FERROUS SULFATE- ferrous sulfate, dried tablet, film coated SPIRIT PHARMACEUTICALS,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.

FERROUS SULFATE TABLETS USP 325 MG

Drug Facts

Active ingredients (in each Caplet)

Dried Ferrous Sulfate 325 mg

Purpose

Iron Supplement Therapy

Ferrous Sulphate is an iron supplement for iron deficiency and iron deficiency anemia when the need for such therapy has been determined by 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 certain antibiotics, these products should not be taken within tow hours of each other. Occasional gastrointestinal discomfort (such as nausea) may be minimized by taking with meals. Iron-containing products may occasionally cause constipation or diarrhea.

If are pregnant or nursing a baby, seek the advise of a health professional before using this products.

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.

Direction

- * adults and children 12 years and over: take 1 tablet daily or as directed by a doctor
- * Children under 12 years : consult a physician..

Other information

* Store at room temperature

Inactive ingredients

Starch USP, Calcium Carbonate USP, Guar Gum, Magnesium Stearate USP, Talc USP, Colloidal Silicon Dioxide USP, Carnuba Wax

PRINCIPAL DISPLAY PANEL - 65 mg Tablet Carton

Ferrous

Sulfate

NDC # 68210-1520-0

Iron Supplement Therapy

- #1 doctor recommended iron supplement
- Easy to swallow
- 65 mg of elemental iron per tablet 360% of daily value

TAMPER EVIDENT – SEE SIDE PANEL

100 TABLETS





Supplement Facts
Serving Size: 1 Tablet

Amount per Tablet % Daily Value Iron 65 mg 360 %

INGREDIENTS: Dried Ferrous Sulfate 200 mg (65 mg elemental iron), equivalent to 325 mg Ferrous Sulfate per tablet, Calcium Carbondte Guar Gurn, Magnesium Stearate, Talc, Sticon Dioxide, Carnuba Wax, Hypromello se, Tranium Dioxide, Carnuba Wax, Aluminum Oxide, Polythylene Glycol, FD.8C Yellow #5, FD.8C#8.

Tamper-Evident: Do not use if imprinted foil seal under cap is broken or missing.

STORE AT ROOM TEMPERATURE (59°-86° F). Not USP for dissolution.

Distributed by: Spirit Pharmaceuticals, LLC, PA19030 Ferrous Suffets Tablets provide the body with ferroussuffate. Ferrous Suffate is an iron supplement for iron deliciency and iron deficiency anemia when the need for such therapy has been determined by a physician.

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FERROUS SULFATE

ferrous sulfate, dried tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-1520
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
FERROUS SULFATE, DRIED (UNII: RIB00980VW) (IRON - UNII:E1UOL152H7)	FERROUS SULFATE, DRIED	325 mg	

Inactive Ingredients		
Ingredient Name	Strength	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)		
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)		
GUAR GUM (UNII: E8911637KE)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
TALC (UNII: 7SEV7J4R1U)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)		
ALUMINUM O XIDE (UNII: LMI26O6933)		

Product Characteristics			
Color	GREEN	Score	no score
Shape	TRIANGLE	Size	14mm
Flavor		Imprint Code	FS
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:68210-1520-0	1 in 1 CARTON		
1	100 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		12/15/2010	

Labeler - SPIRIT PHARMACEUTICALS,LLC (179621011)

Revised: 12/2010 SPIRIT PHARMACEUTICALS,LLC