Rx Only

Ferralet® 90

90 mg Dual-Iron Delivery

Your patients will

Feel

the Ferralet® 90 difference

Rx Only

Ferralet® 90
90 mg Dual-Iron Delivery

FERRALET® 90 FOR FEWER GI SIDE EFFECTS*

*As compared to ferrous sulfate iron.

INDICATIONS: Ferralet® 90 (iron [carbonyl iron, ferrous gluconate] 90 mg, folic acid 1 mg, vitamin B_{12} [cyanocobalamin] 12 mcg, vitamin C [ascorbic acid] 120 mg, docusate sodium 50 mg) is indicated for the treatment of all anemias responsive to oral iron therapy, such as hypochromic anemia associated with pregnancy, chronic or acute blood loss, dietary needs, metabolic disease and post-surgical convalescence.

Important Safety Information

CONTRAINDICATIONS: Ferralet 90 is contraindicated in patients:

- With known hypersensitivity to any of the ingredients
- With hemolytic anemia, hemochromatosis, or hemosiderosis

Please see the following page for additional Important Safety Information and full Prescribing Information on page 4.

ferralet.com

The Ferralet® 90 Difference

INDICATED FOR THE TREATMENT OF ALL ANEMIAS[1]

- Ferralet® 90 is indicated for the treatment of all anemias that are responsive to oral iron therapy (i.e., hypochromic anemia associated with pregnancy, chronic and/or acute blood loss, metabolic disease, postsurgical convalescence, and dietary needs)

EASE OF USE

- Small pill
- Vanilla scent

TWO COMPLEMENTARY IRON COMPOUNDS

- Ferr-Ease®*, a unique, patented way to deliver oral iron therapy[1,2]:
  - Immediate absorption: Ferrous gluconate
  - Prolonged absorption: Carbonyl iron

CONVENIENCE

- Once-a-day dosing[1]

COMFORT

- Dual-iron formulation for fewer GI side effects[3,†]
- Docusate sodium to alleviate constipation[4]
- Lactose and gluten free[1]

SPECIALLY CHOSEN COMBINATION OF ACTIVE INGREDIENTS

- Vitamin C to enhance iron absorption[5]
- Folic acid to increase red blood cell development[6]
- Vitamin B_{12} to support blood cell production[7]

GI=gastrointestinal.
*US Patent no. 6,521,247
†Large, randomized, double-blind trial, carbonyl iron dosed at 600 mg was tolerated with gastrointestinal side effects similar to those observed with a 60 mg dose of ferrous sulfate.

Important Safety Information (cont'd)

WARNINGS: 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. Before starting Ferralet 90, determine type and underlying cause(s) of anemia and obtain hemoglobin, hematocrit, and reticulocyte counts. Repeat laboratory testing periodically during prolonged treatment to determine whether therapy needs to be continued without change or if a dose change is indicated.

Please see the following page for additional Important Safety Information and full Prescribing Information on page 4.

Ferr-Ease® Therapy — Overcoming the common drawbacks of regular iron therapy

HELP PATIENTS MEET YOUR THERAPEUTIC GOALS

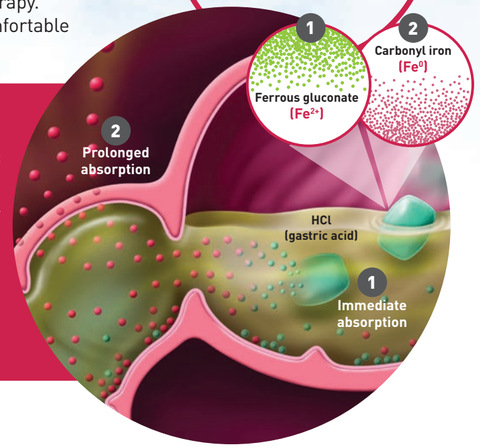
Gastrointestinal (GI) side effects are a common problem associated with oral iron therapy. Ferralet® 90 with Ferr-Ease® was formulated to make iron therapy as gentle and comfortable as possible for your patients.[8]

30-70%
of patients on oral iron supplements report **gastrointestinal side effects**, which may lead to poor adherence to treatment.[8]

DUAL-IRON FOR COMPLEMENTARY ABSORPTION

Ferr-Ease® dual-iron formulation contains both ferrous gluconate and carbonyl iron[1]:

1. **FERROUS GLUCONATE (Fe^{2+})** enters the body in the ferrous state, ready for quick dissolution and absorption to start restoring your patients' vital iron levels.[5]
2. **PARTICULATE CARBONYL IRON (Fe^0)** requires conversion from its elemental form to the soluble ionized form ($Fe^0 + 2H^+Cl^- \rightarrow Fe^{2+}Cl_2 + H_2$). It is naturally regulated by the patients' production of gastric acid for gradual absorption.[2,9] Overall, the bioavailability of carbonyl iron is similar to ferrous salts.[2]



Important Safety Information (cont'd)

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 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 this product since folic acid may mask the symptoms of pernicious anemia.

