FOLIFLEX- ferrous fumarate, 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.

Foliflex

DESCRIPTION:

Full Prescribing Information:

Each Serving Size of 2 caplets contain:

Vitamin A (as Retinyl Acetate) 3000 mcg RAE
Vitamin C (as Ascorbic Acid) 500 mg
Vitamin D3 (as Cholecalciferol) 27.5 mcg (1100 IU)
Vitamin E (as DL-alpha Tocopheryl Acetate) 90 mg
Thiamin (as Thiamine Mononitrate) 6.5 mg
Riboflavin 6.7 mg
Niacin (as Niacinamide) 45 mg
Vitamin B6 (as Pyridoxine HCl) 12 mg
Folate 1700 mcg DFE
(as L-5-Methyltetrahydrofolate calcium salt) (1000 mcg as L-Methyfolate)
Vitamin B12 (as Methylcobalamin) 26 mcg
Biotin 200 mcg
Pantothenic Acid (as Calcium Pantothenate) 30 mg
Calcium (as Calcium Carbonate) 150 mg
Iron (as Ferrous Fumarate) 18 mg
Iodine (as Potassium Iodide) 50 mcg
Magnesium (as Magnesium Oxide) 75 mg
Zinc (as Zinc Gluconate) 30 mg
Selenium (as Selenomethionine) 60 mcg
Copper (as Copper Oxide) 2 mg
Manganese (as Manganese Sulfate) 1.5 mg
Chromium (as Chromium Polynicotinate) 75 mcg
Molybdenum (as Sodium Molybdate) 50 mcg
Potassium (as Potassium Chloride) 49 mg
Boron (as Boron Citrate) 50 mcg

Other Ingredients: Microcrystalline Cellulose, Silicon Dioxide, Crospovidone, Magnesium Stearate, Coating:(Sodium Carboxymethylcellulose, Dextrose Monohydrate, Titanium Dioxide, Dextrin, Purified Stearic Acid, FD&C Yellow #6/Sunset Yellow FCF Aluminum Lake).

INDICATIONS:

Foliflex ™ is indicated for the treatment of iron deficiency anemia and folate deficiency as in extended convalescence, menorrhagia, pregnancy, puberty, excessive blood loss,

and advanced age. Also for the treatment of the condition in which iron deficiency and vitamin C deficiency occur together, along with a deficient intake or increased need for B-Complex vitamins in chronic and acute illness, as well as cases of metabolic stress, and in convalescence.

CONTRAINDICATIONS:

This product is contraindicated in patients with known hypersensitivity to any of its ingredients; also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemias. Pernicious anemia is a contraindication, as folate may obscure its signs and symptoms.

WARNING:

Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately. Administration of folate alone is improper therapy for pernicious anemia and other megaloblastic anemias in which vitamin B_{12} is deficient.

Precaution Section

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:

Foliflex ™ 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:

Folate: Allergic sensitizations have been reported following both oral and parenteral

administration of folate.

Ferrous Fumarate: Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation) occur occasionally, but are usually mild and may subside with continuation of therapy. Although the absorption of iron is best when taken between meals, giving **Foliflex ™** after meals may control occasional gastrointestinal disturbances. **Foliflex ™** is best absorbed when taken at
bedtime.

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.

OVERDOSE:

Iron: Signs and Symptoms: Iron is toxic. Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis, melena, shock, drowsiness, and coma. The estimated overdose of orally ingested iron is 300 mg/kg body weight. When overdoses are ingested by children, severe reactions, including fatalities, have resulted. **Foliflex ™** should be stored beyond the reach of children to prevent against accidental iron poisoning. **Keep this and all other drugs out of reach of children.**

Treatment:

For specific therapy, exchange transfusion and chelating agents should be used. For general management, perform gastric lavage with sodium bicarbonate solution or milk. Administer intravenous fluids and electrolytes and use oxygen.

DOSAGE AND ADMINISTRATION:

Adults (persons over 12 years of age) Two (2) **Foliflex ™** caplet daily, between meals, or as directed by a physician. Do not administer to children under the age of 12.

HOW SUPPLIED:

Foliflex ™ are yellow with slightly brown speckled, oblong, coated caplets. Bottles contain 60 caplets – NDC 59088-480-58. 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 it if the 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 **1-877-921-7873.**

Chronocap

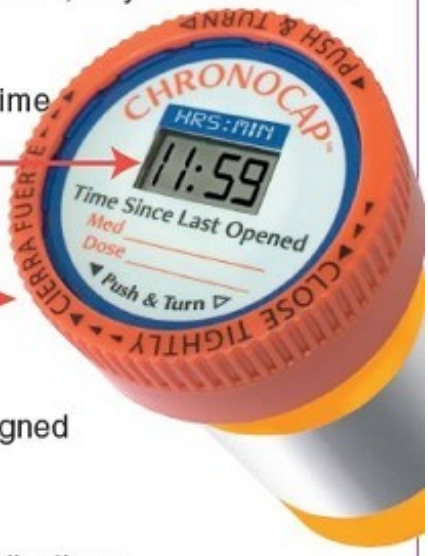
Chronocap™

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.

