

FE C TAB- iron, vitamin c 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.

Unknown Title

FE C Tab

Supplement Facts		
Serving Size 1 Tablet		
Amount Per Tablet		% Daily Value
Iron (as Carbonyl Iron)	100 mg	556%
Vitamin C (as Ascorbic Acid)	250 mg	417%

Inactive ingredients: Black iron oxide, dicalcium phosphate, FD&C Blue #2, FD&C Red #40, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, propylene glycol, red iron oxide, silicon dioxide, stearic acid, titanium dioxide, triacetin, yellow iron oxide.

STORE AT CONTROLLED ROOM TEMPERATURE 20°-25°C (68°-77°F)

DIRECTIONS: Adults and Children 12 years and over – One tablet daily or as directed by a physician. Children under 12 years: Consult a physician.

WARNINGS: Do not exceed recommended dosage. The treatment of any anemic condition should be under the advice and supervision of a physician. Since oral iron products interfere with absorption of oral tetracycline antibiotics, these products should not be taken within two hours of each other. Occasional gastrointestinal discomfort (such as nausea) may be minimized by taking with meals. Iron products may occasionally cause constipation or diarrhea. If you are pregnant or nursing a baby, seek the advice of a health professional before using this product.

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.

DO NOT ACCEPT IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING.

Manufactured for: **Boca Pharmacal, LLC** Coral Springs, FL 33065
www.bocapharmacal.com 1-800-354-8460 Rev. 08/13 077T

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



NDC 64376-803-01

FE C Tab



Each Tablet Contains:
Iron (as Carbonyl Iron) 100 mg
Vitamin C (as Ascorbic Acid) 250 mg

100 TABLETS

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Manufactured for: Boca Pharnacal, LLC, Coral Springs, FL 33065
www.bocapharmaceutical.com 1-800-354-6460 Rev. 08/13 0771

Lot #:

Exp. Date:



Made in the USA



N 3 64376 80301 7

FE C TAB

iron, vitamin c tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:64376-803
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	250 mg
IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z) (FERROUS CATION - UNII:GW895810WR)	FERROUS CATION	100 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64376-803-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/19/2010	11/30/2017

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		08/19/2010	11/30/2017

Labeler - Boca Pharmacal, LLC (170266089)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	MANUFACTURE(64376-803, 64376-803)

Revised: 9/2013

Boca Pharmacal, LLC