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

Please see the following page for additional Important Safety Information and full Prescribing Information on page 4.

Carbonyl iron with proven safety and tolerability

Rx Only

Ferralet® 90
90 mg Dual-Iron Delivery

Carbonyl iron was **tolerated at 10-15X the standard dose** of ferrous sulfate iron, while having nearly the same side effects, and significantly less toxicity.[3,9]

Carbonyl iron was shown to be **250-300X as safe as ferrous sulfate** because of its prolonged absorption.[10]

Ferralet® 90 also contains 50 mg docusate sodium, a gentle and effective stool softener that helps prevent the constipation that might occur in patients sensitive to iron therapy.[4]

References: 1. Ferralet 90 Prescribing Information. San Antonio, TX: Mission Pharmacal Company. **2.** Huebers HA, Brittenham GM, Csiba E, Finch CA. Absorption of carbonyl iron. *J Lab Clin Med.* 1986;108(5):473-478. **3.** Gordeuk VR, Brittenham GM, Hughes M, Keating LJ, Opplt JJ. High-dose carbonyl iron for iron deficiency anemia: a randomized double-blind trial. *Am J Clin Nutr.* 1987;46(6):1029-1034. **4.** Medscape. Docusate (OTC). http://reference.medscape.com/drug/colace-dss-docusate-342012. Accessed April 18, 2018. **5.** Beck KL, Conlon CA, Kruger R, Coad J. Dietary Determinants of and Possible Solutions to Iron Deficiency for Young Women Living in Industrialized Countries: A Review. *Nutrients.* 2014; 6(9):3747-3776. **6.** Martin, LJ. WebMD. Folic acid. http://www.webmd.com/diet/folic-acid. Published June 23, 2016. Accessed May 8, 2018. **7.** Mayo Clinic Staff. Vitamin B_{12}. https://www.mayoclinic.org/drugs-supplements-vitamin-b12/art-20363663. Updated October 17, 2017. Accessed May 8, 2018. **8.** Muñoz M, Gómez-Ramírez S, Bhandari S. The safety of available treatment options for iron-deficiency anemia. *Expert Opin Drug Saf.* 2018;17(2):149-159. **9.** Gordeuk VR, Brittenham GM, McLaren CE, Hughes MA, Keating LJ. Carbonyl iron therapy for iron deficiency anemia. *Blood.* 1986;67(3):745-752. **10.** Brittenham GM, Klein HG, Kushner JP, Ajioka RS. Preserving the national blood supply. *Hematol Am Soc Hematol Educ Program.* 2001:422-432.

Important Safety Information (cont'd)

Geriatric Use: Clinical studies on this product have not been performed in sufficient numbers of subjects aged 65 and over to determine whether elderly subjects respond differently from younger subjects. Dose selection for an elderly patient should be administered with caution, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

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.

Please see page 4 for full Prescribing Information.

Rx Only

Ferralet® 90

90 mg Dual-Iron Delivery

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

Iron (carbonyl iron, ferrous gluconate)	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, magnesium stearate, FD&C Yellow No. 5, vitamin A palmitate, magnesium silicate, FD&C Blue No. 1, polyethylene glycol, 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 for 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, and reticulocyte counts 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 administered with caution. 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 cirrhosis, 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. Do not chew tablet.

STORAGE: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

NOTICE: Contact with moisture can discolor or erode the tablet.

HOW SUPPLIED: Ferralet® 90 (**NDC** 0178-0089-90) is a green, modified rectangle shaped, film-coated tablet, debossed with "F6" on one side and blank on the other, and packaged in bottles of 90.

To report a serious adverse event or obtain product information, call (800) 298-1087.

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Ferr-Ease® Dual-Iron delivery

Trademark of Mission Pharmacal Company
U.S. Patent No. 6,521,247

Mission® PHARMACAL

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