TL-FOL 500- ferrous sulfate, ascorbic acid, and folic acid tablet, film coated
Trigen Laboratories, Inc.

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TL-Fol 500
Caplets

Rx Only

DESCRIPTION

TL-Fol 500 caplets are a hematinic for oral administration containing iron in a controlled-release dose form; Vitamin C for enhancement of iron absorption; and Folic Acid. TL-Fol 500 caplets are oval, maroon, film-coated caplets debossed "TL51".

Supplement Facts
Servings per Bottle: 30

<table>
<thead>
<tr>
<th>Serving Size: 1 Caplet</th>
<th>%DV for Pregnant and Lactating Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>Each Caplet contains:</td>
<td></td>
</tr>
<tr>
<td>Ferrous Sulfate* (equivalent to 105 mg of elemental iron)</td>
<td>525 mg  2917%</td>
</tr>
<tr>
<td>Vitamin C (ascorbic acid)</td>
<td>500 mg  833%</td>
</tr>
<tr>
<td>Folic Acid</td>
<td>800 mcg  100%</td>
</tr>
</tbody>
</table>

* In controlled release dose form

Inactive Ingredients

Microcrystalline Cellulose, Silicified Microcrystalline Cellulose, Polyvinyl Alcohol, TriPotassium Citrate, Titanium Dioxide, Shellac, Citric Acid, Croscarmellose Sodium, Silicon Dioxide, Stearic Acid, Magnesium Stearate, FD&C Red #40, Talc, Polyethylene Glycol, Acetylated Monoglycerides, Polysorbate 80, Glycerin, Potassium Sorbate.

CLINICAL PHARMACOLOGY

When oral iron is administered between meals it is absorbed most efficiently. Traditional iron preparations frequently cause gastric irritation when taken on an empty stomach. Studies with iron in controlled release form have indicated that relatively little of the iron is released in the stomach, gastric intolerance occurs infrequently, and hematologic response is consistent with that obtained from immediate release ferrous sulfate.

Iron is found in the body principally as hemoglobin. It is stored in the liver, spleen, and bone marrow in the form of ferritin. Concentrations of plasma iron and the total iron-binding capacity of plasma vary greatly in different physiological conditions and disease states.

Vitamin C (Ascorbic Acid) plays a role in anemia therapy. It augments the conversion of folic acid to its active form, folinic acid. In addition, Vitamin C promotes the reduction of ferric iron in food to the more readily absorbed ferrous form. Severe and prolonged Vitamin C deficiency is associated with an anemia that is usually hypochromic but occasionally megaloblastic in type.

Iron and Folic Acid are absorbed in the proximal small intestine, particularly the duodenum. While folic acid is absorbed maximally and rapidly at this site, iron is absorbed in a descending gradient from the duodenum distally.
Folic Acid, after absorption, is rapidly converted into its metabolically active forms. Half of the folic acid stored in the body is found in the liver. It is also concentrated in the spinal fluid. Approximately two-thirds is bound to plasma protein. The percentage of absorption of food folates averages about 10% except for the folates ingested in egg yolk, liver and yeast.

INDICATIONS AND USAGE

Non-pregnant Adults
For the treatment of iron deficiency and prevention of concomitant folic acid deficiency.

Pregnant Females
For the prevention and treatment of iron deficiency and to supply a maintenance dosage of folic acid.

CONTRAINDICATIONS

Contraindicated in patients with pernicious anemia and in the rare instance of hypersensitivity to folic acid. Hemochromatosis and hemosiderosis are contraindications to iron therapy.

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.

PRECAUTION

Anemia is a manifestation that requires appropriate investigation to determine its cause or causes. Folic acid alone is unwarranted in the treatment of vitamin B₁₂ deficiency states such as pernicious anemia. Folic acid, especially in doses above 100 mcg daily may obscure pernicious anemia in that hematological remission may occur while neurological manifestations remain progressive. Concomitant parenteral therapy with vitamin B₁₂ may be necessary for adequate treatment of patients with a deficiency of vitamin B₁₂. Pernicious anemia is rare in women of childbearing age, and the likelihood of its occurrence along with pregnancy is reduced by the impairment of fertility associated with vitamin B₁₂ deficiency. In older patients and those with conditions tending to lead to vitamin B₁₂ depletion, serum B₁₂ levels should be regularly assessed during treatment.

Drug Interactions

Absorption of iron is inhibited by magnesium trisilicate and antacids containing carbonates. Since oral iron products interfere with absorption of oral tetracycline antibiotics, these products should not be taken within two hours of each other. Iron absorption may also be inhibited by the ingestion of milk or eggs.

Carcinogenesis

Adequate data are not available on long-term potential for carcinogenesis in animals and humans.

Pregnancy

Pregnancy Category A

Studies in pregnant women have not shown that the ingredients in TL-Fol 500 caplets formula increase the risk of fetal abnormalities if administered during pregnancy. If this product is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility
of harm, however, TL-Fol 500 caplets should be used during pregnancy only if clearly needed.

