Ferrex™ 150 Forte Plus Capsules

Medical Food

Each Ferrex™ 150 Forte Plus Capsule contains:

Vitamin C	
Ascorbic Acid (as Calcium Ascorbate)	60 mg
Threonic Acid (as Calcium Threonate)	0.8 mg
Folic Acid, USP	1 mg
Vitamin B_{12} (Cyanocobalamin)	25 mcg
Elemental Iron:	
(as *Sumalate®)	50 mg
(as Polysaccharide Complex)	100 mg
Succinic Acid	50 mg

Other ingredients: Gelatin, Crospovidone, Croscarmellose Sodium, Citric Acid, Stearic Acid, Microcrystalline Cellulose, Polyethylene Glycol, Dicalcium Phosphate, Titanium Dioxide, Polyvinylpyrrolidone, FD&C Red No. 40 Lake, Silica and FD&C Blue No. 1 Lake.

*Sumalate® (Ferrous Asparto Glycinate) is a registered trademark of Albion International, Inc., Clearfield, Utah and is licensed exclusively to Breckenridge Pharmaceutical, Inc., for certain iron products.

INDICATIONS AND USAGE:

Ferrex™ 150 Forte Plus Capsules are indicated for the dietary management of individuals with distinct nutritional needs for iron deficiencies and/or nutritional megaloblastic anemias. Ferrex 150 Forte Plus 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 the 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:

Ferrex™ 150 Forte Plus is contraindicated in patients with a known hypersensitivity to any of the components of this product. Hemochromatosis and hemosiderosis are contraindications to the use of this product.

WARNINGS:

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.

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} is deficient.

PRECAUTIONS:

General: Do not exceed recommended dose.

The type of anemia and the underlying cause or causes should be determined before starting with Ferrex™ 150 Forte Plus. Since the anemia may be a result of a systemic disturbance, such as recurrent blood loss, the underlying cause or causes should be corrected, if possible.

Folic Acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive. Pernicious anemia should be excluded before using this product since folic acid may mask the symptoms of pernicious anemia.

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.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Clinical studies on this product have not been performed in subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS:

Adverse reactions with iron therapy may include constipation, diarrhea, nausea, vomiting, dark stools and abdominal pain. Adverse reactions with iron therapy are usually transient.

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

OVERDOSAGE:

The clinical course of acute iron overdosage can be variable. Initial symptoms may include abdominal pain, nausea, vomiting, diarrhea, tarry stools, melena, hematemesis, hypotension, tachycardia, metabolic acidosis, hyperglycemia, dehydration, drowsiness, pallor, cyanosis, lassitude, seizures, shock and coma.

DOSAGE AND ADMINISTRATION:

Usual adult dosage is 1 capsule daily, or as directed by a physician or health-care provider.

HOW SUPPLIED

Ferrex™ 150 Forte Plus Capsules are available as a white/red capsule, imprinted “B 798”. Supplied in bottles of 90 capsules, 51991-798-90.

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 a tight, light-resistant container with a child-resistant closure as defined in the USP/NF.

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

Manufactured by: Contract Pharmacal Corp.
Hauppauge, NY 11788 USA

Distributed by: Breckenridge Pharmaceutical, Inc.
Boca Raton, FL 33487

***U.S. Patent Nos. 5,516,925; 6,716,814; 8,007,846.**
Other U.S. patents pending.

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