Rx Only

DESCRIPTION: Each green film-coated tablet for oral administration contains:
Iron (Carbonyl iron, ferrous gluconate)................. 90 mg
Folic Acid.............................................. 1 mg
Vitamin B12 (Cyanoacobalamin)......................... 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, 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 erythrocytosis. Folic acid is the precursor of tetrahydrofolate acid, which is involved as a cofactor for transformation 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, postsurgical 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 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 dosage 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 anabolic steroids, 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, packaged in bottles of 90.

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

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What is Iron Deficiency Anemia (IDA)?

Iron Deficiency Anemia, or IDA, is a condition in which your body does not have enough healthy red blood cells. These cells carry oxygen through the blood to the tissues to give your body energy and your skin a healthy color. As the name suggests, Iron Deficiency Anemia results from insufficient iron. When your body does not have an adequate supply of iron, it will make fewer red blood cells or red blood cells that are too small.

What causes IDA?

There are many causes of IDA. These include:

- A diet consistently low in iron
- Blood loss due to heavy menstrual bleeding
- Poor iron absorption from food due to intestinal surgery or diseases of the intestine
- Pregnancy (when the need for iron increases significantly)

Women in general are at higher risk of IDA, not only because they lose blood during menstruation but also because their bodies store less iron.

What are the symptoms?

Some of the symptoms most commonly associated with IDA are fatigue, weakness, and headache. Symptoms may also include light-headedness, pale skin, shortness of breath, and cold hands and feet, among others. As the body becomes more deficient in iron and anemia worsens, the symptoms worsen as well.

How is IDA diagnosed?

A diagnosis is made primarily through blood tests. The doctor checks your hematocrit, the percentage of your blood volume made up of red blood cells and hemoglobin. A lower than normal hemoglobin level indicates anemia. If a patient tests positive for IDA, additional tests may be ordered to identify an underlying cause.

Does IDA lead to health complications?

Mild cases of IDA usually don’t cause complications. However, left untreated, IDA can increase in severity and contribute to serious health problems. For example, it may lead to a rapid or irregular heartbeat, a complicated pregnancy that can put the mother at risk for a premature delivery or low-birth-weight baby, and delayed growth in infants and children. The good news is that, because IDA is easily treatable, its potential health consequences are generally avoidable.

How is IDA treated?

It’s essential to increase the amount of iron in your diet. Foods rich in iron include meat, fish, poultry, and whole grain breads. However, in most cases of IDA, diet alone isn’t enough to correct the problem. Iron supplementation is usually needed for several months. Your doctor has prescribed oral iron, a safe and effective iron supplement to help restore your body’s iron to normal levels. Plus, it offers the convenience of once-daily dosing. Together with an iron-rich diet, taking this prescription every day can make a big difference in helping restore your body’s iron, and with it your energy and overall feeling of well-being.