

Rx Only

Ferralet[®] 90
90 mg Dual-Iron Delivery

Get back to

Per**Fe**cting

your stroke with
Ferralet[®] 90



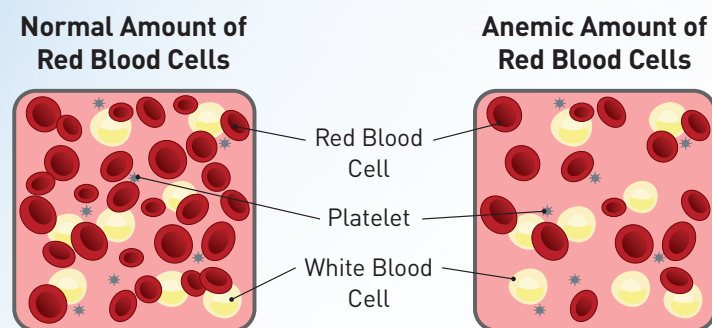


Your doctor has prescribed Ferralet® 90 to treat your iron-deficiency anemia

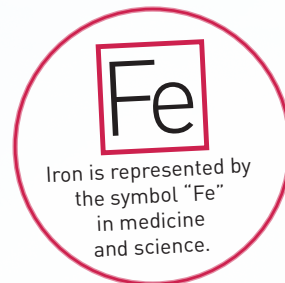
What Exactly Is Iron-deficiency Anemia (IDA)?¹

Iron-deficiency anemia (IDA) is a common type of **anemia** – a condition in which there is not enough healthy red blood cells in the body.

IDA is caused by a lack of iron in the blood. Without enough iron, your body can't produce enough **hemoglobin** – a substance in red blood cells that allows them to carry oxygen.



Adapted from the National Institutes of Health²



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.

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. Your doctor may prescribe Ferralet 90 if you have iron-deficiency anemia due to pregnancy, blood loss, or certain metabolic diseases, or if you are recovering from surgery, or do not have enough iron in your diet.

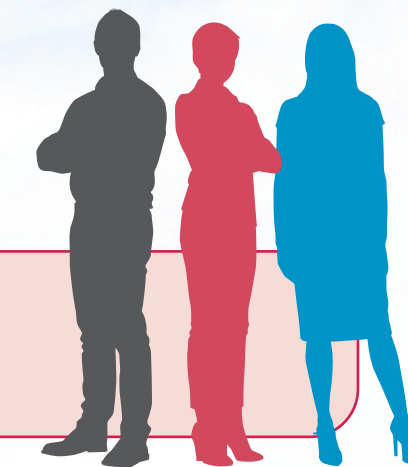
Please see the following page for additional Important Safety Information and full Prescribing Information on page 4.

Will It Go Away on Its Own?

No, 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 problems during pregnancy.¹

FERRALET® 90: DESIGNED WITH YOU IN MIND

There are many oral iron supplements out there³ (“oral” means it is taken by mouth), but your doctor has decided that Ferralet® 90 is best suited for you. Be sure to follow your doctor’s advice and take your medication exactly as he or she tells you to, for as long as he or she tells you to. This will help ensure you get the full benefit of therapy.⁴



In the U.S., the occurrence of IDA varies widely by gender and race⁵

2% adult men

9-12% non-Hispanic white women

~20% black and Mexican-American women

Visit ferralet.com for more information on IDA, tips, and a valuable savings card.

Important Safety Information

You should not use Ferralet 90 if:

- you are allergic to any of the ingredients
- you have hemolytic anemia, or certain iron overload disorders such as hemochromatosis, or hemosiderosis

The safety and effectiveness of Ferralet 90 has not been studied in children.

Ferralet 90 is not for everyone. Before you take Ferralet 90, you should tell your doctor about any medical conditions that you may have, including if you have allergies to medicines, foods, or other substances. If you have certain types of anemia (pernicious anemia, or other types of anemia where your vitamin B₁₂ levels are low), folic acid alone is not enough to treat your condition. Doses of 0.1 mg folic acid per day can hide the symptoms of these anemias, making them difficult to diagnose. Consult with your doctor if this treatment is not right for you.

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

The Ferralet® 90 Difference



TWO IRON COMPOUNDS

Ferr-Ease® is a unique **dual-iron formulation**. Two iron formulations work together to mimic the way the body absorbs iron^{6,7}:

- **Ferrous gluconate** is absorbed quickly
- **Carbonyl iron** is absorbed more slowly and bit by bit



EASY ON THE STOMACH

- Dual-iron formulation was shown to be easier on the stomach with **fewer digestive side effects**^{8*}
- Contains **docusate sodium**, a gentle stool softener that helps ease constipation⁹
- Lactose- and gluten-free⁷

*In a large, randomized, double-blind trial, carbonyl iron dosed at 600 mg was tolerated with digestive side effects similar to those observed with a 60 mg dose of ferrous sulfate.

