FERROUS SULFATE- iron tablet
Boca Pharmacal, LLC

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.

Ferrous Sulfate Tablets, USP

DESCRIPTION

Supplement Facts

Serving Size: 1 Tablet	
Amount Per Tablet	**% Daily Value**
Iron 65 mg	361 %

Other ingredients: Calcium phosphate, cellulose, croscarmellose sodium, FD&C red #40, hypromellose, magnesium stearate, mineral oil, polyethylene glycol, sodium starch glycolate, stearic acid (veg. grade), talc, and titanium dioxide.

Formula: Each tablet contains 200 mg of dried ferrous sulfate USP (65 mg of elemental iron), equivalent to 325 mg of ferrous sulfate USP.

DOSAGE AND ADMINISTRATION

Directions: Adults and children over 12 years of age: 1 tablet daily as a dietary supplement, preferably with a meal or as directed by a doctor. Do not exceed 2 tablets in 24 hours. Not for frequent or prolonged use except on the advice of a doctor. **Do not give to children under 12 years of age. Do not exceed recommended dosage.**

Caution: Since oral iron products interfere with absorption of certain antibiotics, these products should not be taken within two hours of each other. If you are pregnant, nursing or taking any medications, consult your doctor before use. Discontinue use and consult your doctor if any adverse reactions occur.

HOW SUPPLIED

Storage and Handling

STORE AT 20°- 25°C (68° - 77°F); Excursions permitted to 15°- 30°C (59° - 86°F), see USP Controlled Room Temperature. Store away from heat and moisture. Keep tightly closed.

Tamper resistant: Do not use if seal under cap is broken or missing.

Manufactured for:
Boca Pharmacal, LLC
Coral Springs, FL 33065
www.bocapharmacal.com
1-800-354-8460
Rev. 09/13

BOXED 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.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Ferrous Sulfate Tablets, USP 325mg

1000ct

NDC: 64376-809-10

[Rev. 10]

FERROUS SULFATE

iron tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:64376-809
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FERROUS SULFATE (UNII: 39R4TAN1VT) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	65 mg

Inactive Ingredients	
Ingredient Name	**Strength**
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
MINERAL OIL (UNII: T5L8T28FGP)	
CALCIUM PHOSPHATE (UNII: 97Z1WI3NDX)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	RED	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64376-809-10	1000 in 1 BOTTLE; Type 0: Not a Combination Product	09/14/2010	06/30/2018

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		09/14/2010	06/30/2018

Labeler - Boca Pharmacal, LLC (170266089)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	MANUFACTURE(64376-809)

Revised: 9/2013 Boca Pharmacal, LLC