**FERROUS SULFATE - ferrous sulfate tablet, film coated**
**Central Texas Community Health Centers**

*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.*

---

**Ferrous Sulfate Film Coated Tablets**

**ACTIVE INGREDIENT(S)**

EACH TABLET CONTAINS:

| Amount per tablet | % Daily Value |
|---|---|
| Iron 65 mg | 361% |

Dried Ferrous Sulfate, equivalent to 325 mg Ferrous Sulfate per tablet.

**INACTIVE INGREDIENTS**

**Other ingredients for Red Tablets:** microcrystalline cellulose, dibasic calcium phosphate dihydrate, croscarmellose sodium, sodium starch glycolate, hypromellose, stearic acid, polyethylene glycol (PEG) 400, FD&C red #40 aluminum lake, magnesium stearate, titanium dioxide, polyethylene glycol (PEG) 8000, carnauba wax

**Other ingredients for Green Tablets:** microcrystalline cellulose, dibasic calcium phosphate dihydrate, croscarmellose sodium, sodium starch glycolate, hypromellose, stearic acid, polyethylene glycol (PEG) 400, magnesium stearate, riboflavin, FD&C bule #1 aluminum lake, titanium dioxide, FD&C blue #2 aluminum lake, polyethylene glycol (PEG) 8000, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, carnauba wax

**PURPOSE**

Dietary Supplement

**USE(S)**

One tablet daily or as directed by a physician. For children under 12, consult a physician before using this product.

**WARNINGS**

Iron may interfere with absorpiton of certain antibiotics; these products should not be taken within two hours of each other.

Occasional gastrointestinal discomfort (such as nausea) may be minimized by taking iron with meals. Iron-containing products may occassionally cause constipation or diarrhea. If pregnant or nursing consult a physicial before using this product.

**DO NOT USE**

**TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING**

**OTHER REQUIRED WARNINGS**

**The information on this label has not been evaluated by the Food and Drug Administration. This**

**product is not intended to diagnose, trea, cure or prevent any disease.**

To report a serious adverse event or to obtain product information, contact 800-818-4555.

**KEEP OUT OF REACH OF CHILDREN**

**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.**

**DIRECTIONS**

One tablet daily or as directed by a physician. For children under 12, consult a physical before using this product.

**Do not exceed recommended dosage.**

**Do not use except under the advice and supervision of a physician.**

**STORAGE**

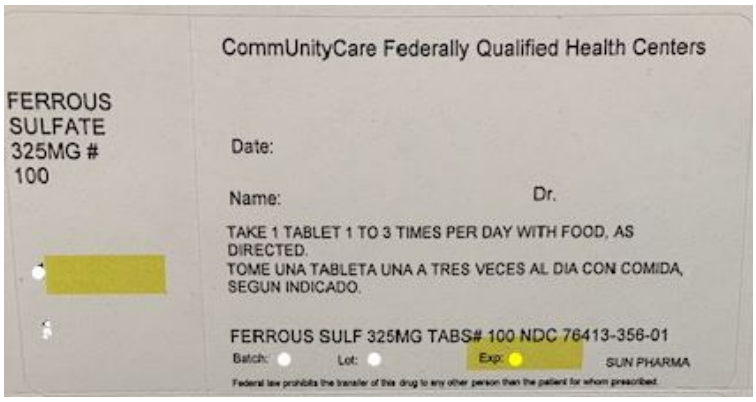
Store at 25˚C (77˚F); excursions permitted between 15˚-30˚C (59˚-86˚F)

**HOW SUPPLIED**

Product: 76413-356

NDC: 76413-356-01 100 TABLET, FILM COATED in a BOTTLE

**FERROUS SULFATE TABLET, FILM COATED**




## FERROUS SULFATE

ferrous sulfate tablet, film coated

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:76413-356(NDC:57664-070) |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **FERROUS SULFATE** (UNII: 39R4TAN1VT) (FERROUS CATION - UNII:GW89581OWR) | FERROUS CATION | 325 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **DIBASIC CALCIUM PHOSPHATE DIHYDRATE** (UNII: O7TSZ97GEP) | |
| **CROSCARMELLOSE SODIUM** (UNII: M28OL1HH48) | |
| **SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **POLYETHYLENE GLYCOL 400** (UNII: B697894SGQ) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |
| **POLYETHYLENE GLYCOL 8000** (UNII: Q662QK8M3B) | |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **RIBOFLAVIN** (UNII: TLM2976OFR) | |
| **FD&C BLUE NO. 1** (UNII: H3R47K3TBD) | |
| **FD&C BLUE NO. 2** (UNII: L06K8R7DQK) | |
| **FD&C YELLOW NO. 6** (UNII: H77VEI93A8) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | GREEN | **Score** | no score |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:76413-356-01 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 01/02/2019 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| UNAPPROVED DRUG OTHER | | 07/01/2014 | |

## Labeler - Central Texas Community Health Centers (079674019)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Central Texas Community Health Centers | | 079674019 | RELABEL(76413-356) , REPACK(76413-356) |