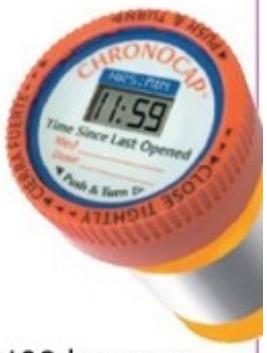
Instructions:
Time shown on display is the time elapsed since Chronocap™ was last opened.

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

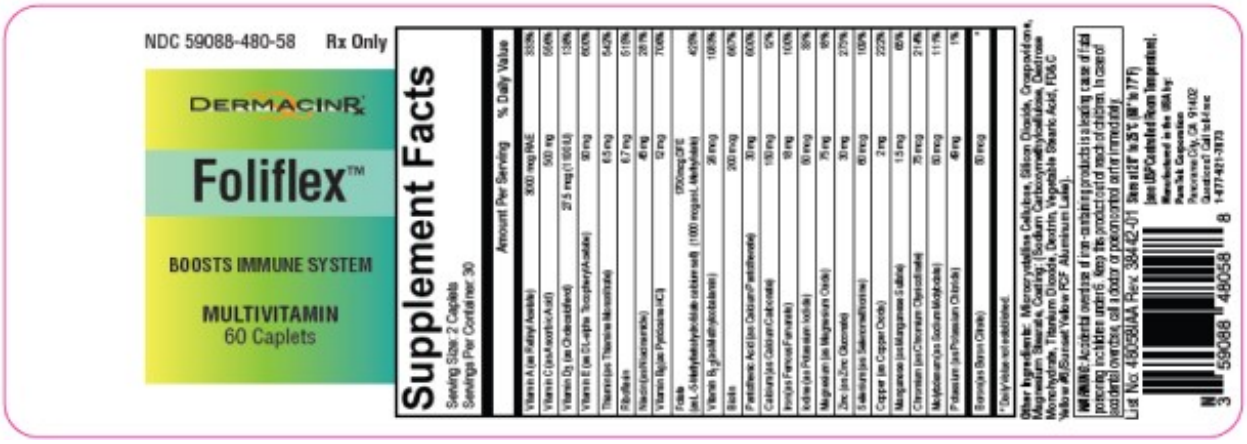
- Screen continues to count minutes and hours since the Chronocap™ was last opened, until 99:59, then the screen will appear blank

Please Note:
Chronocap™ battery should last 12 months.

Rev. 37968

Foliflex ™

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



FOLIFLEX

ferrous fumarate, folic acid tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-480
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1500 ug
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	250 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	13.75 ug
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	45 mg
THIAMINE MONONITRATE (UNII: 8K0I04919X) (THIAMINE ION - UNII:4ABT0J945J)	THIAMINE	3.25 mg
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.35 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	22.5 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	6 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	500 ug
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	13 ug
BIOTIN (UNII: 6SO6U10H04) (BIOTIN - UNII:6SO6U10H04)	BIOTIN	100 ug
PANTOTHENIC ACID (UNII: 19F5HK2737) (PANTOTHENIC ACID - UNII:19F5HK2737)	PANTOTHENIC ACID	15 mg
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	75 mg
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	9 mg
POTASSIUM IODIDE (UNII: 1C4QK22F9J) (IODIDE ION - UNII:09G4I6V86Q)	IODIDE ION	25 ug
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CATION	37.5 mg
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	15 mg
SELENIUM (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	30 ug
CUPROUS OXIDE (UNII: T8BEA5064F) (CUPROUS OXIDE - UNII:T8BEA5064F)	CUPROUS OXIDE	1 mg
MANGANESE SULFATE (UNII: W00LYS4T26) (MANGANESE CATION (2+) - UNII:H6EP7W5457)	MANGANESE CATION (2+)	0.75 mg
CHROMIUM NICOTINATE (UNII: A150AY412V) (NIACIN - UNII:2679MF687A)	CHROMIUM NICOTINATE	37.5 ug
MOLYBDENUM (UNII: 81AH48963U) (MOLYBDENUM - UNII:81AH48963U)	MOLYBDENUM	25 ug

POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152)	POTASSIUM CATION	24.5 mg
BORON (UNII: N9E3X5056Q) (BORON - UNII:N9E3X5056Q)	BORON	25 ug

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CROSPOVIDONE (UNII: 2S7830E561)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ICODEXTRIN (UNII: 2NX48Z0A9G)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	yellow (With Slightly Brown Specks)	**Score**	no score
Shape	CAPSULE	**Size**	20mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-480-58	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/25/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/25/2021	

Labeler - PureTek Corporation (785961046)

Revised: 6/2024 PureTek Corporation