

**VITAFOL CAPLET- vitamin a, ascorbic acid, vitamin d, .alpha.-tocopherol, thiamine mononitrate, riboflavin, niacin, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium, and iron capsule
Everett Laboratories, 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®
Multivitamin and Mineral Supplement**

Rx

COMPOSITION

Each caplet contains:

Vitamin A (as acetate)	6000 IU
Vitamin C (as ascorbic acid)	60 mg
Vitamin D-3 (as cholecalciferol)	400 IU
Vitamin E (as d-alpha tocopheryl acetate)	30 IU
Thiamine Mononitrate	1.1 mg
Vitamin B-2 (as riboflavin)	1.8 mg
Niacinamide (Vitamin B-3)	15 mg
Pyridoxine HCl	2.5 mg
Folic Acid	1.0 mg
Vitamin B-12 (as cyanocobalamin)	5 mcg
Calcium (as calcium carbonate)	125 mg
Iron (as ferrous fumarate)	65 mg

Other Ingredients: Microcrystalline Cellulose, Stearic Acid, Croscarmellose Sodium, Crospovidone, Dicalcium Phosphate, Silica, Acacia, Maltodextrin, Hypromellose, Citric Acid, Soy Polysaccharide, Sodium Lauryl Sulfate, Magnesium Stearate, Titanium Dioxide, Magnesium Silicate, Gum Arabic, Polyethylene Glycol, Mineral Oil, Polyvinylpyrrolidone, FD&C Red #40 Lake, D&C Red #27 Lake and FD&C Blue #1 Lake. **Contains Soy.**

INDICATIONS AND USAGE

Vitafol® is indicated to provide vitamin, mineral supplementation to support optimum vitamin levels.

CONTRAINDICATIONS

Vitafol® 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 B-12).

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 therapeutic use of iron salts may produce iron storage disease.

WARNING

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or a Poison Control Center immediately.

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.

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.

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[®].

DOSAGE AND ADMINISTRATION

One caplet daily, preferably after a meal or as prescribed by a physician.

HOW SUPPLIED

Vitafol[®] is available as a pink, capsule shaped caplet, debossed EV0072. Available in box of unit dose pack of 100 (0642-0072-12).

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

Rx only

Manufactured for
EVERETT LABORATORIES, INC.
Chatham, NJ 07928
1-877-324-9349

Vitafol® is a trademark of Everett Laboratories, Inc.
(Rev. 12/13)

