FERROUS SULFATE- ferrous sulfate tablet, film coated
Central Texas Community Health Centers

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 Film Coated Tablets

ACTIVE INGREDIENT(S)

EACH TABLET CONTAINS:

Amount per tablet	% Daily Value
Iron 65 mg	361%

Dried Ferrous Sulfate, equivalent to 325 mg Ferrous Sulfate per tablet.

INACTIVE INGREDIENTS

Other ingredients for Red Tablets: microcrystalline cellulose, dibasic calcium phosphate dihydrate, croscarmellose sodium, sodium starch glycolate, hypromellose, stearic acid, polyethylene glycol (PEG) 400, FD&C red #40 aluminum lake, magnesium stearate, titanium dioxide, polyethylene glycol (PEG) 8000, carnauba wax

Other ingredients for Green Tablets: microcrystalline cellulose, dibasic calcium phosphate dihydrate, croscarmellose sodium, sodium starch glycolate, hypromellose, stearic acid, polyethylene glycol (PEG) 400, magnesium stearate, riboflavin, FD&C bule #1 aluminum lake, titanium dioxide, FD&C blue #2 aluminum lake, polyethylene glycol (PEG) 8000, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, carnauba wax

PURPOSE

Dietary Supplement

USE(S)

One tablet daily or as directed by a physician. For children under 12, consult a physician before using this product.

WARNINGS

Iron may interfere with absorpiton of certain antibiotics; these products should not be taken within two hours of each other.

Occasional gastrointestinal discomfort (such as nausea) may be minimized by taking iron with meals. Iron-containing products may occassionally cause constipation or diarrhea. If pregnant or nursing consult a physicial before using this product.

DO NOT USE

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING

OTHER REQUIRED WARNINGS

The information on this label has not been evaluated by the Food and Drug Administration. This

product is not intended to diagnose, trea, cure or prevent any disease.

To report a serious adverse event or to obtain product information, contact 800-818-4555.

KEEP OUT OF REACH OF CHILDREN

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.

DIRECTIONS

One tablet daily or as directed by a physician. For children under 12, consult a physical before using this product.

Do not exceed recommended dosage.

Do not use except under the advice and supervision of a physician.

STORAGE

Store at 25˚C (77˚F); excursions permitted between 15˚-30˚C (59˚-86˚F)

PRINCIPAL DISPLAY PANEL - 325 MG Tablet Bottle Label

CommUnityCare Federally Qualified Health Centers

FERROUS
SULFATE
325MG #
100

Date:

Name:
Dr.

TAKE 1 TABLET 1 TO 3 TIMES PER DAY WITH FOOD, AS DIRECTED.

123456

1/1/01

FERROUS SULF 325MG TABS# 100 NDC 76413-308-01

Batch: 123456
Lot: 123456
Exp: 1/1/01
SUN PHARMA

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

CommUnityCare Federally Qualified Health Centers

FERROUS SULFATE 325MG # 100

Date:

Name: Dr.

TAKE 1 TABLET 1 TO 3 TIMES PER DAY WITH FOOD, AS DIRECTED.
TOME UNA TABLETA UNA A TRES VECES AL DIA CON COMIDA, SEGUN INDICADO.

123456

1/1/01

FERROUS SULF 325MG TABS# 100 NDC 76413-308-01

Batch: 123456 Lot: 123456 Exp: 1/1/01 SUN PHARMA

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

FERROUS SULFATE

ferrous sulfate tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76413-308(NDC:57664-071)
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**
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

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:76413-308-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		07/01/2014	

Labeler - Central Texas Community Health Centers (079674019)

Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-308) , RELABEL(76413-308)

Revised: 3/2016 Central Texas Community Health Centers