

FERROUS SULFATE- ferrous sulfate solution
Rising Pharma Holdings, Inc.

Ferrous Sulfate Oral Solution USP
Iron Supplement Therapy
300 mg/5 mL
(Equivalent to approximately 60 mg elemental iron)
• **Alcohol Free**
• **Cinnamon Flavor**
FOR INSTITUTIONAL USE ONLY

Supplement Facts

Serving Size: 5mL (1 Unit Dose)

Amount per serving		% Daily Value*
Calories	4	
Total Carbohydrate	1g	<1%
Sugars	1g	**
Includes 1g Added Sugars		4%
Iron (elemental) (as ferrous sulfate)	60mg	333%

*Percent Daily Value based on a 2,000 calorie diet

**Daily Value not established

Other ingredients: Purified water, sucrose, citric acid, sodium benzoate, and cinnamon flavor.

Use: Ferrous Sulfate Oral Solution is an iron supplement for the treatment and prevention of iron deficiency and iron deficient anemia when the need for such therapy has been determined by a healthcare professional.†

Directions:

May be mixed with water or fruit juice and drink through a straw to avoid temporary staining of teeth. Do not mix with milk or wine based vehicles.

As directed by a doctor or as follows

- Prevention of iron deficiency
Adults: 5mL (1 unit dose) daily
Children under 12 years of age: Consult of doctor
- Iron replacement therapy in deficiency states
Adults: 5mL (1 unit dose) two (2) to four (4) times daily preferable between meals
Children under 12 years of age: Consult of doctor

Do not use

- If you are taking other iron containing supplements
- For more than six months unless directed by a doctor

Oral Iron Supplements

- May interfere with absorption of certain antibiotics (e.g. tetracycline and other medications). These products should not be taken with two (2) hours of each other.
- May cause occasional bowel effects such as constipation or diarrhea.

Warnings

Do not exceed recommended dosage: The treatment of anemic conditions should be under the advice and supervision of a doctor. Occasional gastrointestinal or discomfort (such as nausea) may be minimized by taking supplement between meals. Also in order to minimize gastrointestinal or discomfort, may begin by taking 5 mL (1 unit dose) and increase dosage over time. Staining of teeth may occur with ferrous sulfate oral solution.

Warning: Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under six (6). Keep out of reach of children. In case of accidental overdose call a doctor or contact a Poison Control Center right away. (1-880-222-1222)

If pregnant or breast-feeding, ask a doctor before use.

Storage

- store at 20° to 25°C (68°to 77°F). [See USP Controlled Room Temperature]
- preserve in tight, light-resistant containers
- protect from freezing and light
- do not use if lid is torn or broken

Questions or comments? Call-1-844-474-7464

†This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease

Distributed by:

Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816
FG-27/Iss.:03/2023

Case label -57237-311-51 (100 x 5 mL Unit-Dose Cups)



57237-311-51

**FERROUS SULFATE
ORAL SOLUTION USP****Iron Supplement
Therapy****300 mg/5 mL**(Equivalent to approximately
60 mg elemental iron)

- Alcohol Free
- Cinnamon Flavor

USUAL DOSAGE: See attached
Supplement FactsFOR INSTITUTIONAL USE
ONLY**100 x 5 mL Unit-Dose Cups****Supplement Facts**

Serving size: 5mL (1 Unit Dose)

Amount per serving	%Daily Value*
Calories	4
Total Carbohydrate	1g
Sugars	1g
Includes 1 g Added Sugars	4%
Iron (elemental) (as ferrous sulfate)	333%

*Percent Daily Value based on a 2,000 calorie diet

**Daily Value not established

Other Ingredients: Purified water, sucrose, citric acid, sodium benzoate, and cinnamon flavor.**Use:** Ferrous Sulfate Oral Solution is an iron supplement for the treatment and prevention of iron deficiency and iron deficient anemia when the need for such therapy has been determined by a healthcare professional.†**Directions:**

May be mixed with water or fruit juice and drink through a straw to avoid temporary staining of teeth. Do not mix with milk or wine based vehicles.

As directed by a doctor or as follows

- Prevention of iron deficiency

Adults: 5mL (1 unit dose) daily

Children under 12 years of age: Consult of doctor

- Iron replacement therapy in deficiency states

Adults: 5mL (1 unit dose) two (2) to four (4) times daily preferable between meals

Children under 12 years of age: Consult of doctor

Do not use

- If you are taking other iron containing supplements

- For more than six months unless directed by a doctor

Oral Iron Supplements

- May interfere with absorption of certain antibiotics (e.g. tetracycline and other medications). These products should not be taken with two (2) hours of each other.
- May cause occasional bowel effects such as constipation or diarrhea.

Warnings**Do not exceed recommended dosage:** The treatment of anemic conditions should be under the advice and supervision of a doctor. Occasional gastrointestinal or discomfort (such as nausea) may be minimized by taking supplement between meals. Also in order to minimize gastrointestinal or discomfort, may begin by taking 5 mL (1 unit dose) and increase dosage over time. Staining of teeth may occur with ferrous sulfate oral solution.**Warning:** Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under six (6). Keep out of reach of children. In case of accidental overdose call a doctor or contact a Poison Control Center right away. (1-800-222-1222)**If pregnant or breast-feeding, ask a doctor before use.****Storage**

- store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]
- preserve in tight, light-resistant containers
- protect from freezing and light
- do not use if lid is torn or broken

Questions or comments? Call 1-844-474-7464

†This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease

Distributed by:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

FG-27 /ISS..03/2023



3 57237 31151 6

57237-311-51



3 57237 31151 6

**FERROUS SULFATE
ORAL SOLUTION USP**
300 mg/5 mL**100 x 5 mL Unit-Dose Cups**

LOT#

Exp. Date:

Unvarnished Area

Lid Label -57237-311-05 (Delivers 5 mL)

Delivers 5 mL

Ferrous Sulfate

Oral Solution USP

300 mg/5 mL

(Equivalent to approximately 60 mg elemental iron)

FOR INSTITUTIONAL USE ONLY

Exp: YYYY/MM **Lot#:** XXXXXX

Dist. By: Rising Pharma Holdings, Inc.

East Brunswick NJ, 08816

Iss. 03/2023 FG-27 SEE LABEL



5723731105

L4



FERROUS SULFATE

ferrous sulfate solution

Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:57237-311
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FERROUS SULFATE (UNII: 39R4TAN1VT) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	300 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NHRIC:57237-311-51	100 in 1 BOX, UNIT-DOSE		
1	NHRIC:57237-311-05	5 mL in 1 CUP, UNIT-DOSE		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
dietary supplement			05/22/2023	

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

Labeler - Rising Pharma Holdings, Inc. (116880195)

Revised: 5/2025

Rising Pharma Holdings, Inc.