# MULTITAM- folic acid tablet PureTek Corporation

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.

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Multitam Multivitamin Multivitamin Rx Only

v2 Update color notes to "Beige speckled caplet" from "yellow to brown speckled caplet"

### **DESCRIPTION:**

# Each caplet contains:

Vitamin A (as retinyl acetate) 1500 mcg (5000 IU)
Vitamin C (as ascorbic acid)
Vitamin D3 (as cholecalciferol)
Vitamin E (dl-alpha tocopheryl acetate) 30 mg (30IU)
Thiamin (as thiamine mononitrate)
Riboflavin (vitamin B2)
Niacin (as niacinamide)
Vitamin B6 (as pyridoxine hydrochloride)
Folate (as folic acid) 1700 mcg DFE (1000 mcg folic acid)
Vitamin B12 (as cyanocobalamin) 8 mcg
Calcium (as calcium carbonate) 200 mg
Magnesium (as magnesium oxide) 200 mg
Zinc (as zinc oxide)
Selenium (as selenium amino acid chelate) 55 mcg
Manganese (as manganese sulfate) 2.3 mg
Chromium (as chromium polynicotinate) 35 mcg
Molybdenum (as molybdenum amino acid chelate) 45 mcg

# Other Ingredients:

Organic cocoa powder, croscarmellose sodium, crospovidone, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid. Clear coating: (hydroxypropyl methylcellulose, PEG-8).

### INDICATIONS:

**Multitam**<sup>™</sup> is indicated to provide vitamin supplement to men and women. Folic acid is effective in the treatment of megaloblastic anemias due to a deficiency of folic acid (as may be seen in tropical or nontropical sprue) and in anemias of nutritional origin, pregnancy, infancy, or childhood.

### **CONTRAINDICATIONS:**

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

### **WARNING:**

Administration of folic acid alone is improper therapy for pernicious anemia and other megaloblastic anemias in which vitamin B  $_{12}$  is deficient.

### **PRECAUTIONS:**

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia, in that hematologic remission can occur while neurological manifestations remain progressive. There is a potential danger in administering folic acid to patients with undiagnosed anemia, since folic acid may obscure the diagnosis of pernicious anemia by alleviating the hematologic manifestations of the disease while allowing the neurologic complications to progress. This may result in severe nervous system damage before the correct diagnosis is made. Adequate doses of vitamin B  $_{12}$  may prevent, halt, or improve the neurologic changes caused by pernicious anemia.

The patient's medical conditions and consumption of other drugs, herbs, and/or supplements should be considered.

# For use on the order of a healthcare practitioner.

Call your doctor about side effects. To report side effects, call **PureTek Corporation** at **1-877-921-7873** or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

# **Drug Interactions:**

**Multitam**™ is not recommended for and should not be given to patients receiving levodopa because the action of levodopa is antagonized by pyridoxine. There is a possibility of increased bleeding due to pyridoxine interaction with anticoagulants (e.g., Aspirin, Heparin or Clopidogrel).

# **Adverse Reactions:**

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

Adverse reactions have been reported with specific vitamins and minerals but generally at levels substantially higher than those contained herein. However, allergic and idiosyncratic reactions are possible at lower levels. Iron, even at the usual recommended levels, has been associated with gastrointestinal intolerance in some patients.

# **DOSAGE AND ADMINISTRATION:**

One (1) **Multitam**™ caplet daily, between meals or as directed by a physician. Do not administer to children under the age of 12.

### **HOW SUPPLIED:**

**Multitam**™ are beige speckled, oblong, coated caplets in bottles containing 30 caplets – NDC 59088-525-54. Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure.

Store at controlled room temperature 20° to 25°C (68° to 77°F). [See USP]. Protect from light and moisture and avoid excessive heat.

# Storage

# Do not use if bottle seal is broken. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

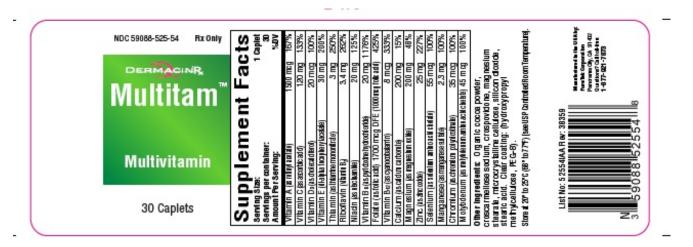
Store at controlled room temperature 20°-25°C (68°-77°F). [See USP]. Protect from light and moisture and avoid excessive heat. To report a serious adverse event or to obtain product information, contact

# **Multitam**

877-921-7873.

Manufactured in the USA by:

PureTek Corporation Panorama City, CA 91402 Questions? Call toll-free: 1-877-921-7873



# MULTITAM folic acid tablet Product Information Product Type HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:59088-525 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
.ALPHATOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHATOCOPHEROL, DL UNII:7QWA1RIO01)	.ALPHA TOCOPHEROL, DL-	30 mg	
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	200 mg	
CHROMIUM NICOTINATE (UNII: A150AY412V) (CHROMIC CATION - UNII:X1N4508KF1)	CHROMIUM NICOTINATE	35 ug	
<b>PYRIDOXINE HYDROCHLORIDE</b> (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII: KV2JZ 1BI6Z)	PYRIDOXINE	20 mg	
MOLYBDENUM (UNII: 81AH48963U) (MOLYBDENUM - UNII:81AH48963U)	MOLYBDENUM	45 ug	
SELENIUM (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	55 ug	
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	20 ug	
RIBOFLAVIN (UNII: TLM29760FR) (RIBOFLAVIN - UNII:TLM29760FR)	RIBOFLAVIN	3.4 mg	
NIACINAMIDE (UNII: 25X5118RD4) (NIACINAMIDE - UNII:25X5118RD4)	NIACINAMIDE	20 mg	
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg	
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1000 ug	
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	8 ug	
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg	
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1500 ug	
THIAMINE MONONITRATE (UNII: 8K0104919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 mg	
MANGANESE SULFATE (UNII: WOOLYS4T26) (MANGANESE CATION (2+) - UNII: H6EP7W5457)	MANGANESE CATION (2+)	2.3 mg	

Inactive Ingredients			
Ingredient Name	Strength		
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
COCOA (UNII: D9108TZ9KG)			
CROSPOVIDONE (UNII: 2S7830E561)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			

Product Characteristics			
Color	yellow (Beige speckled caplet)	Score	no score
Shape	CAPSULE (Oblong Caplet)	Size	19mm
Flavor		Imprint Code	
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/17/2022	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/17/2022	

# Labeler - PureTek Corporation (785961046)

Revised: 2/2022 PureTek Corporation