FERROUS SULFATE - ferrous sulfate tablet MARTIN EKWEALOR PHARMACEUTICALS, INC.

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.

Active Ingredients

Supplemental Facts

Serving Size 1 Tablet Servings per Container 100

Amount Per Tablet % Daily Value

Iron (as Ferrous Sulfate) 65 mg 361%

Calcium 20 mg 2%

Purpose

NATURAL IRON SUPPLEMENT

Keep out of reach of children.

WARNING: Accidental overdose of iron-containing products is a leading cause of poisoning in children under 6. Keep this product out of the reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

Indications and Usage

NATURAL IRON SUPPLEMENT. The treatment of any anemic condition should be under the advise and supervision of a doctor.

WARNINGS: PRECAUTIONS:

WARNING: Do not exceed recommended dosage. The treatment of any anemic condition should be under the advice and supervision of a doctor. Occasional gastrointestinal discomfort like nausea may be minimized with meals. Iron-containing drugs may cause constipation or diarrhea.

PRECAUTIONS: Since oral iron products interfere with absorption of tetracycline antibiotics, these products should not be taken within two hours of each other.

DIRECTIONS:

Adults only. One tablet daily, preferably with a meal or as directed by a physician.

Other Ingredients:

Dicalcium phosphate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, FD and C red #40 (AL Lake), FD and C blue #2/Indigo Carmine (Al Lake), macrogol, PEG 400, silicon dioxide, titanium dioxide, talc, vanillin.

STORAGE:

Store between 15° - 30° C (59° -86° F)

FERROUS SULFATE Product Label

58607-113-10

NATURAL IRON SUPPLEMENT

FERROUS SULFATE

5 gr (325 mg)

100 Tablets

MADE WITH PRIDE IN THE U.S.A.

M.E. Pharmaceuticals, Inc. Richmond, IN 47374

Lot No: Exp Date:

DIRECTION: Adults only: One tablet daily, preferably with a meal or as directed by a physician.

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FERROUS SULFATE

ferrous sulfate tablet

Product Information

| | Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58607-113 |
|---|-------------------------|----------------|--------------------|---------------|
| ı | Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| FERROUS SULFATE (UNII: 39R4TAN1VT) (FERROUS CATION - UNII:GW895810WR) | FERROUS CATION | 65 mg |
| CALCIUM (UNII: SY70814VUP) (CALCIUM - UNII:SY70814VUP) | CALCIUM | 20 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CALCIUM PHO SPHATE, DIBASIC, ANHYDRO US (UNII: L11K75P92J) | |
| CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U) | |
| CROSCARMELLOSE SODIUM (UNII: M28 OL 1HH48) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A) | |
| POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) | |
| SILICON DIO XIDE (UNII: ETJ7Z6 XBU4) | |
| TITANIUM DIO XIDE (UNII: 15FIX9 V2JP) | |
| TALC (UNII: 7SEV7J4R1U) | |
| VANILLIN (UNII: CHI530446X) | |

| Product Characteristics | | | |
|-------------------------|---------------|--------------|----------|
| Color | red (RED) | Score | no score |
| Shape | ROUND (ROUND) | Size | 4mm |
| Flavor | | Imprint Code | NONE |
| Contains | | | |

| Packaging | | | | |
|-----------|------------------|---------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:58607-113-10 | 100 in 1 BOTTLE | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved drug other | | 09/01/2014 | |
| | | | |

Labeler - MART IN EKWEALOR PHARMACEUT ICALS, INC. (624528386)

Registrant - MART IN EKWEALOR PHARMACEUT ICALS, INC (624528386)

| Establishment | | | |
|--------------------------------------|---------|-----------|----------------------------|
| Name | Address | ID/FEI | Business Operations |
| MARTIN EKWEALOR PHARMACEUTICALS, INC | | 624528386 | manufacture (58607-113) |

Revised: 9/2014 MARTIN EKWEALOR PHARMACEUTICALS, INC.