

FERROUS SULFATE- ferrous sulfate tablet
Paddock Laboratories, LLC

FERROUS SULFATE
ENTERIC-COATED TABLETS

Dietary Supplement

CONTAINS:

Each tablet contains 324 mg of ferrous sulfate, equivalent to 65 mg of elemental iron, providing 362% of the U.S. recommended daily intake (RDI) of iron for adults and children 4 and older.

DIRECTIONS FOR USE:

Do not crush or chew tablets. Adult Serving Size: 1 tablet two to three times daily. Children: Consult a physician.

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 take within 2 hours of taking oral tetracycline antibiotics, since oral iron products tend to interfere with absorption of tetracycline. May cause gastrointestinal discomfort, nausea, constipation or diarrhea. If you are pregnant or nursing a baby, seek advice of a health professional before using this product. U.S. Consumer Product Safety Commission requires that iron-containing medicines and vitamins with iron be packaged in child-resistant closures. Parents should always properly resecure safety closures.

STORAGE:

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]

Supplement Facts

Serving Size 1 Tablet		
Amount Per Tablet	% Daily Value	
Iron (as ferrous sulfate)	65 mg	362%

Other ingredients: Corn Starch, Calcium Stearate, Powdered Cellulose, Lactose, Talc, Copovidone, Polyethylene Glycol, Maltodextrin, Sucrose, Povidone, Calcium Carbonate, Titanium Dioxide, Magnesium Stearate, Shellac, Cocoa Butter, FD&C Red No. 40 Aluminum Lake, Sodium Starch Glycolate A, Sodium Lauryl Sulfate, Colloidal Silicon Dioxide, Methacrylic Acid Copolymer Type C, Sodium Hydroxide, Simethicone Emulsion, Diethyl Phthalate, Hypromellose, Carnauba Wax, White Wax.

Packaged by: Paddock Laboratories, Inc.

Minneapolis, MN 55427
(01-08)

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

Perrigo®
NDC 0574-0608-01
Ferrous Sulfate
Enteric-Coated Tablets
324 mg
Dietary
Supplement

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Net Contents 100 Tablets



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Packaged By Perrigo
Minneapolis, MN 55427 2200623 Rev 03-13 B



0574-0608-01 2

FERROUS SULFATE

ferrous sulfate tablet

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:0574-0608
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength

FERROUS SULFATE (UNII: 39R4TAN1VT) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	65 mg
Inactive Ingredients		
Ingredient Name		Strength
STARCH, CORN (UNII: O8232NY3SJ)		
CALCIUM STEARATE (UNII: 776XM7047L)		
POWDERED CELLULOSE (UNII: SMD1X3XO9M)		
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)		
TALC (UNII: 7SEV7J4R1U)		
COPOVIDONE K25-31 (UNII: D9C330MD8B)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
MALTODEXTRIN (UNII: 7CVR7L4A2D)		
SUCROSE (UNII: C151H8M554)		
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)		
CALCIUM CARBONATE (UNII: H0G9379FGK)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
SHELLAC (UNII: 46N107B71O)		
COCOA BUTTER (UNII: 512OYT1CRR)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
SODIUM LAURYL SULFATE (UNII: 368GB5141J)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
DIETHYL PHTHALATE (UNII: UF064M00AF)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
CARNAUBA WAX (UNII: R12CBM0EIZ)		
WHITE WAX (UNII: 7G1J5DA97F)		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:0574-0608-01	100 in 1 BOTTLE		
2	NHRIC:0574-0608-11	10 in 1 CARTON		
2		10 in 1 BLISTER PACK		
3	NHRIC:0574-0608-10	1000 in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		08/06/2012	

Supplement Facts	
Serving Size :	Serving per Container :
Amount Per Serving	% Daily Value

color	
scoring	1
shape	
size (solid drugs)	11 mm

Labeler - Paddock Laboratories, LLC (967694121)

Establishment

Name	Address	ID/FEI	Business Operations
Paddock Laboratories, LLC		967694121	LABEL, PACK

Establishment

Name	Address	ID/FEI	Business Operations
Quality By Design Packaging, Inc.		830254210	PACK

Establishment

Name	Address	ID/FEI	Business Operations
Lomapharm Rudolf Lohmann GmbH KG		315866525	MANUFACTURE

Revised: 8/2017

Paddock Laboratories, LLC