

Re-Order No. 081119



Ferrex™-150

Polysaccharide-Iron Complex Capsules

DIETARY SUPPLEMENT

FOR DISPENSING PURPOSE ONLY

DO NOT USE IF BLISTER SEALS ARE BROKEN

10 x 10 Capsules

Distributed by:
MAJOR PHARMACEUTICALS
31778 Enterprise Drive
Livonia, MI 48150 USA

To Report Serious Adverse Effects Call: 800-616-2471

SUPPLEMENT FACTS

Serving Size: 1 Capsule

	Amount Per Capsule	% Daily Value
Iron (Elemental) (As Polysaccharide-Iron)	150 mg.	833%

Other Ingredients: Sodium Lauryl Sulfate, Gelatin, Microcrystalline Cellulose, Stearic Acid, Polyethylene Glycol, Citric Acid, Croscarmellose Sodium, Titanium Dioxide, Polyvinylpyrrolidone, FD&C Yellow No. 5 Lake*, FD&C Red No. 40 Lake, FD&C Red No. 3 Lake and FD&C Blue No. 1 Lake.

* Contains FD&C Yellow No. 5 Lake (Tartrazine) as a color additive.

Ferrex™ 150 Polysaccharide-Iron complex capsules are a product of ferric iron complexed to a low molecular weight polysaccharide. This polysaccharide is a product of extensive hydrolysis of starch. Ferrex™ 150 is a dark brown powder that forms a very dark brown solution when dissolved in water. It is tasteless and odorless. As an organic complex, it contains no free irons.

INDICATIONS AND USAGE:

Ferrex™ 150 may be used for the dietary management of iron deficiencies.

CONTRAINDICATIONS:

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

PRECAUTIONS:

This product contains FD&C Yellow No. 5 Lake (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 Lake (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

The type of anemia and the underlying cause or causes should be determined before initiating supplementation with Ferrex™ 150. Since the anemia may be a result of a systematic disturbance, such as a recurrent blood loss, the underlying cause or causes should be corrected if possible. Since oral iron products interfere with absorption of certain antibiotics, these products should not be taken within two hours of each other.

As with all oral iron preparations, Ferrex™ 150 should be stored out of the reach of children to protect against accidental iron poisoning. Patients should not exceed the recommended dosage unless directed by a physician. Patients should be informed that iron products can cause dark or black stools.

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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.

ADVERSE REACTIONS:

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

OVERDOSE:

The clinical cause of acute iron overdose 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:

Adults: One or two capsules daily, or as prescribed by a physician.

HOW SUPPLIED:

Unit Dose blister packs, 10 capsules per card, orange/brown capsules imprinted B-203.

Keep this and all medications out of the reach of children.

Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature.

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.

Manufactured by:
Contract Pharmacal Corp.
Hauppauge, NY 11788

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M-29 Rev. 09/11

