BIOFERR 90- dual-iron tablet, film coated
Biocomp Pharma, 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.

BioFerr™ 90

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.

DESCRIPTION:

Each green film-coated tablet for oral administration contains:

Iron (Carbonyl iron, ferrous gluconate)	90	mg
Folic Acid	1	mg
Vitamin B_{12} (Cyanocobalamin)	12	mcg
Vitamin C (Ascorbic acid)	119	mg
Docusate sodium	50	mg

Inactive Ingredients:

Povidone, croscarmellose sodium, acrylic resin, color added, magnesium stearate, FD&C Yellow No. 5, magnesium silicate, FD&C Blue No. 1, polyethylene glycol, vitamin A palmitate, ethyl vanillin.

CLINICAL PHARMACOLOGY:

Oral iron is absorbed most efficiently when administered between meals. Iron is critical for normal hemoglobin synthesis to maintain oxygen transport for energy production and proper function of cells. Adequate amounts of iron are necessary for effective erythropolesis. Iron also serves as a cofactor of several essential enzymes, Including cytochromes, which are involved in electron transport. Folic acid is required for nucleoprotein synthesis and the maintenance of normal erytropolesis. Folic acid is the precursor of tetrahydrofolic acid, which is involved as a cofactor for transformylation reactions In the biosynthesis of purines and thymidylates of nucleic acids. Deficiency of folic acid may account for the defective deoxyribonucleic acid (DNA) synthesis that leads to megaloblast formation and megaloblastic macrocytic anemias. Vitamin B_{12} is essential to growth, cell reproduction, hematopolesis, nucleic acid, and myelin synthesis. Deficiency may result in megaloblastic anemia or pernicious anemia.

INDICATIONS AND USAGE:

BioFerr™ 90 is indicated for the treatment of all anemias that are responsive to oral iron therapy. These include: hypochromic anemia associated with pregnancy, chronic and/or acute blood loss, metabolic disease, post-surgical convalescence, and dietary needs.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients. Hemolytic anemia, hemochromatosis, and hemosiderosis are contraindications to iron therapy.

WARNING:

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

PRECAUTIONS:

General:

Take 2 hours after meals. Do not exceed recommended dose. Discontinue use if symptoms of intolerance appear. The type of anemia and underlying cause or causes should be determined before starting therapy with BioFerr™ 90 tablets. Ensure Hgb, Hct, and reticulocyte count are determined before starting therapy to determine if it needs to be continued without change or if a dose change is indicated. This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

Folic Acid:

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 these products since folic acid may mask the symptoms of pernicious anemia.

Pediatric Use:

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use:

Dosing for elderly patients should be administered with caution. Due to the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy, dosing should start at the lower end of the dosing range.

ADVERSE REACTIONS:

Adverse reactions with iron therapy may include GI irritation, constipation, diarrhea, nausea, vomiting, and dark stools. Adverse reactions with iron therapy are usually transient. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

DRUG INTERACTIONS:

Prescriber should be aware of a number of iron/drug interactions, including antacids, tetracyclines, or fluoroquinolones.

OVERDOSAGE:

Symptoms: abdominal pain, metabolic acidosis, anuria, CNS damage, coma, convulsions, death, dehydration, diffuse vascular congestion, hepatic cirrhosis, hypotension, hypothermia, lethargy, nausea, vomiting, diarrhea, tarry stools, melena, hematernesis, tachycardia, hyperglycemia, drowsiness, pallor, cyanosis, lassitude, seizures, and shock

DOSAGE AND ADMINISTRATION

One tablet daily or as directed by a physician.

Do not chew tablet.

STORAGE:

Store at 20°C to 25°C (68°F to 77°F). Excursions permitted between 15°C and 30°C (between 59°F and 86°F). (See USP Controlled Room Temperature.)

NOTICE:

Contact with moisture can discolor or erode the tablet.

HOW SUPPLIED:

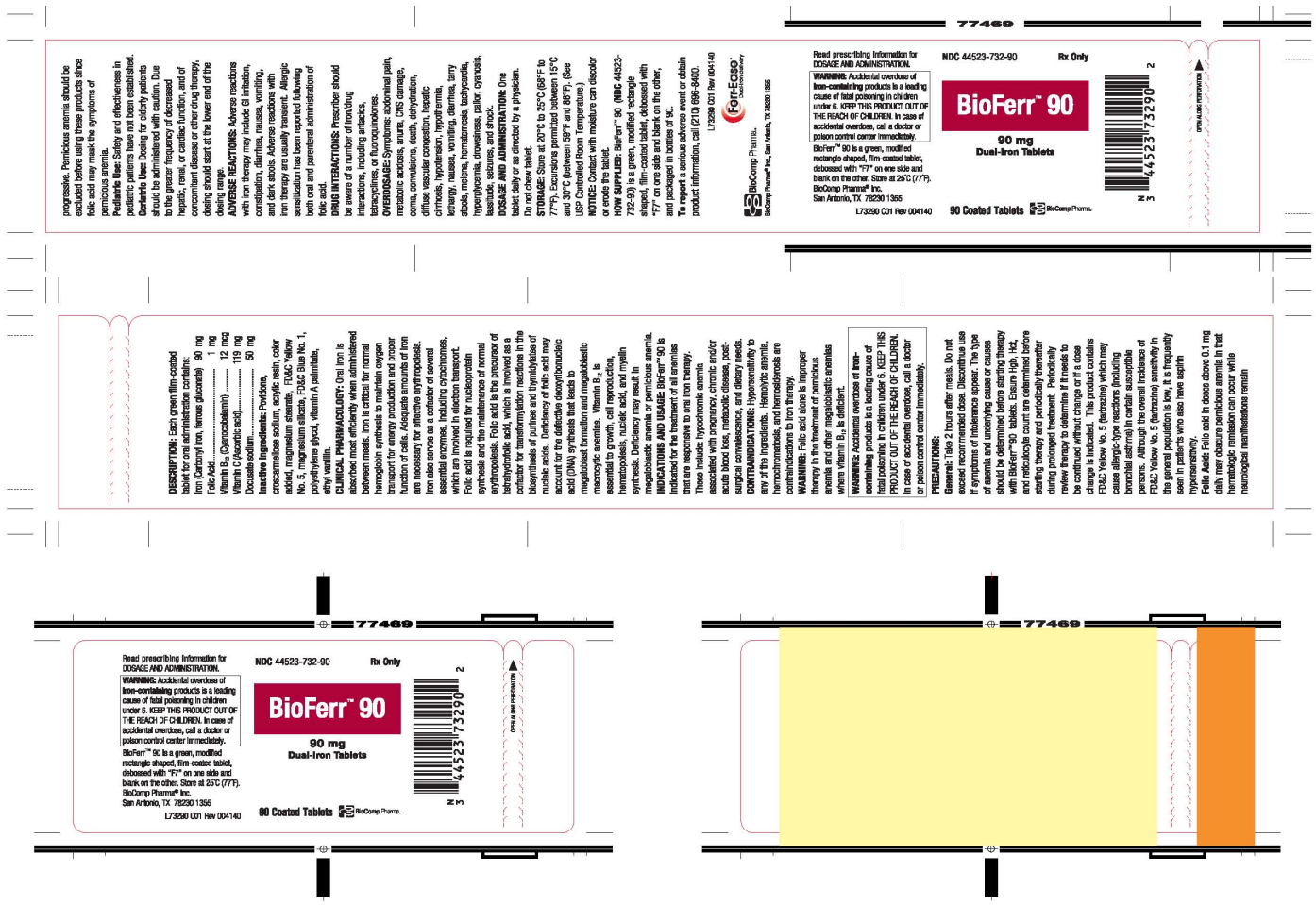
BioFerr™ 90 (**NDC** 44523-732-90) is a green, modified rectangle shaped, film-coated tablet, debossed with “F7” on one side and blank on the other, and packaged in bottles of 90.

To report a serious adverse event or obtain product information, call (210) 696-8400.

L73290 C01 Rev 004140

BioComp Pharma® Inc., San Antonio, TX 78230 1355

BioFerr™ 90
90 mg Dual-Iron Tablets
NDC 44523-732-90



BIOFERR 90

dual-iron tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:44523-732
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	138 mg
IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	88.5 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	55 mg
FERROUS GLUCONATE (UNII: U1B11I423Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	13.2 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1.4 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	16.8 ug

Inactive Ingredients	
Ingredient Name	**Strength**
POVIDONES (UNII: FZ989GH94E)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	

DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	

Product Characteristics

Color	GREEN	**Score**	no score
Shape	RECTANGLE (modified rectangle)	**Size**	9mm
Flavor		**Imprint Code**	F7
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44523-732-90	90 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		07/01/2014	

Labeler - Biocomp Pharma, Inc. (829249718)

Registrant - Mission Pharmacal Company (927726893)

Establishment

Name	Address	ID/FEI	Business Operations
Mission Pharmacal Company		927726893	MANUFACTURE(44523-732)

Revised: 6/2014 Biocomp Pharma, Inc.