PRINCIPAL DISPLAY PANEL - 100 Caplet Carton

0642-0072-12

VITAFOL®

Multivitamin Supplement

10 X 10 UNIT DOSE PACK

100 CAPLETS

R_x

0642-0072-12

VITAFOL®

Multivitamin Supplement

10 X 10 UNIT DOSE PACK
100 CAPLETS

R_x

VITAFOL®

Multivitamin Supplement

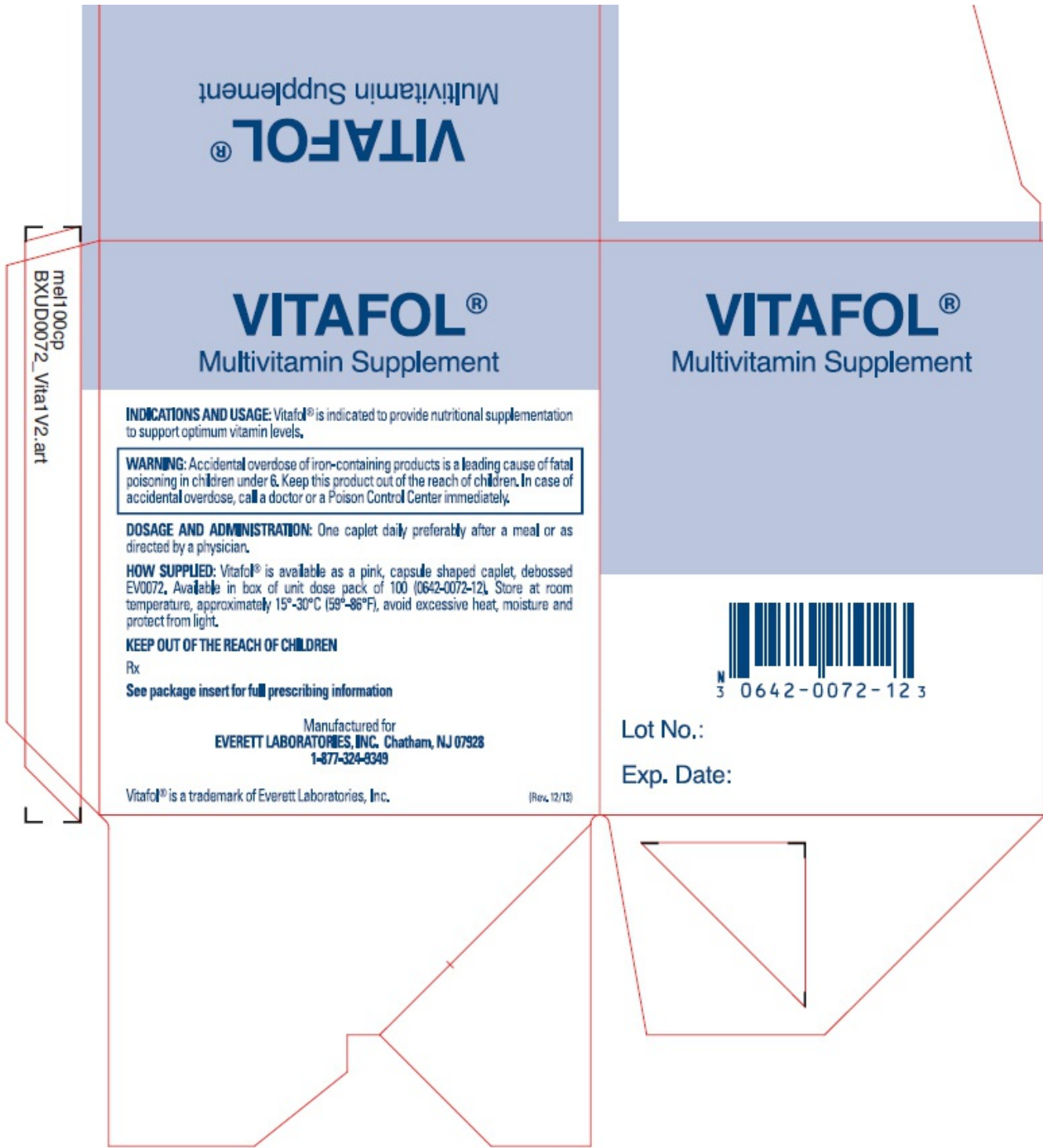
Supplement Facts

Serving Size 1 Caplet
Servings Per Box 100

Each Caplet contains	% Daily Value	
Vitamin A (as acetate)	6000 IU	120%
Vitamin C (as ascorbic acid)	60 mg	100%
Vitamin D3 (as cholecalciferol)	400 IU	100%
Vitamin E (as d-alpha tocopheryl acetate)	30 IU	100%
Thiamine Mononitrate	1,1 mg	73%
Vitamin B2 (as riboflavin)	1,8 mg	106%
Niacinamide (Vitamin B3)	15 mg	75%
Pyridoxine HCl	2,5 mg	125%
Folic Acid	1 mg	250%
Vitamin B12 (as cyanocobalamin)	5 mcg	83%
Calcium (as calcium carbonate)	125 mg	13%
Iron (as ferrous fumarate)	65 mg	361%

Other Ingredients: Microcrystalline Cellulose, Stearic Acid, Croscarmellose Sodium, Crospovidone, Dicalcium Phosphate, Silica, Acacia, Maltodextrin, Hypromellose, Citric Acid, Soy Polysaccharide, Sodium Lauryl Sulfate, Magnesium Stearate, Titanium Dioxide, Magnesium Sulfate, Gum Arabic, Polyethylene Glycol, Mineral Oil, Polyvinylpyrrolidone, FD&C Red #40 Lake, D&C Red #27 Lake and FD&C Blue #1 Lake, **Contains: Soy.**

100 CAPLETS
10 X 10 UNIT DOSE PACK



VITAFOL CAPLET

vitamin a, ascorbic acid, vitamin d, .alpha.-tocopherol, thiamine mononitrate, riboflavin, niacin, pyridoxine hydrochloride, folic acid, cyanocobalamin, calcium, and iron capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0642-0072
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Vitamin A (UNII: 81G40H8B0T) (Vitamin A - UNII:81G40H8B0T)	Vitamin A	6000 [iU]
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg
Vitamin D (UNII: 9VU1KI44GP) (Cholecalciferol - UNII:1C6V77QF41)	Vitamin D	400 [iU]
.Alpha.-Tocopherol (UNII: H4N855PNZ1) (.Alpha.-Tocopherol - UNII:H4N855PNZ1)	.Alpha.-Tocopherol	10 [iU]
Thiamine Mononitrate (UNII: 8K0I04919X) (Thiamine Ion - UNII:4ABT0J945J)	Thiamine	1.1 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	15 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	1 mg
Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	5 ug
Calcium (UNII: SY7Q814VUP) (Calcium - UNII:SY7Q814VUP)	Calcium	125 mg
Iron (UNII: E1UOL152H7) (Iron - UNII:E1UOL152H7)	Iron	27 mg

Inactive Ingredients

Ingredient Name	Strength
Cellulose, Microcrystalline (UNII: OP1R32D61U)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Crospovidone (UNII: 68401960MK)	
Calcium Phosphate, Dibasic, Anhydrous (UNII: L11K75P92J)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Acacia (UNII: 5C5403N26O)	
Maltodextrin (UNII: 7CVR7L4A2D)	
Hypromelloses (UNII: 3NXW29V3WO)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Lecithin, Soybean (UNII: 1DI56QDM62)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Magnesium Stearate (UNII: 70097M6I30)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Polyethylene Glycols (UNII: 3WJQ0SDW1A)	
Mineral Oil (UNII: T5L8T28FGP)	
Povidone K30 (UNII: U725QWY32X)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
D&C Red No. 27 (UNII: 2LRS185U6K)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	PINK	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	EV0072
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:0642-0072-12	100 in 1 BOX; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER			05/01/1985	

Labeler - Everett Laboratories, Inc. (071170534)

Revised: 9/2014

Everett Laboratories, Inc.