FERRAPLUS 90 - docusate sodium, folic acid, carbonyl iron, cyanocobalamin, and ascorbic acid tablet, film coated
Trigen Laboratories, LLC

FerraPlus 90
Tablets with 90 mg Carbonyl Iron

SUPPLEMENT FACTS
CONTRAINDICATIONS

Hypersensitivity to any of the ingredients. Hemolytic anemia, hemochromatosis, and hemosiderosis are contraindications to iron therapy.
WARNINGS

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B₁₂ is deficient.

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.

PRECAUTIONS

General: Take 2 hours after meals. Do not exceed recommended dose. Discontinue use if symptoms of intolerance appear. The type of anemia and underlying cause or causes should be determined before starting therapy with FerraPlus 90 tablets. Ensure Hgb, Hct, reticulocyte count are determined before starting therapy and periodically thereafter during prolonged treatment. Periodically review therapy to determine if it needs to be continued without change or if a dose change or if a dose change is indicated.

Folic Acid: Folic acid in doses above 0.1 mg daily may obscure pernicious anemia assessment, such that hematologic remission can occur while neurological manifestations remain progressive. Pernicious anemia should be excluded before using these products since folic acid may mask the symptoms of pernicious anemia.

Pediatric Use: Safety and effectiveness of this product have not been established in pediatric patients.

Geriatric Use: Safety and effectiveness of this product have not been established in elderly patients.

DRUG INTERACTIONS

Prescriber should be aware of a number of iron/drug interactions, including antacids, tetracyclines, or fluoroquinolones.

ADVERSE REACTIONS

Adverse reactions with iron therapy may include GI irritation, constipation, diarrhea, nausea, vomiting, and dark stools. Adverse reactions with iron therapy are usually transient. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

OVERDOSAGE

Symptoms: Abdominal pain, metabolic acidosis, anuria, CNS damage, coma, convulsions, death, dehydration, diffuse vascular congestion, hepatic cirrhosis, hypotension, hypothermia, lethargy, nausea, vomiting, diarrhea, tarry stools, melena, hematemesis, tachycardia, hyperglycemia, drowsiness, pallor, cyanosis, lassitude, seizures, and shock.
DESCRIPTION
FerraPlus 90 is a grey speckled, oval, film-coated tablet, debossed "TL012".

DIRECTIONS FOR USE
One tablet daily or as directed by a physician. Do not chew tablet.

HOW SUPPLIED
FerraPlus 90 is packaged in bottles of 90 tablets.
Product Code: 13811-012-90

STORAGE
Store at 20° - 25°C (68° - 77°F), excursions permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature]. Protect from moisture (contact with moisture can discolor or erode the tablet). Dispense in a tight container with a child-resistant closure.

KEEP OUT OF THE REACH OF CHILDREN.
For use on the order of a healthcare practitioner.
Call your doctor about side effects. To report side effects, call Trigen Laboratories at 1-877-482-3788 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Customer Service: 1-888-987-4436
Rev. 05/2020

 Manufactured for:

Trigen Laboratories, LLC
Bridgewater, NJ 08807

PRINCIPAL DISPLAY PANEL
13811-012-90
FerraPlus 90
Tablets
WITH 90 MG CARBONYL IRON
90 COATED TABLETS
TRIGEN
LABORATORIES
**Product Information**

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Dietary Supplement</th>
<th>Item Code (Source)</th>
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<tr>
<td>Route of Administration</td>
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**Active Ingredient/Active Moiety**

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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)</td>
<td>DOCUSATE SODIUM</td>
<td>50 mg</td>
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<tr>
<td>FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)</td>
<td>FOLIC ACID</td>
<td>1 mg</td>
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<tr>
<td>IRON PENTACARBONYL (UNII: 6WQ62TAQ6Z) (FERROUS CATION - UNII:GW89581OWR)</td>
<td>FERROUS CATION</td>
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<td>CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)</td>
<td>CYANOCOBALAMIN</td>
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<td>ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)</td>
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**Inactive Ingredients**

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MICROCRYSTALLINE CELLULOSE (UNII: OPIR32D61U)
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)
POTASSIUM CITRATE ANHYDROUS (UNII: 86R1NVR0HW)
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OB5311)
ACACIA (UNII: 5C5403N26O)
POVIDONE K30 (UNII: U725QWY32X)
CROSCARMELLOSE SODIUM (UNII: M28O11H48)
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)
STEARIC ACID (UNII: 4ELV7Z65AP)
MAGNESIUM STEARATE (UNII: 70097M6E0)
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)
ICODEXTRIN (UNII: 2NX48Z0A9G)
DEXTROSE (UNII: IY9XDZ35W2)
SODIUM CITRATE (UNII: 1Q73Q2JULR)
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)

Packaging

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<td>1</td>
<td>NHRIC:13811-012-90</td>
<td>90 in 1 BOTTLE</td>
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Marketing Information

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Supplement Facts

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<td>Amount Per Serving</td>
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<td>color</td>
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<td>shape</td>
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<td>size (solid drugs)</td>
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Labeler - Trigen Laboratories, LLC (830479668)

Revised: 5/2020