MYFERON 150 FORTE - iron sucrose, folic acid, cyanocobalamin 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.

DESCRIPTION:

Myferon 150 Forte capsules are highly water soluble low molecular weight polysaccharide iron complex and vitaminns.

Each capsule contains:

Elemental Iron ..... 150 mg
(as Polysaccharide Iron Complex)

Folic Acid ..... 1 mg

Vitamin B 12 ..... 25 mcg.
(Cyanocobalamin)

Other ingredients: Microcrystalline Cellulose, Gelatin, Dicalcium, Phosphate, Stearic Acid, Pharmaceutical Glaze, Magnesium Stearate, Iron Oxides, Titanium Dioxide, FD and C Red #40 Lake and FD and C Blue #1 Lake.

CLINICAL PHARMACOLOGY:

Iron is an essential component in the formation of hemoglobin. Adequate amounts of iron are necessary for effective erythropoiesis. Iron also serves as a cofactor of several enzymes, including cytochromes that are involved in electron transport. Folic acid is required for nucleoprotein synthesis and the maintenance of normal erythropoiesis. Folic acid is converted in the liver and plasma to its metabolically active form, tetrahydrofolic acid by dihydrofolate reductase. Vitamin B 12 is required for the maintenance of normal erythhropoiesis, nucleoprotein and myelin synthesis, cell reproduction and normal growth. Intrinsic factor, a glycoprotein secreted by the gastric mucosa, is required for active absorption of Vitamin B 12 from the gastric tract.

INDICATIONS AND USAGE:

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

CONTRAINDICATIONS:

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

WARNINGS:

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 therapy with Myferon 150 Forte. 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: Folic Acid in doses above 1.0 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.

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

Geriatric Use: Clinical studies on this product have not been performed in sufficient numbers of 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.

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.

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.

OVERDOSE:

The clinical course of acute iron overdosage can be variable. Initial symptoms may include abdominal pain, nausea, vomiting, diarrhea, tarry stools, melena, hematamesis, 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 had no adverse effects. The oral LD50 of polysaccharide iron complex was estimated to be greater than 5000 mg/kg in rats.

HOW SUPPLIED:

Myferon 150 Forte is supplied in Unit Dose blister packs, 10 capsules per card. Capsules are opaque maroon. Store at 25° C (77° F); excursions permitted to 15° -30° C (59° -86° F). (See USP controlled Room Temperature). Avoid excessive heat 40° C (104° F). Avoid freezing.

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

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

Myferon 150 Forte Product Label

M.E. PHARMACEUTICALS, Inc.

58607-112-00

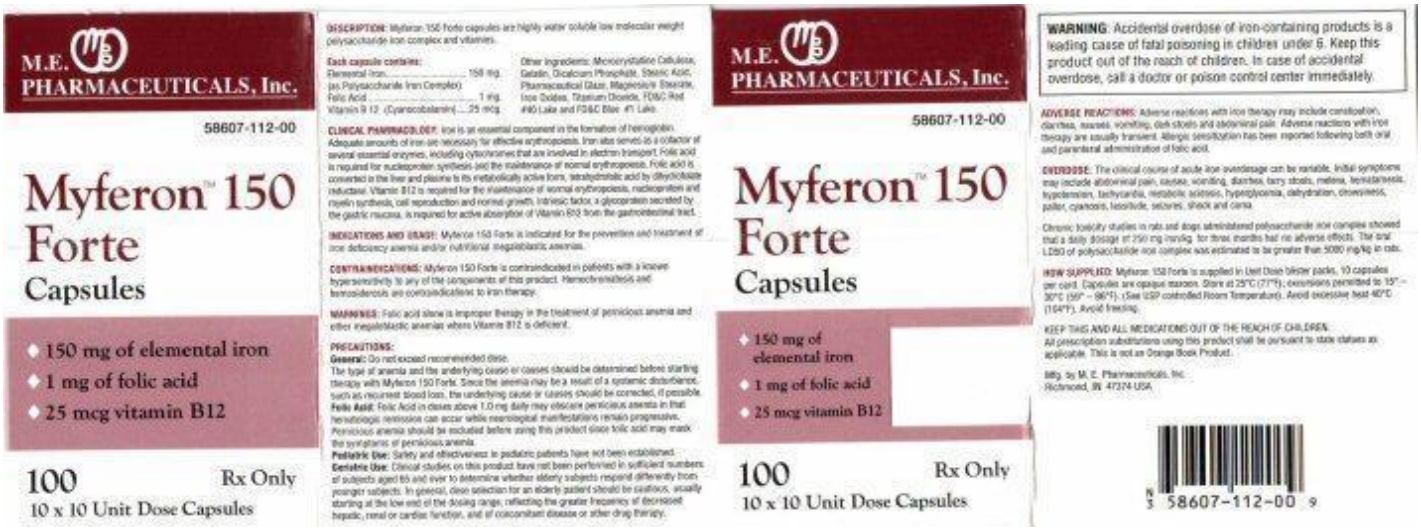
Myferon™ 150 Forte
Capsules

150 mg of elemental iron
1 mg of folic acid
25 mcg vitamin B12

100 Rx Only

10 x 10 Unit Dose Capsules

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



MYFERON 150 FORTE

iron sucrose, folic acid, cyanocobalamin capsule

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:58607-112
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
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	25 ug

Inactive Ingredients	
Ingredient Name	**Strength**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
GELATIN (UNII: 2G86QN327L)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
SHELLAC (UNII: 46N107B71O)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Product Characteristics

Color	red (MAROON)	**Score**	no score
Shape	CAPSULE (CAPSULE)	**Size**	18mm
Flavor		**Imprint Code**	B198
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58607-112-00	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(58607-112)

Revised: 2/2014 MARTIN EKWEALOR PHARMACEUTICALS, INC.