

IMPORTANT ANNOUNCEMENT:

A change in one electronic database may limit your patients' access to important prescription iron tablets

Dear Doctor,

We at Mission Pharmacal Company ("Mission Pharmacal") wish to make you aware that First Databank ("FDB"), an electronic drug coding database, has made an incorrect decision to either delete prescription iron tablets from the FDB database or reclassify prescription iron products into a new category on the FDB database. **Many iron tablets, previously classified as prescription products in the FDB database, now fall under a new "Q" category in FDB's database for products that are neither prescription drugs nor medical devices, such as dietary supplements.** One result of such incorrect action by FDB is that the Ferralet[®] 90 Dual-Iron prescription tablets of Mission Pharmacal have been wrongfully deleted by FDB from its database.

FDB's action in this matter could lead to **certain denials of insurance coverage for iron tablets.** Moreover, FDB's decision **contradicts statements from the U.S. Food and Drug Administration ("FDA"),** which recognizes the importance of iron tablets containing folic acid, and has stated that physicians *can* and *do* write prescriptions for iron tablets.

It is our belief that patients with iron deficiency, or Iron Deficiency Anemia ("IDA"), deserve to have their nutritional needs evaluated by a qualified, expert medical professional and receive the highest standard of care. However, **FDB's action could prevent iron deficient patients from getting the nutritional support** that's critical to meeting therapeutic goals for IDA.

Please be aware that all of the other drug coding databases have not made any change to the classification of prescription iron tablets from Mission Pharmacal. These other drug coding databases, such as Medi-Span and others, are used in numerous national and regional pharmacies, including Walgreens, Walmart, H.E.B. and others, which means that your patients should not have any problems filling your prescriptions for the Ferralet[®] 90 Dual-Iron prescription tablets made by Mission Pharmacal at such pharmacies.



Did you know?

IDA will not go away on its own. In fact, left untreated IDA can lead to serious complications, including heart problems, a greater chance of getting infections, and pregnancy problems such as premature births and babies with low birth weight.¹



Why Ferralet[®] 90?

Ferralet[®] 90 (iron [carbonyl iron, ferrous gluconate] 90 mg, folic acid 1 mg, vitamin B₁₂ [cyanocobalamin] 12 mcg, vitamin C [ascorbic acid] 120 mg, docusate sodium 50 mg) is a prescription iron supplement used to treat low levels of iron in the blood caused by certain types of anemia.

Reference: 1. Mayo Clinic Staff. Iron deficiency anemia: symptoms & causes. <https://www.mayoclinic.org/diseases-conditions/iron-deficiency-anemia/symptoms-causes/syc-20355034>. Accessed September 2020.

INDICATIONS: Ferralet[®] 90 (iron [carbonyl iron, ferrous gluconate] 90 mg, folic acid 1 mg, vitamin B₁₂ [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 page 2 for additional Important Safety Information, including boxed warning, and see page 3 for full Prescribing Information.

Ferralet® 90 Dual-Iron tablets will continue to be available – regardless of changes by FDB



We're doing our part to support patients with IDA — nutritionally and financially

We at Mission Pharmacal are taking measures to provide all patients with access to our prescription iron supplement.



- For patients with commercial insurance coverage, we offer a savings card allowing patients to pay as little as \$25*, which we will continue to provide and can be downloaded from the ferralet.com website.

- Ferralet® 90 also continues to be available through managed care plans like Caremark and Express Scripts®, as well as through CVS Caremark® mail order for Caremark members. State Medicaid plans will continue to operate under current conditions, based on plan and member benefit coverage.

*Up to \$50 savings limit per month. Subject to eligibility. Restrictions apply. See back of card for details.



Let's continue to support iron deficient patients — with a specially chosen combination of active ingredients:

- Vitamin C to enhance iron absorption²
- Folic acid to increase red blood cell development³
- Vitamin B₁₂ to support blood cell production⁴

Have questions or concerns about this change by FDB?



If you have questions about this change by FDB or access to Ferralet® 90 Dual-Iron tablets for specific patients, please speak with one of our Customer Service agents.

Contact Mission Pharmacal Customer Service at:

(800) 531-3333

**Monday-Wednesday, 7:00 AM to 5:30 PM CST,
and Thursday, 7:00 AM to 5:00 PM CST**

Reference: 2. 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. 3. Martin, L.J. WebMD. Folate [Folic acid]. <http://www.webmd.com/diet/folic-acid>. Published June 23, 2016. Accessed September 2020. 4. Mayo Clinic Staff. Vitamin B12. <https://www.mayoclinic.org/drugs-supplements-vitamin-b12/art-20363663>. Updated October 17, 2017. Accessed September 2020.

Important Safety Information (cont'd)

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 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.

See full Prescribing Information on page 3 for additional information including additional Precautions, Adverse Reactions and Drug Interactions.

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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, 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 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 B₁₂ 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 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 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.

ferralet.com

