DIATROL- vitamins and mineral 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.

Diatrol

Each Caplet Contains:

Vitamin A (as Retinyl Acetate)..... 900 mcg RAE
Vitamin C (as Ascorbic Acid)..... 50 mg
Vitamin D3 (as Cholecalciferol)..... 18.75 mcg
Vitamin E (as DL-Alpha Tocopheryl Acetate)..... 13.5 mg
Vitamin K1 (as Phytonadione)..... 90 mcg
Thiamin (as Thiamine Mononitrate)..... 4 mg
Riboflavin ..... 4 mg
Niacin (as Niacinamide)..... 24 mg
Vitamin B6 (as Pyridoxine Hydrochloride)..... 8 mg
Folate (as L-5-Methyltetrahydrofolate calcium salt)...1700 mcg DFE
(1000 mcg as L-5-Methylfolate)
Vitamin B12 (as Methylcobalamin)..... 8 mcg
Biotin (as D-biotin)..... 30 mcg
Pantothenic Acid ..... 8 mg
Chromium (as Chromium Nicotinate)..... 200 mcg
Gymnema Sylvestre Leaf Powder..... 100 mg
L-Arginine HCl..... 60 mcg
Vanadyl Sulfate..... 15 mg

Other Ingredients:

Croscarmellose Sodium, Dicalcium Phosphate, Hydroxypropyl Methylcellulose, Magnesium Stearate (Vegetable Source), Microcrystalline Cellulose, PEG-8, Silicon Dioxide, Stearic Acid (Vegetable), Stevia Rebaudiana Leaf Extract, Flavor.

INDICATIONS AND USAGE

Diatrol™ is indicated to provide significant amounts of essential vitamins and mineral. This comprehensive nutrient profile helps prevent nutritional deficiencies of these vitamins and minerals, ensuring that the specific dietary needs are met to support overall health, energy, and vitality. The product is specially formulated to target common vitamin and mineral gaps, thus promoting optimal health, immune function, bone strength, and metabolic balance. It is intended to be used under the guidance of a licensed healthcare practitioner to ensure that any potential for nutritional deficiency is addressed in a manner that supports the individual's overall health and wellbeing.

Contraindications:

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

WARNING

In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

PRECAUTIONS

Folate 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 licensed 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.

Adverse Reactions:

Folate: Allergic sensitizations 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

Take one (1) caplet daily or as directed by a licensed healthcare practitioner.

HOW SUPPLIED

Diatrol™ caplets are light green with brown speckles and dispensed in a child-resistant bottle containing 30 caplets (NDC 59088-162-54). All prescription substitutions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

STORAGE

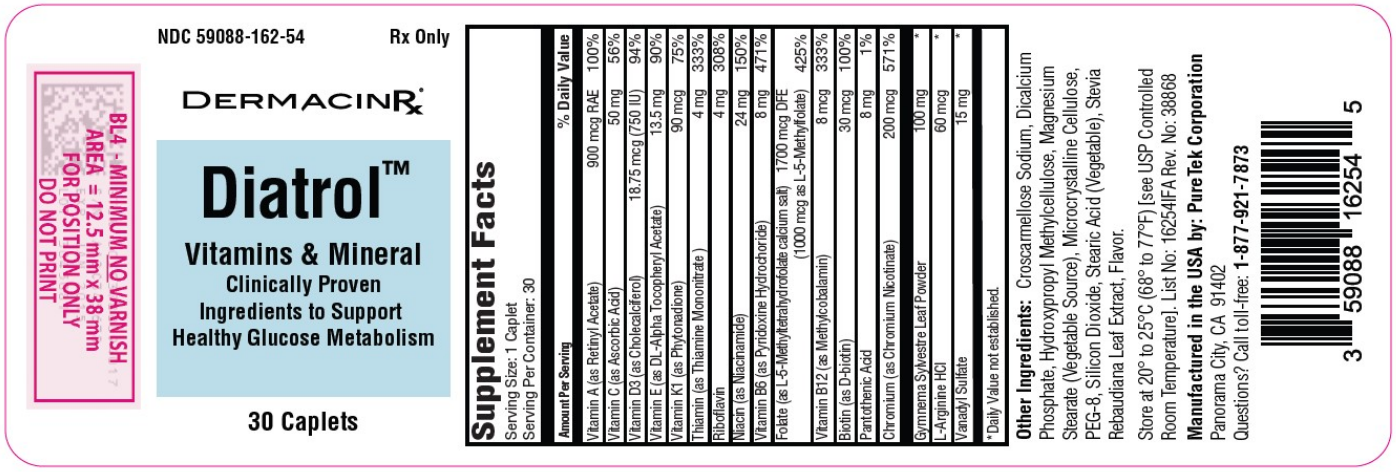
Do not use if bottle seal is broken.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Protect from light and moisture and avoid excessive heat.

Diatrol™

Manufactured in the USA by:
PureTek Corporation
Panorama City, CA 91402
Questions? Call toll-free:
1-877-921-7873



DIATROL
vitamins and mineral tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-162
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	30 ug
VANADYL SULFATE (UNII: 6DU9Y533FA) (VANADIUM - UNII:00J9J9XKDE)	VANADYL SULFATE	15 mg
CHROMIUM NICOTINATE (UNII: A150AY412V) (CHROMIC CATION - UNII:X1N4508KF1)	CHROMIUM NICOTINATE	200 ug
GYMNEMA SYLVESTRE LEAF (UNII: 2ZK6ZS8392) (GYMNEMA SYLVESTRE LEAF - UNII:2ZK6ZS8392)	GYMNEMA SYLVESTRE LEAF	100 mg
ARGININE HYDROCHLORIDE (UNII: F7LTH1E20Y) (ARGININE - UNII:94ZLA3W45F)	ARGININE HYDROCHLORIDE	60 ug
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	13.5 mg
PHYTONADIONE (UNII: A034SE7857) (PHYTONADIONE - UNII:A034SE7857)	PHYTONADIONE	90 ug
VITAMIN A (UNII: 81G40H8B0T) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	900 ug

ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	50 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	18.75 ug
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	8 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	4 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	4 mg
NIACIN (UNII: 2679MF687A) (NIACIN - UNII:2679MF687A)	NIACIN	24 mg
LEVOMEFOLATE CALCIUM (UNII: A9R10K3F2F) (LEVOMEFOLIC ACID - UNII:8S95DH25XC)	LEVOMEFOLATE CALCIUM	1000 ug
METHYLCOBALAMIN (UNII: BR1SN1JS2W) (METHYLCOBALAMIN - UNII:BR1SN1JS2W)	METHYLCOBALAMIN	8 ug
PANTOTHENIC ACID (UNII: 19F5HK2737) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	8 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	

Product Characteristics

Color	green (Light Green with Brown Speckles)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-162-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/26/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/26/2024	

Labeler - PureTek Corporation (785961046)