RX ONLY

Introducing...For the treatment of iron deficiency anemia (IDA) responsive to oral iron therapy

Ferralet® 90

90 mg Carbonyl Iron

Iron therapy transformed™

PRODUCT: Ferralet® 90	
Unit Size	90 Count
NDC Number	00178-0083-90
UPC Number	301780083901
Prescription Legend	Yes
Wholesaler	**Order Number**
Cardinal Health, Inc	**4077145**

Carbonyl iron, effectively treats IDA with a substantially lower risk of iron toxicity than ferrous salts[1]

Iron-containing products should always be kept out of reach of children.

Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} is deficient.

New

FERRALET® 90 provides the safety of carbonyl iron plus the benefits of...

- **1 mg – Folic acid**
  Bolsters development of red blood cells[2]
- **120 mg – Vitamin C**
  Enhances iron absorption[3]
- **12 µg – Vitamin B_{12}**
  Supports red blood cell generation[4]
- **50 mg – Docusate sodium**
  a gentle and effective stool softener that helps prevent the constipation that might occur in patients sensitive to iron therapy

Ferralet® 90
90 mg Carbonyl Iron
Iron therapy transformed™

References: 1. Gordeuk VR, Brittenham GM,McLaren CE, et al. Carbonyl iron therapy for an iron deficiency anemia. Blood. 1986;67:745-752. **2.** Folic acid. WebMD. http://www.webmd.com/diet/folic-acid. Updated March 5, 2007. Accessed April 8, 2008. **3.** Lynch SR, Stoltzfus RJ. Iron and ascorbic acid: proposed fortification levels and recommended iron compounds. J Nutr. 2003;133:2978S-2984S. **4.** Vitamin B12. MayoClinic.com. http://www.mayoclinic.com/print/vitamin-B12/NS_patient-vitaminb12. Published August 1, 2005. Accessed April 7, 2008.

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Ferralet® 90

DESCRIPTION: Each green film-coated tablet for oral administration contains:

Iron (Carbonyl iron)	90 mg
Folic Acid	1 mg
Vitamin B_{12} (Cyanocobalamin)	12 mcg
Vitamin C (Ascorbic acid)	120 mg
Docusate sodium	50 mg

Inactive Ingredients: Povidone, croscarmellose sodium, acrylic resin, color added, FD&C Yellow No. 5, magnesium stearate, magnesium silicate, FD&C Blue No. 1, polyethylene glycol, vitamin A palmitate, ethyl vanillin.

CLINICAL PHARMACOLOGY: Oral iron is absorbed most efficiently when administered between meals. Iron is critical for normal hemoglobin synthesis to maintain oxygen transport energy production and proper function of cells. Adequate amounts of iron are necessary for effective erythropoiesis. Iron also serves as a cofactor of several essential enzymes, including cytochromes, which are involved in electron transport.

Folic acid is required for nucleoprotein synthesis and the maintenance of normal erythropoiesis. Folic acid is the precursor of tetrahydrofolic acid, which is involved as a cofactor for transformylation reactions in the biosynthesis of purines and thymidylates of nucleic acids. Deficiency of folic acid may account for the defective deoxyribonucleic acid (DNA) synthesis that leads to megaloblast formation and megaloblastic macrocytic anemias. Vitamin B_{12} is essential to growth, cell reproduction, hematopoiesis, nucleic acid, and myelin synthesis. Deficiency may result in megaloblastic anemia or pernicious anemia.

INDICATIONS AND USAGE: Ferralet® 90 is indicated for the treatment of all anemias that are responsive to oral iron therapy. These include: hypochromic anemia associated with pregnancy, chronic and/or acute blood loss, metabolic disease, post-surgical convalescence, and dietary needs.

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

WARNING: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B_{12} 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 THE 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 Ferralet® 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 is indicated. This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

Folic Acid: Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in 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 in pediatric patients have not been established.

Geriatric Use: Dosing for elderly patients should be cautious. Due to the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy, dosing should start at the lower end of the dosing range.

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.

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

OVERDOSAGE: Symptoms: abdominal pain, metabolic acidosis, anuria, CNS damage, coma, convulsions, death, dehydration, diffuse vascular congestion, hepatic cirrohosis, hypotension, hypothermia, lethargy, nausea, vomiting, diarrhea, tarry stools, melena, hematemesis, tachycardia, hyperglycemia, drowsiness, pallor, cyanosis, lassitude, seizures, and shock.

DOSAGE AND ADMINISTRATION: One tablet daily or as directed by a physician.

NOTICE: Contact with moisture can discolor or erode the tablet.
Do not chew tablet.

HOW SUPPLIED: Ferralet® 90 (NDC 0178-0083-90) is a green, modified rectangle shaped, film-coated tablet, debossed with "F5" on one side and blank on the other, and packaged in bottles of 90. Store at 25°C (77°F). Excursions permitted to 15°-30°C (59°-86°F). (See USP Controlled Room Temperature.)

If you have questions about Ferralet® 90 please call:
1 (800) 531-3333

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Mission® PHARMACAL

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