

RIBOTIN-E- 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.

Ribotin-E™

DESCRIPTION:

Full Prescribing Information:

Each Serving Size of 2 caplets contain:

Supplement Facts

Serving Size: 2 Caplets
Servings per container: 30
Amount Per Serving: %DV

| | | |
|---|---------------------|-------|
| Vitamin A (as retinyl acetate) | 3000 mcg (10000 IU) | 333% |
| Vitamin C (as ascorbic acid) | 500 mg | 556% |
| Vitamin D ₃ (as cholecalciferol) | 27.5 mcg (1100 IU) | 138% |
| Vitamin E (as dl-alpha tocopheryl acetate) | 90 mg (200 IU) | 600% |
| Thiamin (as thiamine mononitrate) | 6.5 mg | 542% |
| Riboflavin (as vitamin B ₂) | 6.7 mg | 515% |
| Niacin (as niacinamide) | 45 mg | 281% |
| Vitamin B ₆ (as pyridoxine hydrochloride) | 12 mg | 706% |
| Folate (as folic acid) 1700 mcg DFE (1000 mcg folic acid) | | 425% |
| Vitamin B ₁₂ (as cyanocobalamin) | 26 mcg | 1083% |
| Biotin | 200 mcg | 667% |
| Pantothenic Acid (as calcium pantothenate) | 30 mg | 600% |
| Calcium (as calcium carbonate) | 150 mg | 12% |
| Iron (as ferrous fumarate) | 18 mg | 100% |
| Iodine (as potassium iodide) | 50 mcg | 33% |
| Magnesium (as magnesium oxide) | 75 mg | 18% |
| Zinc (as zinc gluconate) | 30 mg | 273% |
| Selenium (as selenomethionine) | 60 mcg | 109% |
| Copper (as copper oxide) | 2 mg | 222% |
| Manganese (as manganese sulfate) | 1.5 mg | 65% |
| Chromium (as chromium polynicotinate) | 75 mcg | 214% |
| Molybdenum (as sodium molybdate) | 50 mcg | 111% |
| Potassium (as potassium chloride) | 49 mg | 1% |
| Boron (as boron citrate) | 50 mcg | * |

* Daily Value not established

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:

Ribotin-E™ 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 folic acid 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 folic acid alone is improper therapy for pernicious anemia and other megaloblastic anemias in which vitamin B12 is deficient.

Precaution Section

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:

Ribotin-E™ 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 **Ribotin-E™** after meals may control occasional gastrointestinal disturbances. **Ribotin-**

E™ 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. **Ribotin-E™** 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) **Ribotin-E™** caplets daily, between meals or as directed by a physician. Do not administer to children under the age of 12 unless directed by a physician.

HOW SUPPLIED:

Ribotin-E™ are yellow with slightly brown speckled, coated caplets. Bottles contain 60 caplets – NDC 59088-182-58. Dispense in a tight, light-resistant container as defined in the USP/NF with a child-resistant closure.

STORAGE:

Do not use 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

Ribotin-E™

Manufactured in the USA by:

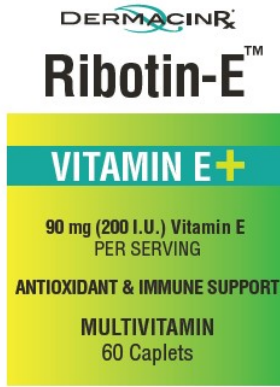
PureTek Corporation

Panorama City, CA 91402

Questions? Call toll-free:

1-877-921-7873

NDC 59088-182-58 Rx Only



| Supplement Facts | |
|--|---|
| Serving Size: | 2 Caplets |
| Servings per container: | 30 |
| Amount Per Serving: | %DV |
| Vitamin A (as retinyl acetate) | 3000 mcg (10000 IU) 333% |
| Vitamin C (as ascorbic acid) | 500 mg 556% |
| Vitamin D ₃ (as cholecalciferol) | 27.5 mcg (1100 IU) 138% |
| Vitamin E (as di-alpha-tocopheryl acetate) | 90 mg (200 IU) 600% |
| Thiamin (as thiamine mononitrate) | 6.5 mg 542% |
| Riboflavin (as vitamin B ₂) | 6.7 mg 515% |
| Niacin (as niacinamide) | 45 mg 281% |
| Vitamin B ₆ (as pyridoxine hydrochloride) | 12 mg 706% |
| Folate (as folic acid) | 1700 mcg DFE (1000 mcg folic acid) 425% |
| Vitamin B ₁₂ (as cyanocobalamin) | 26 mcg 1083% |
| Biotin | 200 mcg 667% |
| Pantothenic Acid (as calcium pantothenate) | 30 mg 600% |
| Calcium (as calcium carbonate) | 150 mg 12% |
| Iron (as ferrous fumarate) | 18 mg 100% |
| Iodine (as potassium iodide) | 50 mcg 33% |
| Magnesium (as magnesium oxide) | 75 mg 18% |
| Zinc (as zinc gluconate) | 30 mg 273% |
| Selenium (as selenomethionine) | 60 mcg 109% |
| Copper (as copper oxide) | 2 mg 222% |
| Manganese (as manganese sulfate) | 1.5 mg 65% |
| Chromium (as chromium polynicotinate) | 75 mcg 214% |
| Molybdenum (as sodium molybdate) | 50 mcg 111% |
| Potassium (as potassium chloride) | 49 mg 1% |
| Boron (as boron citrate) | 50 mcg * |

* Daily Value not established.

Other Ingredients: Microcrystalline Cellulose, Silicon Dioxide, Croscarmellose, Magnesium Stearate, Coating (Sodium Polyacrylate, Polyethylene Glycol, Polyethylene Glycol, Dextrin, Purified Stearic Acid, FD&C Yellow #6, Sunset Yellow FCF, Aluminum Lake).

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.

List No: 182581AA Rev: 38246
 Store at 20° to 25° C (68° to 77° F) (see USP Controlled Room Temperature).
 Manufactured by:
 Paratek Corporation
 Paramarica City, CA 91402
 Questions? Call toll-free:
 1-877-921-7873



RIBOTIN-E

ferrous fumarate, folic acid tablet

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:59088-182 |
| 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: WR1WP1EW8) (.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: 6S06U10H04) (BIOTIN - UNII:6S06U10H04) | 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: 3A3U0G171G) (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 |
|--|----------|
| 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) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| CROSPROVIDONE (UNII: 2S7830E561) | |

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:59088-182-58 | 60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 02/11/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug other | | 02/11/2021 | |

Labeler - PureTek Corporation (785961046)