Nursing Mothers
Folic acid and ascorbic acid are excreted in breast milk.

ADVERSE REACTIONS
Rarely, controlled-release iron produces gastrointestinal reactions, such as diarrhea or constipation. Administering the dose with meals will minimize these effects in the iron-sensitive patient. Allergic sensitization has been reported with both oral and parenteral administration of folic acid.

OVERDOSAGE
Signs and symptoms of iron toxicity, which may be delayed because the iron is in a controlled-release form, may include pallor and cyanosis, vomiting of blood, diarrhea, passage of dark-colored stool, shock, drowsiness and coma. In overdosage, efforts should be made to hasten the elimination of the caplets ingested. An emetic should be administered as soon as possible, followed by gastric lavage if indicated. Immediately following emesis, a large dose of saline cathartic should be used to speed passage through the intestinal tract. X-ray examination may then be considered to determine the position and number of caplets remaining in the gastrointestinal tract.

DOSAGE AND ADMINISTRATION
Adults, including Pregnant Females
The recommended dose is one (1) caplet daily on an empty stomach.

HOW SUPPLIED
TL-Fol 500 is supplied in bottles of 30 caplets.
Product Code: 13811-051-30

STORAGE
Store at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [See USP Controlled Room Temperature].

Call your doctor about side effects. You may report side effects by calling 888 9 TRIGEN (888-987-4436).

KEEP OUT OF THE REACH OF CHILDREN.
Rx Only
All prescriptions using this product shall be pursuant to statutes as applicable. This is not an Orange Book product. There are no implied or explicit claims on therapeutic equivalence.

Manufactured for:
TRIGEN Laboratories, Inc., Sayreville, NJ 08872
www.trigenlab.com
Rev. 05/13

PRINCIPAL DISPLAY PANEL - 30 Caplet Bottle Label
13811-051-30
**Rx Only**
**TL-Fol 500**
Caplets

**30 CAPLETS**
**TRIGEN**
LABORATORIES

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**TL-FOL 500**
ferrous sulfate, ascorbic acid, and folic acid tablet, film coated

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**Product Information**

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<tr>
<th>Product Type</th>
<th>DIETARY SUPPLEMENT</th>
<th>Item Code (Source)</th>
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<tr>
<td>Route of Administration</td>
<td>ORAL</td>
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**Active Ingredient/Active Moiety**

<table>
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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td><strong>Ferrous Sulfate (UNII: 39R4TAN1VT)</strong></td>
<td>FERROUS CATION</td>
<td>525 mg</td>
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<tr>
<td><strong>Ascorbic Acid (UNII: PQ6CK8PD0R)</strong></td>
<td>Ascorbic Acid</td>
<td>500 mg</td>
</tr>
<tr>
<td><strong>Folic Acid (UNII: 935E97BOY8)</strong></td>
<td>Folic Acid</td>
<td>800 µg</td>
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**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tr>
<td>cellulose, microcrystalline (UNII: OPIR32D61IU)</td>
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<tr>
<td>polyvinyl alcohol (UNII: 532B59J990)</td>
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<tr>
<td>potassium citrate anhydrous (UNII: 86RINVR0HW)</td>
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<tr>
<td>titanium dioxide (UNII: 15FIX9V2JP)</td>
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<tr>
<td>citric acid monohydrate (UNII: 2968PHW8QP)</td>
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<tr>
<td>croscarmellose sodium (UNII: M28OL1HH48)</td>
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<tr>
<td>silicon dioxide (UNII: ETJ7Z6XBU4)</td>
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</tbody>
</table>
stearic acid (UNII: 4ELV7Z65AP)
magnesium stearate (UNII: 70097M6I30)
FD&C Red No. 40 (UNII: WZB9127XOA)
talc (UNII: 7SEV7J4RIU)
polyethylene glycols (UNII: 3WJQ0SDW1A)
diacetylated monoglycerides (UNII: 5Z17386USF)
polysorbate 80 (UNII: 6OZP39ZG8H)
glycerin (UNII: PDC6A3C0OX)
potassium sorbate (UNII: 1VPU26JZZ4)

Packaging

<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
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<td>1</td>
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<td>30 in 1 BOTTLE, PLASTIC</td>
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Marketing Information

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<th>Marketing End Date</th>
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<td>DIETARY SUPPLEMENT</td>
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Supplement Facts

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<thead>
<tr>
<th>Serving Size :</th>
<th>Serving per Container :</th>
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<tbody>
<tr>
<td></td>
<td>Amount Per Serving</td>
</tr>
<tr>
<td>color</td>
<td>1</td>
</tr>
<tr>
<td>scoring</td>
<td>1</td>
</tr>
<tr>
<td>shape</td>
<td>19 mm</td>
</tr>
<tr>
<td>size (solid drugs)</td>
<td>19 mm</td>
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Labeler - Trigen Laboratories, Inc. (830479668)

Revised: 6/2013