FERROUS SULFATE- ferrous sulfate elixir
Rij Pharmaceutical Corporation

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.

Drug Facts

Active ingredient (in each 5 mL) (one teaspoonful)

Ferrous Sulfate 220 mg (44 mg of elemental Iron)

Purpose

Iron Supplement

Uses

a therapy for simple iron deficiency and iron deficiency anemia

Warnings

Adverse Reactions:

occasional gastrointestinal discomfort such as nausea dose related bowel effects (such as constipation or diarrhea), gastrointestinal effects may be minimized by the administration with or immediately after meals and bowel effects reduced by giving the minimum effective dosage.

Do not use

- more than directed

The treatment of any anemic condition should be under the advice and supervision of a physician

Ask a doctor or pharmacist before use if you are

taking oral Tetracycline antibiotics. Oral iron products interfere with absorption of oral tetracycline antibiotics. These products should not be taken within two hours of each other.

When using this product

- may occasionally cause constipation or diarrhea
- may cause temporary staining of the teeth (this is less likely when diluted)

If pregnant or breast-feeding

ask a health professional before use.

Keep this and all drugs out of reach of children.

Contains iron, which can be harmful or fatal to children in large doses. In case of accidental overdose, seek professional assistance or contact a Poison Control Center right away.

Treatment of overdose:

quickly induce vomiting, then feed eggs and milk until gastric lavage can be done. Lavage with 1 percent Sodium Bicarbonate and administer an iron chelating agent (such as deferoxamine mesylate) BAL should not be used. Gastric lavage should not be performed after the first hour because the danger of

perforation due to gastric necrosis. Measures to combat shock, dehydration, blood loss and respiratory failure may be necessary.

Directions

Mix with water or fruit juice to avoid temporary staining of the teeth, do not mix with milk or wine-based vehicles

Adults and children 12 years of age and over	1 teaspoonful daily, or as directed by a physician
Children under 12 years of age	Consult a physician

Inactive ingredients

citric acid, FD & C yellow #6, flavor, sodium benzoate, sucrose and water.

Other information

- Store in tight, light-resistant container at room temperature

PRINCIPAL DISPLAY PANEL

Tamper Resistant: Do not use if breakaway band on cap is broken or missing.

NDC 53807-177-16

FERROUS SULFATE ELIXIR

For the treatment of iron deficiency and iron deficiency anemia.

*Compare to the active ingredient of Feosol Elixir®.

Dispense in tight, light-resistant container as described in official compendie.

Store in tight, light-resistant container at room temperature.

*This product is not manufactured or distributed by the owner of the registered trademark of Feosol Elixir®.

16 fl. oz (473 mL)

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RIJ Pharmaceutical Corp.
40 Commercial Avenue
Middletown, NY 10941

Rev. 12/12

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FERROUS SULFATE

ferrous sulfate elixir

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:53807-177
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FERROUS SULFATE (UNII: 39R4TAN1VT) (FERROUS CATION - UNII:GW89581OWR)	FERROUS CATION	220 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SUCROSE (UNII: C151H8M554)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	ORANGE	**Score**	
Shape		**Size**	
Flavor	PEPPERMINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53807-177-08	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	
2	NDC:53807-177-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/16/1999	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		03/16/1999	

Labeler - Rij Pharmaceutical Corporation (144679156)

Establishment

Name	Address	ID/FEI	Business Operations
Rij Pharmaceutical Corporation		144679156	manufacture(53807-177)

Revised: 4/2018 Rij Pharmaceutical Corporation