

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	% Daily Value
Amount per Tablet	
Iron (as ferrous sulfate) 65 mg	360 %

SUGGESTED USE

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

Adults:Children:

Active Ingredient

U.S. RDA* EACH TABLET CONTAINS: %

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. . In case of accidental overdose, call a doctor or Poison Control Center immediately. **Keep this product out of reach of children**

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. **WARNINGS: Do not exceed recommended dosage.**

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

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. **Each tablet contains:**

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

NDC: 50436-5891-1
FERROUS SULFATE 325 MG 30 TABLETS
 IRON SUPPLEMENT
 30 TABLETS, EACH CONTAINING
 325 MG FERROUS SULFATE
 LOT: XXXXX EXP: XXXXX
 DIST. BY: QUALITEST PHARM
 HUNTSVILLE, AL 35811
 WARNING: KEEP OUT OF REACH OF CHILDREN
 STORE AT 15- 30°C (59-86°F) MFG NDC: 0603-0179-32
 MFG LOT: XXXXX
 SEE PACKAGE INSERT FOR DOSAGE INFORMATION
 PKG BY: UNIT DOSE SERVICES LLC, DANIA, FL



50436589101

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:GW895810WR)	FERROUS CATION	325 mg

Inactive Ingredients

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

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (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		

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)

Registrant - Unit Dose Services (831995316)

Establishment

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