FERROUS SULFATE- ferrous sulfate tablet, film coated
RedPharm Drug, Inc.

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.

ACTIVE INGREDIENT(S)

EACH TABLET CONTAINS:

Amount per tablet Iron 65 mg

% Daily Value 361%

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

INACTIVE INGREDIENT SECTIONS

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.

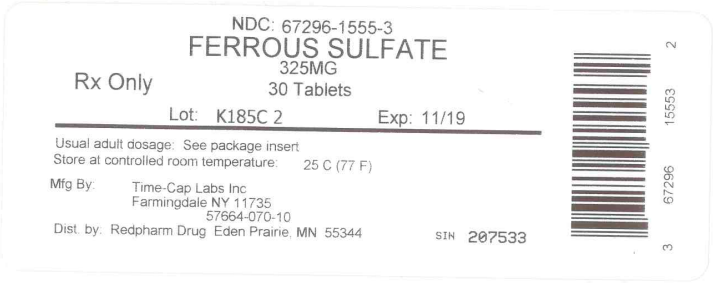
Do not exceed recommended dosage.

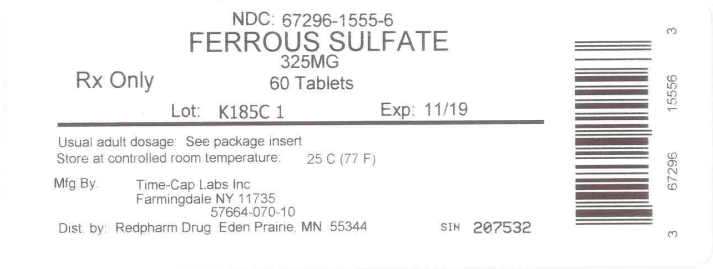
Do not use except under the advice and supervision of a physician.

STORAGE

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

PACKAGE LABEL





FERROUS SULFATE

ferrous sulfate tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67296-1555(NDC:57664-070)
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**
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYETHYLENE GLYCOL 8000 (UNII: Q662QK8M3B)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
RIBOFLAVIN (UNII: TLM2976OFR)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	green	**Score**	no score
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:67296-1555-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2018	
2	NDC:67296-1555-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

unapproved drug other		01/01/2018	

Labeler - RedPharm Drug, Inc. (828374897)

Establishment

Name	Address	ID/FEI	Business Operations
RedPharm Drug, Inc.		828374897	repack(67296-1555) , relabel(67296-1555)

Revised: 1/2020 RedPharm Drug, Inc.