

51991-182-11

# Ferrocite™ Plus Tablets

**DO NOT USE IF BLISTER SEALS ARE BROKEN**

**breckenridge** | A TEVA COMPANY

Medical Food  
100 Unit Dose Tablets

**Description:** Each tablet contains:

Ferrous Fumarate (anhydrous).....	324 mg
(Equivalent to approximately 106 mg of elemental iron)	
Vitamin C (as Sodium Ascorbate).....	200 mg
Vitamin B1 (as Thiamine Mononitrate).....	10 mg
Vitamin B2 (as Riboflavin).....	6 mg
Vitamin B6 (as Pyridoxine HCl).....	5 mg
Vitamin B12 (as Cyanocobalamin).....	15 mcg
Folic Acid.....	1 mg
Niacinamide (Vitamin B3).....	30 mg
Pantothenic Acid (as Calcium Pantothenate).....	10 mg
Zinc (as Zinc Sulfate).....	18.2 mg
Magnesium (as Magnesium Sulfate).....	6.9 mg
Manganese (as Manganese Sulfate).....	1.3 mg
Copper (as Cupric Sulfate).....	0.6 mg

**Other Ingredients:** Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid, Hypromellose, Citric Acid, Crospovidone, Magnesium Silicate, Titanium Dioxide, Silica, Sodium Lauryl Sulfate, Soy Polysaccharide, Magnesium Stearate, Polyethylene Glycol, Mineral Oil and FD&C Blue No. 1 Lake.  
**Allergen:** Contains Soy.

**INDICATIONS:** For the dietary management of individuals with distinct nutritional needs related to iron and folate deficiencies. Also for supplementation of iron deficiencies occurring with Vitamin C and B-Complex deficiencies. Ferrocite™ Plus Tablets is labeled as a medical food intended for use under the active and ongoing medical supervision requiring medical care on a recurring basis for, among other things, instructions on the use of the medical food.

**MEDICAL FOODS:** Medical foods are intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of a normal diet alone. Although a medical-food product is intended for use under the active and ongoing medical supervision, FDA does not require a prescription.

**These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

**CONTRAINDICATIONS:** All iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, and hemolytic anemias. Pernicious anemia is a contraindication, as folic acid may obscure it. This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

**PEDIATRIC USE:** Safety and effectiveness in pediatric patients have not been established.

**ADVERSE REACTIONS:** Gastrointestinal disturbances (anorexia, nausea, diarrhea, constipation) occur occasionally, but are usually mild and subside with continuation of therapy and physician encouragement. Although the absorption of iron is best when taken between meals, occasional G.I. disturbances may be controlled by giving Ferrocite™ Plus shortly after meals.

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Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

**If pregnant, or planning to become pregnant or are currently breast-feeding please contact your physician, or health-care provider before using or continuing use.**

**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.

Like ferrous sulfate, ferrous fumarate may aggravate existing gastrointestinal diseases, i.e., peptic ulcers, regional enteritis, and ulcerative colitis. Patients with steatorrhea or those with a partial gastrectomy may not absorb sufficient amounts of iron to produce a therapeutic response; therefore, this preparation may be ineffective in those cases. Indefinite administration of iron should be avoided.

**WARNINGS:**

**WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN. In case of accidental overdose, call a doctor or poison control center immediately.**

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where Vitamin B12 is deficient.

**DOSAGE AND ADMINISTRATION:** Adults: 1 tablet daily, between meals, orally.

**HOW SUPPLIED:** Ferrocite™ Plus is a blue, film-coated, capsule-shaped tablet, debossed "CPC 1325". Available in 10 blister cards of 10 tablets each (10x10) (100), 51991-182-99. Carton 51991-182-11.

**STORAGE:** Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature. Protect from light and moisture. Dispense in original container.

To open, tear along perforations for each dose individually and peel the paper backing away. Push the dosage through the foil.

All substitutions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

To report a serious adverse event contact: 1-800-367-3395.

**Manufactured by:** Contract Pharmaceutical Corp.  
Hauppauge, NY 11788  
**Distributed by:** Breckenridge Pharmaceutical, Inc.  
Bertin, CT 06037

**WARNING:** Cancer and Reproductive Harm  
[www.FDA.gov](http://www.FDA.gov)