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

What Exactly Is Iron-deficiency Anemia (IDA)?

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.

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.

FERRALET® 90: DESIGNED WITH YOU IN MIND

There are many oral iron supplements out there (“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.

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

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

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Brazilian American: 2%
Non-Hispanic: 7%
Mexican American: 20%
Other: 1%

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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 hemosiderosis, or hemochromatosis

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

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 and provide specific instructions on formulation. It can take months to bring your iron levels back to normal. Do not stop taking Ferralet 90 until your doctor tells you to.

Feel the Ferralet® 90 Difference

STICK WITH IT

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, etc.).

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Important Safety Information (cont’d)

The most common side effects associated with iron therapy include irritation of your stomach or bowels, constipation, diarrhea, 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 the following page for additional Important Safety Information and full Prescribing Information on page 4.

References:
5. Ferr-Ease® * is a unique, dual-iron formulation developed by Ferrallite Corporation. The Ferr-Ease® dual-iron formulation was shown to be easier on the stomach with fewer digestive side effects. Contains docusate sodium, a gentle stool softener that helps ease constipation. May be easier on the stomach due to the differences in iron formulation. It can take months to bring your iron levels back to normal. Do not stop taking Ferralet® 90 until your doctor tells you to. 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.

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Ferralet® 90 is indicated for the treatment of all anemias that are

**INDICATIONS AND USAGE:**
anemia or pernicious anemia.

- Hematopoiesis, nucleic acid, and myelin synthesis. Deficiency may result in megaloblastic macrocytic anemias. Vitamin B12 is essential to growth, cell reproduction, and megaloblastic anemias where vitamin B12 is deficient.

- 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 in case of accidental overdose, call a doctor or poison control center immediately.

**DESCRIPTION:**

Each green film-coated tablet for oral administration contains:

- Folic Acid, 1 mg
- Vitamin B12 (cyanocobalamin), 50 mcg
- Vitamin C (ascorbic acid), 12 mg
- Vitamin B6 (pyridoxine), 2 mg
- Vitamin B1 (thiamine), 12 mg
- Magnesium stearate
- Calcium carbonate
- Magnesium silicate
- FD&C Blue No. 1, polyethylene glycol, ethyl vanillin.

**CLINICAL PHARMACOLOGY:**

Oral iron is absorbed most efficiently when administered

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) sensitizability in the general population is low, it is frequently seen in patients who also have aspirin sensitivity.

**WARNING:**

- Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 is deficient.
- Measuring blood serum iron saturation, total iron binding capacity, and reticulocyte counts are determined before starting therapy and periodically thereafter during therapy.

**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 FDC Blue No. 1 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FDC Blue No. 1 (tartrazine) sensitizability in the general population is low, it is frequently seen in patients who also have aspirin sensitizability.

- Safety and effectiveness in pediatric patients have not been established.

**INDICATIONS AND USAGE:**

Ferralet® 93 is indicated for the treatment of all anemias that are responsive to iron oral therapy. These include: hypochromic anemia associated with pregnancy, iron deficiency, and anemia associated with chronic and/or acute blood loss, metabolic disease, post-surgical convalescence, and dietary needs.

**CONTRAINDICATIONS:**

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

**WARNING:**

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

**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.

**HOW SUPPLIED:**

Ferralet® 90 (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 30.

**NOTICE:**

Contact with moisture can discolor or erode the tablet.

**OVERDOSAGE:**

Symptoms: abdominal pain, metabolic acidosis, anuria, CNO damage, coma, convulsions, death, dehydration, diffuse vascular congestion, hepatic cirrhosis, hyposthenuria, Hypotension, lethargy, nausea, vomiting, diarrhea, tachycardia, hyperglycemia, drowsiness, palpitations, 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.

**WARNING:**

- Ferralet® 90 tablets are a leading cause of fatal poisoning in children under 6. KEEP THIS PRODUCT OUT OF THE REACH OF CHILDREN.

**Notice:**

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

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