FERROUS SULFATE- iron supplement tablet
Unit Dose Services

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 325 mg (5 gr)

Supplement Facts[/S]

Serving Size: 1 Tablet Amount per Tablet	**% Daily Value**
Iron (as ferrous sulfate) 65 mg	360 %

SUGGESTED USE

Adults: One (1) tablet daily, preferably after meals or as directed by the doctor. **Children:** As directed by the doctor.

Active Ingredient

EACH TABLET CONTAINS: **%** U.S. RDA*

Elemental Iron 65 mg 360

(Equivalent to 325 mg of Ferrous Sulfate)

* U.S. Recommended Daily Allowance

Inactive Ingredients

Croscarmellose sodium, dicalcium phosphate, FD&C RED#40 (Al-lake), FD&C yellow #6 (Al-lake), hypromellose, magnesium stearate, microcrystalline cellulose, PEG 400, titanium dioxide

Purpose

Iron Supplement

WARNING:

Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under 6. **Keep this product out of reach of children**. In case of accidental overdose, call a doctor or Poison Control Center immediately.

WARNINGS: Do not exceed recommended dosage. The treatment of any anemic condition should be under the advice and supervision of doctor. Occasional gastrointestinal discomfort (such as nausea) may be minimized by taking with meals. Iron-containing medication may occasionally cause constipation or diarrhea.

As with any drug, if you are pregnant or nursing baby, seek the advice of a health professional before using this product.

DRUG INTERACTION PRECAUTION

Since oral iron products interfere with absorption of oral tetracycline antibiotics , these products should not be taken within two hours of each other.

DOSAGE AND ADMINISTRATION

Each tablet contains: Calcium 20 mg (2% daily value) Store in a dry place at controlled room temperature at 15-30 °C (59°-86° F). Do not expose to excessive heat or moisture.

Questions or Comments

DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP OR BAND AROUND ANY CAPSULE IS MISSING OR DAMAGED

TAMPER EVIDENT: DO NOT USE IF BLISTER UNIT IS BROKEN OR DAMAGED

Distributed by: Qualitest Pharmaceuticals, Inc.

FERROUS SULFATE (IRON SUPPLEMENT) TABLET

FERROUS SULFATE

iron supplement tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50436-5891(NDC:0603-0179)
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FERROUS SULFATE (UNII: 39R4TAN1VT) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	325 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	RED	**Score**	no score
Shape	ROUND	**Size**	8mm
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-5891-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	02/19/2001	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		02/19/2001	

Labeler - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-5891) , RELABEL(50436-5891)

Revised: 7/2017 Unit Dose Services