

**FERROUS SULFATE- ferrous sulfate tablet**  
**PD-Rx Pharmaceuticals, Inc.**

-----  
**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**

<b>Serving Size 1 Tablet</b>		
<b>Amount Per Tablet</b>	<b>% Daily Value</b>	
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)

## **16 HOW SUPPLIED**

Ferrous Sulfate Tablets are available as follows:

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

Available in bottles of 100 tablets (NDC 72789-322-01)

## **PRINCIPAL DISPLAY PANEL - 324 mg Tablet Bottle Label**

NDC 72789-322-01

Ferrous Sulfate  
Enteric-Coated  
Tablets

324 mg

Dietary  
Supplement

Marketed and Packaged By:  
PD-Rx Pharmaceuticals, Inc  
Oklahoma City, OK 73127  
1-405-942-3040 V.01.24.0

100 Tablets

TAMPER EVIDENT: DO NOT USE IF  
SAFETY SEAL IS BROKEN OR MISSING FROM BOTTLE.

### Supplement Facts

Serving Size 1 Tablet

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

**Contains:** Each tablet contains 342 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 (1-800-222-1222)

**Storage:** Store at 20° to 25°C (68° to 77°F)  
[See USP Controlled Room Temperature]

3 72789 32201 8

**Warning:** 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.

**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, Ceramuba Wax, White Wax.

GTIN: 00372789322018  
SNO: A24B76000001  
EXP: 02/2026  
LOT: A24B76



NDC 72789-322-01



## Ferrous Sulfate Enteric-Coated Tablets

**Marketed and Packaged By:**  
PD-Rx Pharmaceuticals, Inc  
Oklahoma City, OK 73127  
1-405-942-3040 V.01.24.0

**324 mg**

**Dietary  
Supplement**

**100 Tablets**

TAMPER EVIDENT: DO NOT USE IF  
SAFETY SEAL IS BROKEN OR MISSING FROM BOTTLE.

## FERROUS SULFATE

ferrous sulfate tablet

### Product Information

<b>Product Type</b>	DIETARY SUPPLEMENT	<b>Item Code (Source)</b>	NHRIC:72789-322(NDC:0574-0608)
<b>Route of Administration</b>	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: O8232NY3S)	
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)	

<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER</b> (UNII: NX76LV5T8J)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>DIETHYL PHTHALATE</b> (UNII: UF064M00AF)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:72789-322-01	100 in 1 BOTTLE, PLASTIC		

### 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** - PD-Rx Pharmaceuticals, Inc. (156893695)

**Registrant** - PD-Rx Pharmaceuticals, Inc. (156893695)

### Establishment

Name	Address	ID/FEI	Business Operations
PD-Rx Pharmaceuticals, Inc.		156893695	repack

### Establishment

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