FERROUS GLUCONATE- ferrous gluconate tablet Paddock Laboratories, LLC

Dietary Supplement

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 gluconate) 38 mg	208%

Other ingredients: Colloidal Silicon Dioxide, Corn Starch, Talc, Powdered Cellulose, Sodium Starch Glycolate, Stearic Acid, Titanium Dioxide, Polyethylene Glycol, Sucrose, Calcium Carbonate, Magnesium Stearate, Copovidone, Shellac, Cocoa Butter, FD&C Blue No. 1 Aluminum Lake, Maltodextrin, Hypromellose, Riboflavin, Carnauba Wax, White Wax.

Packaged by: Paddock Laboratories, Inc. Minneapolis, MN 55427

(01-08)

PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label

Perrigo®

NDC 0574-0508-01

Ferrous Gluconate Tablets, USP

324 mg

Dietary Supplement

CONTAINS: Each tablet contains 324 mg of ferrous gluconate, equivalent to 38 mg of elemental iron,

providing 208% 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 three to four times daily.

Children: Consult a physician.

Net Contents 100 Tablets



FERROUS GLUCONATE

ferrous gluconate tablet

Product Information			
Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:0574-0508
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
FERROUS GLUCONATE (UNII: U1B11I423Z) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	38 mg

Inactive Ingredients	
Ingredient Name	Strength
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
TALC (UNII: 7SEV7J4R1U)	
POWDERED CELLULOSE (UNII: SMD1X3XO9M)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SUCROSE (UNII: C151H8 M554)	
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
COPOVIDONE K25-31 (UNII: D9 C330 MD8 B)	

SHELLAC (UNII: 46 N10 7B710)	
COCOA BUTTER (UNII: 512OYT1CRR)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
RIBOFLAVIN (UNII: TLM2976OFR)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
WHITE WAX (UNII: 7G1J5DA97F)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NHRIC:0574-0508-01	100 in 1 BOTTLE				
2	NHRIC:0574-0508-11	10 in 1 CARTON				
2		10 in 1 BLISTER PACK				
3	NHRIC:0574-0508-10	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 F	'acts	
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 GmbHKG		315866525	MANUFACTURE

Revised: 8/2017 Paddock Laboratories, LLC