VITREXYL- 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.

Vitrexyl
Multivitamin
Rx Only

DESCRIPTION:

Each caplet contains:

Vitamin A (as retinyl acetate)..... 1500 mcg (5000 IU)
Vitamin C (as ascorbic acid)..... 120 mg
Vitamin D3 (as cholecalciferol)..... 20 mcg (800 IU)
Vitamin E (dl-alpha tocopheryl acetate)..... 30 mg (30IU)
Thiamin (as thiamine mononitrate)..... 3 mg
Riboflavin (vitamin B2)..... 3.4 mg
Niacin (as niacinamide)..... 20 mg
Vitamin B6 (as pyridoxine hydrochloride)..... 20 mg
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)..... 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. Clear coating: (hydroxypropyl methylcellulose, PEG-8).

INDICATIONS:

Vitrexyl™ 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 B12 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:

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

HOW SUPPLIED:

Vitrexyl™ are yellow to brown speckled, oblong, coated caplets with "PT A16" debossed horizontally on one side, bottles containing 30 caplets – NDC 59088-164-54. Dispense in a tight, light-resistant container as defined in the USP/NF with a child-resistant closure.

Store at controlled room temperature 20º-25ºC (68º-77ºF). [See USP]. Protect from light and moisture and avoid excessive heat.

Storage

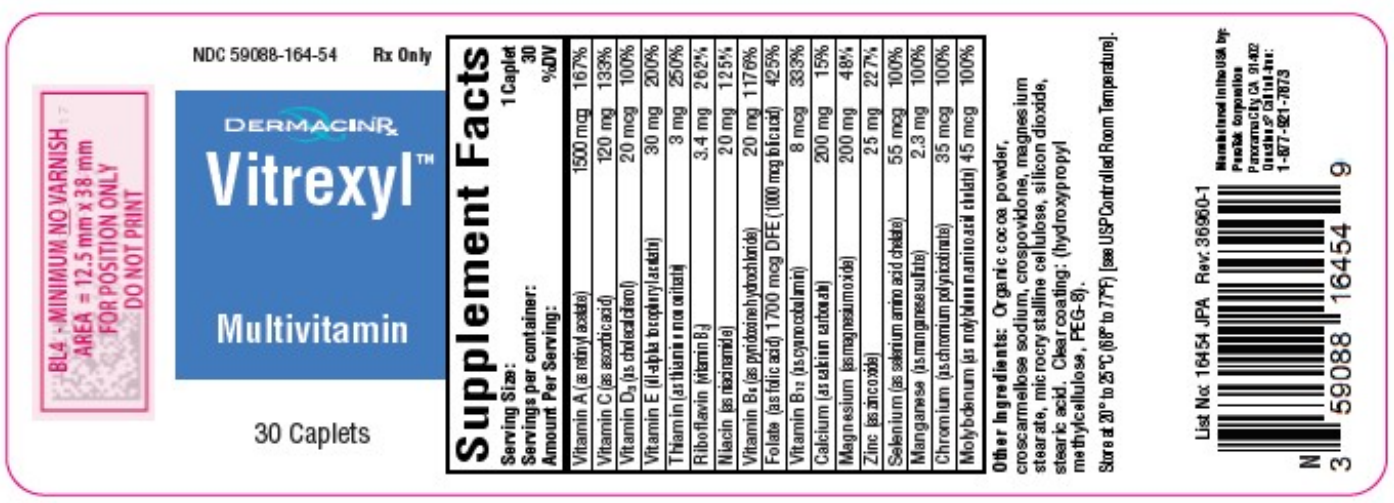
Do not use if bottle seal is broken.
KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.
Store at controlled room temperature 20º-25ºC (68º-77ºF). [See USP].
Protect from light and moisture and avoid excessive heat.
To report a serious adverse event or to obtain product information, contact 877-921-7873.

Vitrexyl

Manufactured in the USA by:

PureTek Corporation
Panorama City, CA 91402
For questions or information
call toll-free: **877-921-7873**

List No: 16454 JPA Rev: 36960



VITREXYL

folic acid tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-164
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, 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
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
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: 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
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
COCOA (UNII: D9108TZ9KG)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (UNII: 2S7830E561)	

Product Characteristics

Color	yellow (Yellow to Brown speckled caplet)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	PT;A16
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-164-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/29/2020	

Labeler - PureTek Corporation (785961046)

Establishment

Name	Address	ID/FEI	Business Operations
PureTek Corporation		785961046	manufacture(59088-164) , pack(59088-164) , label(59088-164)

Revised: 1/2023 PureTek Corporation