MYFERON 150 - iron sucrose capsule
MARTIN EKWEALOR PHARMACEUTICALS, INC.

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.

SUPPLEMENTAL FACTS

Serving Size: 1 Capsule

	Amount Per Serving	% Daily Value
Iron (Elemental) (As Polysaccharide Iron Complex)	150 mg	833%

INDICATIONS:

prevention and treatment of iron deficiency and/or other nutritional megaloblastic anemias

WARNING: Keep this product out of reach of children.

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.

INDICATIONS AND USAGE:

Myferon 150 is indicated for the prevention and treatment of iron deficiency anemia and/or nutritional megaloblastic anemias.

WARNING:

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.

DOSAGE AND ADMINISTRATION:

One or two capsules daily or as prescribed by a physician.

Inactive Ingredients OTHER INGREDIENTS:

D and C Red #7, D and C Red #28, D and C Yellow #10, FD and C Blue #1, FD and C Red #40, FD and C Yellow #6, Gelatin, Pharmaceutical Glaze, Sodium Lauryl Sulfate, Titanium Dioxide, Dicalcium Phosphate.

DESCRIPTION:

Myferon 150, Polysaccharide Iron Complex capsules are a preparation of ferric Iron complexed to a low molecular weight polysaccharide. This polysaccharide is obtained by extensive hydrolysis of starch.

Myferon 150 is a dark brown powder that when dissolved in water, forms a very dark brown solution. As an organic complex, polysaccharide iron contains no free iron. It is tasteless, odorless and readily soluble in water.

CLINICAL PHARMACOLOGY:

Iron is an essential compound in the formation of hemoglobin. Adequate amounts of iron are necessary for the effective erythropoiesis. Iron also serves as a cofactor of several essential enzymes, including cytochromes that are involved in electron transport.

A radioiscope tracer study in man demonstrated that absorption of a polysacchride-iron is comparable to that of ferrous sulfate. Clinical studies demonstrate that polysaccharide-iron produces good hematological response shown by increases in hemoglobin and hematocrit in children and adult patients. Polysaccharide-iron is effective in maintaining the hematopoietic status in end-stage kidney disease patients receiving epoetin alfa therapy.

CONTRAINDICATIONS:

Myferon 150 is contraindicated in patients with a known hypersensitivity to any of the components of this product. Hemochromatosis and hemosiderosis are contraindications to iron therapy.

PRECAUTIONS:

The type of anemia and the underlying cause or causes should be determined before initiating treatment with Myferon 150. 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. As with all oral iron preparations, Myferon 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.

ADVERSE REACTIONS:

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

Chronic toxicity studies in rats and dogs administered polysaccharide-iron complex showed that a daily dosage of 250 mg iron/kg for three months has no adverse effects. The Oral LD 50 of polysaccharide-iron complex was estimated to be greater than 5000 mg. iron/kg in rats.

HOW SUPPLIED:

Myferon 150 capsules are supplied in unit dose blister packs, 10 capsules per card, orange/brown capsules.

Store at 25° C (77° F); excursions permitted to 15°-30° C (59°-86° F). See USP controlled room temperature.

Myferon 150 Product Label

M.E. PHARMACEUTICALS, Inc.

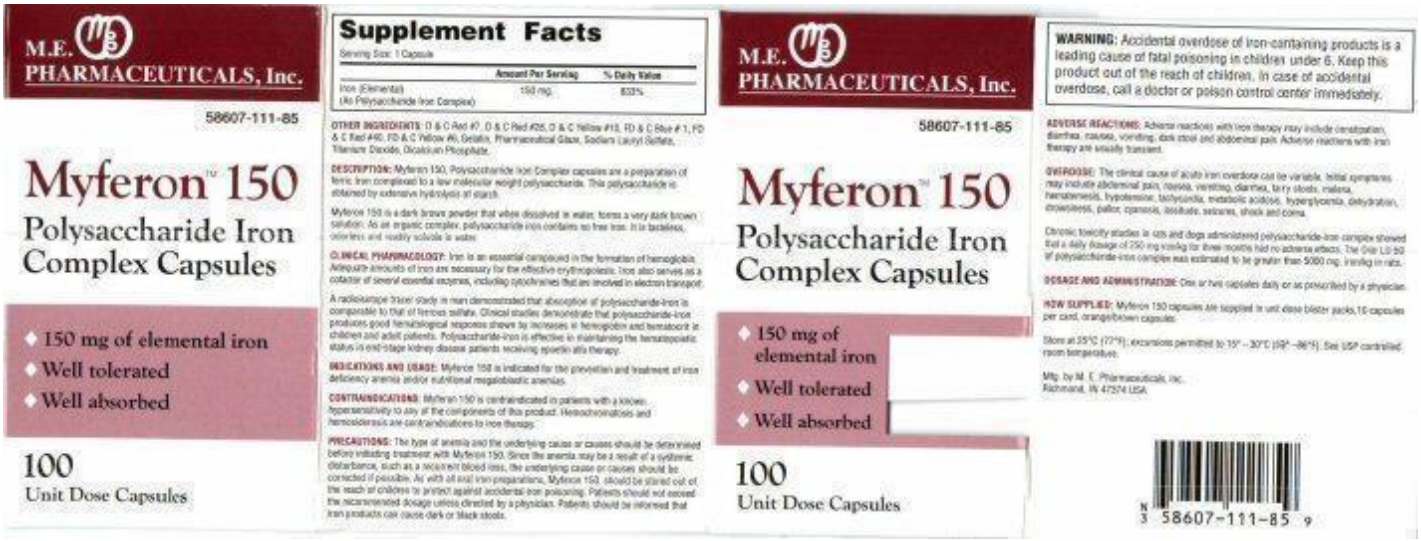
58607-111-85

Myferon™ 150
Polysaccharide Iron Complex Capsules

150 mg of elemental iron
Well tolerated
Well absorbed

100 Unit Dose Capsules

Mfg by M.E. Pharmaceuticals, Inc.
Richmond, IN 47374 USA



MYFERON 150

iron sucrose capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58607-111
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IRON SUCROSE (UNII: FZ7NYF5N8L) (FERRIC CATION - UNII:91O4LML611)	FERRIC CATION	150 mg

Inactive Ingredients	
Ingredient Name	**Strength**
D&C RED NO. 7 (UNII: ECW0LZ41X8)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
SHELLAC (UNII: 46N107B71O)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	

Product Characteristics

Color	orange (ORANGE;BROWN)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	B203
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58607-111-85	100 in 1 BOX		
1		10 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/01/1996	

Labeler - MARTIN EKWEALOR PHARMACEUTICALS, INC. (624528386)

Registrant - MARTIN EKWEALOR PHARMACEUTICALS, INC. (624528386)

Establishment

Name	Address	ID/FEI	Business Operations
MARTIN EKWEALOR PHARMACEUTICALS, INC.		624528386	manufacture(58607-111)

Revised: 2/2014 MARTIN EKWEALOR PHARMACEUTICALS, INC.