

VENTRIXYL- 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.

Ventrixyl
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 and Usage:

Ventrixyl™ is indicated 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:

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 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:

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

How Supplied:

VentrixyL™ are beige speckled, oblong, coated caplets in bottles containing 30 caplets –

NDC 59088-186-54. 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° to 25°C (68° to 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

877-921-7873.

Chronocap

Chronocap™

Child Resistant

- The Chronocap™ is a patented Smart Cap with a built-in LCD timer that works like a stopwatch, letting you know exactly how long it has been since you last opened your medication bottle.
- Every time you open the cap, the timer resets back to zero. When you close the cap, the timer automatically begins counting-up the hours and minutes since you last opened your medication bottle, so you don't have to.

Instructions:

Time shown on display is the time elapsed since Chronocap™ was last opened.

Opening and closing the Chronocap™ resets the LCD stopwatch timer to zero.



Additional information:

- Non-replaceable battery designed to last one year.
- Disposable design to avoid cross-contamination with medications.
- Display goes to “sleep” after 100hrs and wakes up upon re-opening.
- Clean with damp cloth only. Do not immerse in water.

Chronocap™

Screen Instructions Continued



- Screen appears blank & stops after 100 hours or if cap is not placed onto the bottle



- Screen shows time elapsed, *NOT* the current time of day



- Screen shows: SEC1, SEC2, then 10, 11 ... etc. for the first minute



- Screen continues to count minutes and hours since the Chronocap™ was last opened, until 99:59, then the screen will appear blank

Please Note:

Chronocap™ battery should last 12 months.

Rev. 37968

Ventrixyℓ™

Manufactured in the USA by:

PureTek Corporation

Panorama City, CA 91402

Questions? Call toll-free:

1-877-921-7873

List No: 18654IAA Rev: 38311



Active Ingredients:

Vitamin A (as retinyl acetate)	1500 mcg
Vitamin C (as ascorbic acid)	120 mg
Vitamin D ₃ (as cholecalciferol)	20 mcg
Vitamin E (dl- α -tocopheryl acetate)	30 mg
Thiamin (as thiamin mononitrate)	3 mg
Riboflavin (Vitamin B ₂)	3.4 mg
Niacin (as niacinamide)	20 mg
Vitamin B ₆ (as pyridoxine hydrochloride)	20 mg
Folate (as folic acid)	1700 mcg DFE (1000 mcg folic acid)
Vitamin B ₁₂ (as cyanocobalamin)	8 mcg
Calcium (as calcium carbonate)	200 mg
Magnesium (as magnesium oxide)	200 mg
Zinc (as zinc oxide)	25 mg
Selenium (as selenum amino acid chelate)	55 mcg
Manganese (as manganese sulfate)	2.3 mg
Chromium (as chromium polynicotinate)	35 mcg
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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).

Dosage and Administration: One (1) VentrixyL caplet daily, between meals or as directed by a licensed healthcare practitioner. Do not administer to children under the age of 12.

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

List No: 186541AA Rev: 38311-01
 Manufactured in the USA by
 Parke-Davis
 Parsippany, NJ 07054
 1-877-821-7873



VENTRIXYL

folic acid tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:59088-186
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	20 ug	
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	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	
SELENIUM (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	55 ug	
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	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	30 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	

Inactive Ingredients		
Ingredient Name		Strength

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
COCOA (UNII: D9108TZ9KG)	
CROSPVIDONE (UNII: 2S7830E561)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	yellow (beige speckled, oblong, coated caplets)	Score	no score
Shape	CAPSULE ((Caplet))	Size	19mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-186-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/18/2021	

Labeler - PureTek Corporation (785961046)