

MULTITOL-M- multivitamin, folate 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.

Multitol-M
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 RAE
Vitamin C (as Ascorbic Acid)	120 mg
Vitamin D3 (As Cholecalciferol)	20 mcg (800 IU)
Vitamin E (DL-alpha Tocopheryl Acetate)	13.5 mg
Thiamin (As Thiamine Mononitrate)	3 mg
Riboflavin	3.4 mg
Niacin (as Niacinamide).....	20 mg
Vitamin B6 (as Pyridoxine Hydrochloride).....	20 mg
Folate (as L-5-Methyltetrahydrofolate calcium salt) ...	2040 mcg DFE (1200 mcg as L-5-Methylfolate)
Vitamin B12 (as Methylcobalamin).....	8 mcg
Calcium (as Calcium Carbonate).....	200 mg
Magnesium (as Magnesium Oxide).....	200 mg
Zinc (as Zinc Oxide).....	25 mg
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. Coating: (Hydroxypropyl Methylcellulose [HPMC], PEG-8).

INDICATIONS:

Multitol-M™ is indicated to provide vitamins and minerals supplement to men and women. Folate is effective in the treatment of megaloblastic anemias due to a deficiency of folate (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 folate alone is improper therapy for pernicious anemia and other megaloblastic anemias in which vitamin B₁₂ is deficient.

PRECAUTIONS:

Folate 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 folate to patients with undiagnosed anemia, since folate 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 B₁₂ 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:

Multitol-M™ 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 folate. 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.

DOSAGE AND ADMINISTRATION:

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

HOW SUPPLIED:

Multitol-M™ are beige speckled, oblong, coated caplets in bottle containing 30 caplets (NDC 59088-005-54).

Dispense in a tight, light-resistant container as defined in the USP/NF with a child resistant closure.

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].

Multitol-M™

Manufactured in the USA by:

PureTek Corporation


Panorama City, CA 91402

For questions or information

call toll-free: **877-921-7873**

NDC 59088-005-54
Rx Only

BL4 - MINIMUM NO VARNISH
 AREA = 12.5 mm x 38 mm
 FOR POSITION ONLY
 DO NOT PRINT



DERMACINR[®]

Multitol-M™

Multivitamin

30 Caplets

Supplement Facts

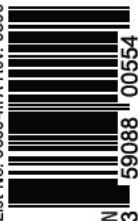
Serving Size: 1 Caplet

Amount Per Serving	% Daily Value
Vitamin A (as Retinyl Acetate)	1500 mcg RAE 167%
Vitamin C (as Ascorbic Acid)	120 mg 133%
Vitamin D ₃ (as Cholecalciferol)	20 mcg (800 IU) 100%
Vitamin E (DL-alpha Tocopheryl Acetate)	13.5 mg 90%
Thiamine (as Thiamine Mononitrate)	3 mg 250%
Riboflavin	3.4 mg 262%
Niacin (as Niacinamide)	20 mg 125%
Vitamin B ₆ (as Pyridoxine Hydrochloride)	20 mg 1176%
Folate (as L-5-Methyltetrahydrofolate calcium salt) (2040 mcg DFE (as L-5-Methyltetrahydrofolate calcium salt) (120 mcg as L-5-Methyltetrahydrofolate))	510%
Vitamin B ₁₂ (as Methylcobalamin)	8 mcg 333%
Calcium (as Calcium Carbonate)	200 mg 15%
Magnesium (as Magnesium Oxide)	200 mg 48%
Zinc (as Zinc Oxide)	25 mg 227%
Selenium (as Selenium Amino Acid Chelate)	55 mcg 100%
Manganese (as Manganese Sulfate)	2.3 mg 100%
Chromium (as Chromium Polynicotinate)	35 mcg 100%
Molybdenum (as Molybdenum Amino Acid Chelate)	45 mcg 100%

Other Ingredients: Organic Cocoa Powder, Croscarmellose Sodium, Crospovidone, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide, Stearic Acid, Coating: (Hydroxypropyl)Methylcellulose [HPMC], PEG-6).

Store at 20° to 25° C (68° to 77° F) [see USP Controlled Room Temperature].

List No.: 00554IFA Rev: 38931



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

N 59088 00554 5

MULTITOL-M

multivitamin, folate tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59088-005
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: VR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	13.5 mg
MAGNESIUM OXIDE (UNII: 3A3U0G171G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	200 mg
CHROMIUM NICOTINATE (UNII: A150AY412V) (CHROMIC CATION - UNII:X1N4508KF1)	CHROMIUM NICOTINATE	35 ug
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	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: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.4 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	2040 ug
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	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: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 mg
MANGANESE SULFATE (UNII: W00LYS4T26) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	2.3 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
COCOA (UNII: D9108TZ9KG)	
CROSPVIDONE (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
1	NDC:59088-005-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/17/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/17/2024	

