VENTRIXYL FE- 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.

Ventrixyl™ Fe
Prescribing Information

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 (30 IU)
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
Iron (as ferrous fumarate)..... 27 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™ FE 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 conditions 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 folic acid may obscure its signs and symptoms.

Warnings:

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 folic acid alone is improper therapy for pernicious anemia and other megaloblastic anemias in which vitamin B_{12} 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 ™ FE 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:

Folic Acid: Allergic sensitizations have been reported following both oral and parenteral administration of folic acid.

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

Ventrixyl ™ FE after meals may control occasional gastrointestinal disturbances. **Ventrixyl ™ FE** 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. **Ventrixyl™ FE** 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) One (1) **Ventrixyl™ FE** caplet daily, between meals or as directed by a physician. Do not administer to children under the age of 12.

How Supplied:

Ventrixyl™ FE are beige speckled, oblong, coated caplets, in bottles containing 30 caplets – NDC 59088-187-54. 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.

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™

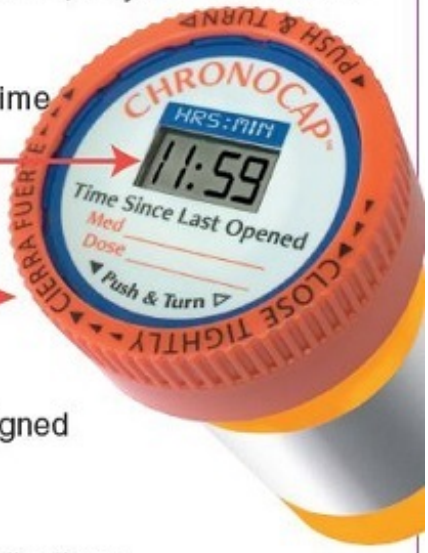
Child Resistant

- 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

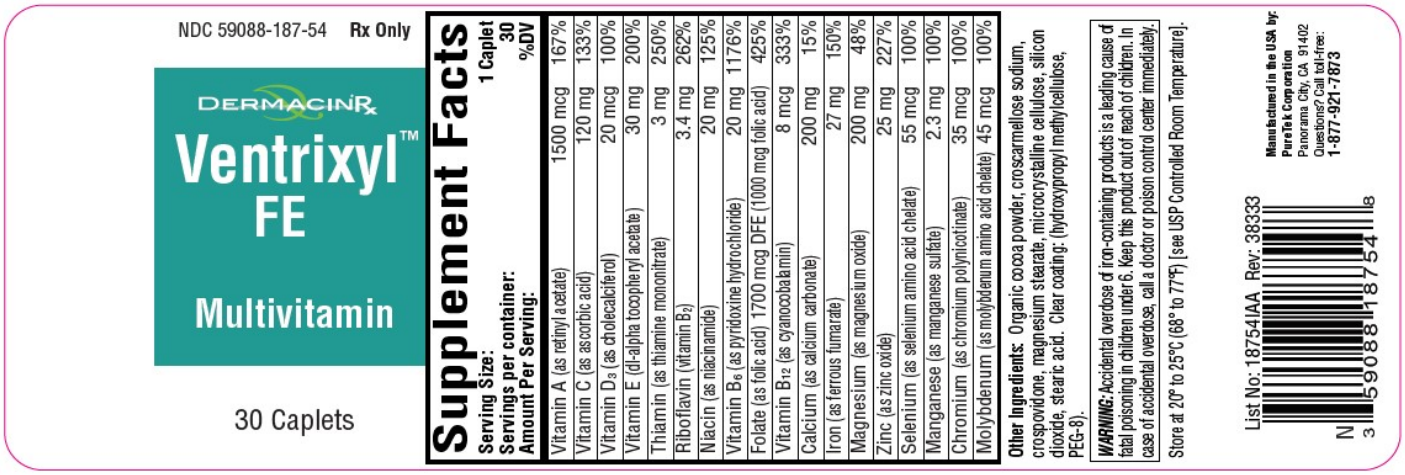
- Screen continues to count minutes and hours since the Chronocap™ was last opened, until 99:59, then the screen will appear blank

Please Note:
Chronocap™ battery should last 12 months.

Rev. 37968

Ventrixyl™ FE

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



VENTRIXYL FE

ferrous fumarate, folic acid tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59088-187
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHROMIUM NICOTINATE (UNII: A150AY412V) (CHROMIC CATION - UNII:X1N4508KF1)	CHROMIUM NICOTINATE	35 ug
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1000 ug
VITAMIN A ACETATE (UNII: 3LE3D9D6OY) (VITAMIN A - UNII:81G40H8B0T)	VITAMIN A	1500 ug
RIBOFLAVIN (UNII: TLM2976OFR) (RIBOFLAVIN - UNII:TLM2976OFR)	RIBOFLAVIN	3.4 mg
NIACINAMIDE (UNII: 25X51I8RD4) (NIACINAMIDE - UNII:25X51I8RD4)	NIACINAMIDE	20 mg
PYRIDOXINE HYDROCHLORIDE (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1BI6Z)	PYRIDOXINE	20 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	8 ug
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	200 mg
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
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
FERROUS FUMARATE (UNII: R5L488RY0Q) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	27 mg
MAGNESIUM OXIDE (UNII: 3A3U0GI71G) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM OXIDE	200 mg
MOLYBDENUM (UNII: 81AH48963U) (MOLYBDENUM - UNII:81AH48963U)	MOLYBDENUM	45 ug
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8) (.ALPHA.-TOCOPHEROL, DL- - UNII:7QWA1RIO01)	.ALPHA.-TOCOPHEROL, DL-	30 mg
CHOLECALCIFEROL (UNII: 1C6V77QF41) (CHOLECALCIFEROL - UNII:1C6V77QF41)	CHOLECALCIFEROL	20 ug
SELENIUM (UNII: H6241UJ22B) (SELENIUM - UNII:H6241UJ22B)	SELENIUM	55 ug

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COCOA (UNII: D9108TZ9KG)	
CROSPOVIDONE (UNII: 2S7830E561)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	yellow (Beige)	**Score**	no score
Shape	CAPSULE (Oblong Tablet)	**Size**	19mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59088-187-54	30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/11/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/11/2021	

Labeler - PureTek Corporation (785961046)

Revised: 1/2023

PureTek Corporation