 g
Sugars	0 g
Vitamin B6 (as pyridoxine hydrochloride)	2.5 mg
Folic Acid	1 mg
Vitamin B12 (as cyanocobalamin)	12 mcg
Vitamin D (as cholecalciferol)	1000 IU

Other Ingredients:

Sentry Polyox WSR N80 LEO, maltitol syrup, methocel (hydroxypropyl methylcellulose), sodium citrate anhydrous, lemon flavor, sucralose, butylated hydroxytoluene, peceol, water.

USAGE

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

CONTRAINDICATIONS

Vitafol® Strips 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.

Cyanocobalamin is contraindicated in patients with sensitivity to cobalt or to cyanocobalamin (vitamin B12).

WARNINGS/PRECAUTIONS

This product is intended for use as directed by your healthcare provider. Please do not share with others.

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.

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.

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.

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® Strips. 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, take one Vitafol® Strip daily, or as directed by a physician.

HOW SUPPLIED

Vitafol® Strips is available as an orange rectangular film with "V" logo printed on one side. Available

in Box of Unit-Dose pack in pouch of 30 counts, Item No. 0642-7468-30 and as physician sample in pouch of 3 counts, Item No. 0642-7468-01.

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

To report suspected adverse event contact Exeltis USA, Inc., at 1-877-324-9349 or at FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

Vitafol® is a trademark of Exeltis USA, Inc.

Rev. August 2018

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PRINCIPAL DISPLAY PANEL - 30 Strip Pouch Box

0642-7468-30

VITAFOL
STRIPS

Prenatal Supplement Strips
with 1 mg folic acid

Fast Dissolving Strip

Unit Dose Pack / 30 Strips

R_x Only
DIETARY SUPPLEMENT

0642-7468-30

VITAFOL™

STRIPS

Prenatal Supplement Strips
with 1mg folic acid

Fast Dissolving Strip

Unit Dose Pack / 30 Strips

Essential nutrients in a fast dissolving strip

VITAFOL STRIPS
Prenatal Supplement Strips with 1mg folic acid

R_x Only

DIETARY SUPPLEMENT

Lot No:

Exp. Date:

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Prenatal Supplement Strips with 1mg folic acid

VITAFOL

cholecalciferol, pyridoxine hydrochloride, cyanocobalamin, and folic acid strip

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0642-7468
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHOLECALCIFEROL (UNII: 1C6V77QF41) (Cholecalciferol - UNII:1C6V77QF41)	CHOLECALCIFEROL	1000 [iU]
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	Pyridoxine Hydrochloride	2.5 mg
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	12 ug
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1 mg

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
MALTITOL (UNII: D65DG142WK)	
HYPROMELLOSE 2906 (4000 MPA.S) (UNII: 5EYA69XGAT)	
ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450LGA)	
Sucralose (UNII: 96K6UQ3ZD4)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GLYCERYL OLEATE (UNII: 4PC054V79P)	
1-METHYLCYCLOHEXA-1,3-DIENE (UNII: NZ9H475GT1)	

Product Characteristics			
Color	ORANGE	**Score**	
Shape	RECTANGLE	**Size**	
Flavor		**Imprint Code**	V
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0642-7468-30	30 in 1 BOX	06/15/2019	
1		1 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:0642-7468-01	3 in 1 POUCH; Type 0: Not a Combination Product	06/15/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		06/15/2019	

Labeler - Exeltis USA, Inc. (071170534)

Establishment

Name	Address	ID/FEI	Business Operations
Aquestive Therapeutics, Inc.		079269181	ANALYSIS(0642-7468) , MANUFACTURE(0642-7468)

Revised: 1/2021 Exeltis USA, Inc.