Important Safety Information (cont'd)

Iron supplements can interfere with certain medicines, including certain antibiotics and antacids. Tell your doctor about all prescription and over-the-counter medicines, vitamins, minerals, other supplements, and herbal products you use. Do not start a new medication without telling your doctor.

Once you start taking Ferralet 90, take it 2 hours after meals. Do not exceed the recommended dose. Your doctor will order blood tests periodically during treatment to determine whether your dose of Ferralet 90 needs to be changed.

Ferralet 90 contains FD&C Yellow No. 5 (tartrazine), a food coloring additive, which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons, such as those who have allergic reactions or sensitivity to aspirin. The overall rate of FD&C Yellow No.5 (tartrazine) allergic reactions in the general population is low. Some patients taking folic acid have also experienced allergic reactions. Call your doctor and discontinue use of this product if you develop any unusual symptoms.

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



EASY TO TAKE

- Small, coated pill⁷
- Easy to swallow
- Taken 2 hours after a meal⁷
- Vanilla scent⁷



CONVENIENT

- Once-a-day dosing⁷



SPECIALLY CHOSEN COMBINATION OF ACTIVE INGREDIENTS

- **Vitamin C** to help your body absorb iron¹⁰
- **Folic acid** to increase red blood cell development¹¹
- **Vitamin B₁₂** to support growth and blood cell production⁷



STICK WITH IT

Staying on therapy is important.

It can take months to bring your iron levels back to normal.¹²

Do not stop taking **Ferralet® 90** until your doctor tells you to.



Have trouble remembering to take your medication?

Set a reminder on your mobile device, watch, or laptop, or link taking your medication to something else you do 2 hours after a meal so that it becomes a habit (i.e., going for a morning break at work, putting pajamas on in the evening, etc.)

References: 1. Mayo Clinic staff. Iron-deficiency anemia: symptoms & causes. <https://www.mayoclinic.org/diseases-conditions/iron-deficiency-anemia/symptoms-causes/syc-20355034>. Updated November 11, 2016. Accessed October 2022. 2. US National Library of Medicine. Genetics Home Reference. Beta Thalassemia. <https://ghr.nlm.nih.gov/condition/beta-thalassemia>. Accessed October 2022. 3. Cleveland Clinic. Iron Supplement (Ferrous Sulfate). <https://my.clevelandclinic.org/health/drugs/14568-iron-oral-supplements-for-anemia>. Accessed October 2022. 4. US Food & Drug Administration. Why You Need to Take Your Medications as Prescribed or Instructed. <https://www.fda.gov/drugs/special-features/why-you-need-to-take-your-medications-prescribed-or-instructed>. Accessed October 2022. 5. Killip S, Bennett JM, Chambers MD. Iron-deficiency anemia. *Am Fam Physician*. 2007;75(5):671-678. 6. Huebers HA, Brittenham GM, Csiba E, Finch CA. Absorption of carbonyl iron. *J Lab Clin Med*. 1986;108(5):473-478. 7. Ferralet 90 Prescribing Information. San Antonio, TX: Mission Pharmacal Company. 8. Gordeuk VR, Brittenham GM, Hughes M, Keating LJ, Oppl J. High-dose carbonyl iron for iron-deficiency anemia: a randomized double-blind trial. *Am J Clin Nutr*. 1987;46(6):1029-1034. 9. Medscape. Docusate (OTC). <http://reference.medscape.com/drug/colace-dss-docusate-342012>. Accessed October 2022. 10. 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. 11. Web MD. Griffin, RM. WebMD. Folate (Folic Acid). <https://www.webmd.com/diet/supplement-guide-folic-acid>. Accessed October 2022. 12. National Heart, Lung and Blood Institute (NHLBI). Iron-Deficiency Anemia. <https://www.nhlbi.nih.gov/health/anemia/iron-deficiency-anemia>. Accessed October 2022.

Important Safety Information (cont'd)

The most common side effects associated with iron therapy include irritation of your stomach or bowels, constipation, diarrhea, nausea, vomiting, and dark stools. These side effects are generally temporary, however, check with your doctor if any side effect persists or becomes bothersome.

Ferralet 90 contains iron. Accidental overdose of iron is a leading cause of fatal poisoning in children under the age of 6 years. Symptoms of overdose can include: stomach pain, metabolic acidosis (when the body has high levels of acid), reduction in urine production, brain damage, coma (loss of consciousness), convulsive seizures, death, dehydration, congestion of blood vessels, liver disease, low blood pressure, drop in body temperature, tiredness, nausea, vomiting, diarrhea, black or tarry stools, vomiting blood, rapid heart rate, high blood sugar, feeling drowsy, abnormal pale or bluish skin color, lack of energy, and shock. In case of accidental overdose, call a doctor or poison control center immediately.

KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN.

To report negative side effects, contact Mission Pharmacal Company at 1-800-298-1087 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information on page 4.

Rx Only
Ferralet® 90
90 mg Dual-Iron Delivery

Feel the Ferralet® 90 Difference

Mission
PHARMACAL



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



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