

VITRANOL- folic acid tablet
VITREXATE- 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.

Vitrexate & Vitranol

DESCRIPTION:

Each caplet contains:

Vitamin A (as retinyl acetate).....	1500 mcg
Vitamin C (as ascorbic acid).....	120 mg
Vitamin D3 (as cholecalciferol).....	20 mcg
Vitamin E (dl-alpha tocopheryl acetate).....	30 mg
Thiamine (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:

To provide vitamin supplements 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:

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 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:

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 usually recommended levels, has been associated with gastrointestinal intolerance in some patients.

DOSAGE AND ADMINISTRATION:

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

HOW SUPPLIED:

Vitrexate™ and Vitranol™ are beige speckled, oblong, coated caplets, bottles containing 30 caplets –

NDC 59088-167-54

NDC 59088-171-54

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

Store at controlled room temperature 20°-25°C (68°-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 **1-877-921-7873**.

Vitrexate™

Manufactured in the USA by:

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



Supplement Facts	
Serving Size:	1 Caplet
Servings per container:	30
Amount Per Serving:	%DV
Vitamin A (as retinyl acetate)	1500 mcg 167%
Vitamin C (as ascorbic acid)	120 mg 133%
Vitamin D ₃ (as cholecalciferol)	20 mcg 100%
Vitamin E (dl-alpha tocopheryl acetate)	30 mg 200%
Thiamine (as thiamine mononitrate)	3 mg 250%
Riboflavin (vitamin B ₂)	3.4 mg 262%
Niacin (as niacinamide)	20 mg 125%
Vitamin B ₆ (as pyridoxine hydrochloride)	20 mg 1176%
Folate (as folic acid) 1700 mcg DFE (1000 mcg folic acid)	425%
Vitamin B ₁₂ (as cyanocobalamin)	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. Clear coating: (hydroxypropyl methylcellulose, PEG-8).

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



Vitrinol™

NDC 59088-171-54

Rx Only



30 Caplets

Supplement Facts

Serving Size:	1 Caplet
Servings per container:	30
Amount Per Serving:	%DV
Vitamin A (as retinyl acetate)	1500 mcg 167%
Vitamin C (as ascorbic acid)	120 mg 133%
Vitamin D ₃ (as cholecalciferol)	20 mcg 100%
Vitamin E (dl-alpha tocopheryl acetate)	30 mg 200%
Thiamin (as thiamine mononitrate)	3 mg 250%
Riboflavin (vitamin B ₂)	3.4 mg 262%
Niacin (as niacinamide)	20 mg 125%
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Other Ingredients: Organic cocoa powder, croscarmellose sodium, crospovidone, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid. Clear coating: (hydroxypropyl methylcellulose, PEG-8).

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

List No: 17154.JPA Rev: 38226
 Manufactured in the USA by:
 Pure Itk Corporation
 Paramus, NY 11402
 Call for more information:
 1-877-921-7873



VITRANOL

folic acid tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59088-171
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	PYRIDOXINE	20 mg
SELENIUM (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	55 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1000 ug
MAGNESIUM OXIDE (UNII: 3A3U0G171G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	200 mg
MOLYBDENUM (UNII: 81AH48963U) (MOLYBDENUM - UNII:81AH48963U)	MOLYBDENUM	45 ug
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	8 ug
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1500 ug
CHROMIUM NICOTINATE (UNII: A150AY412V) (CHROMIC CATION - UNII:X1N4508KF1)	CHROMIUM NICOTINATE	35 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
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	30 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	25 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
MANGANESE SULFATE (UNII: W00LYS4T26) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	2.3 mg

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
COCOA (UNII: D9108TZ9KG)	
CROSPVIDONE (UNII: 2S7830E561)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	brown (Beige Speckled Caplet)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-171-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/11/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/11/2021	

VITREXATE

folic acid tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59088-167
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
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MANGANESE SULFATE (UNII: W00LYS4T26) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	2.3 mg

Inactive Ingredients

Ingredient Name	Strength
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HYDROXYMETHYL CELLULOSE (UNII: 273FM27VK1)	
COCOA (UNII: D9108TZ9KG)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	brown (Beige speckled caplet)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-167-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/30/2020	

Labeler - PureTek Corporation (785961046)

Revised: 1/2023

PureTek Corporation