FERRALET 90- iron, folic acid, cyanocobalamin, ascorbic acid, and docusate sodium tablet, film coated
Mission Pharmacal Company

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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	1	mg
Vitamin B_{12} (Cyanocobalamin)	12	mcg
Vitamin C (Ascorbic acid)	120	mg
Docusate sodium 50	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 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, 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 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, reticulocyte count 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 cautious. 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 cirrohosis, 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.

NOTICE

Contact with moisture can discolor or erode the tablet.

Do not chew 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. Store at 25°C (77°F). Excursions permitted to 15°-30°C (59°-86°F). (See USP Controlled Room Temperature.)

To report a serious adverse event or obtain product information, call (210) 696-8400.

If you have questions about Ferralet ® 90 please call: 1 (800) 531-3333

MISSION PHARMACAL COMPANY
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FEP-14 C01 Rev 012090

Ferralet® 90
90 mg Dual-Iron Delivery

RX ONLY

THERAPEUTIC GUIDELINES FOR THE PATIENT

Some facts you should know about Iron Deficiency Anemia

Iron Deficiency Anemia, or IDA, is a common type of anemia. It's a condition in which blood lacks an adequate supply of healthy red blood cells. These cells carry oxygen to tissues. It is oxygenated blood that gives your body energy and your skin a healthy color.

As the name suggests, Iron Deficiency Anemia results from insufficient iron. Your body needs iron to make a substance called hemoglobin. It's the hemoglobin in red blood cells that enables them to carry oxygen.

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.

How common is it?

IDA is a common nutritional deficiency, with women most widely affected. Up to 20% of women have IDA.

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. Also, blood tests for IDA typically include a measurement of ferritin, a protein that helps store iron in your body. When the level of ferritin is low, usually the level of iron is, too. 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 Ferralet ® 90, 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 Ferralet ® 90 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.

PRINCIPAL DISPLAY PANEL - 90 mg Tablet Bottle Label

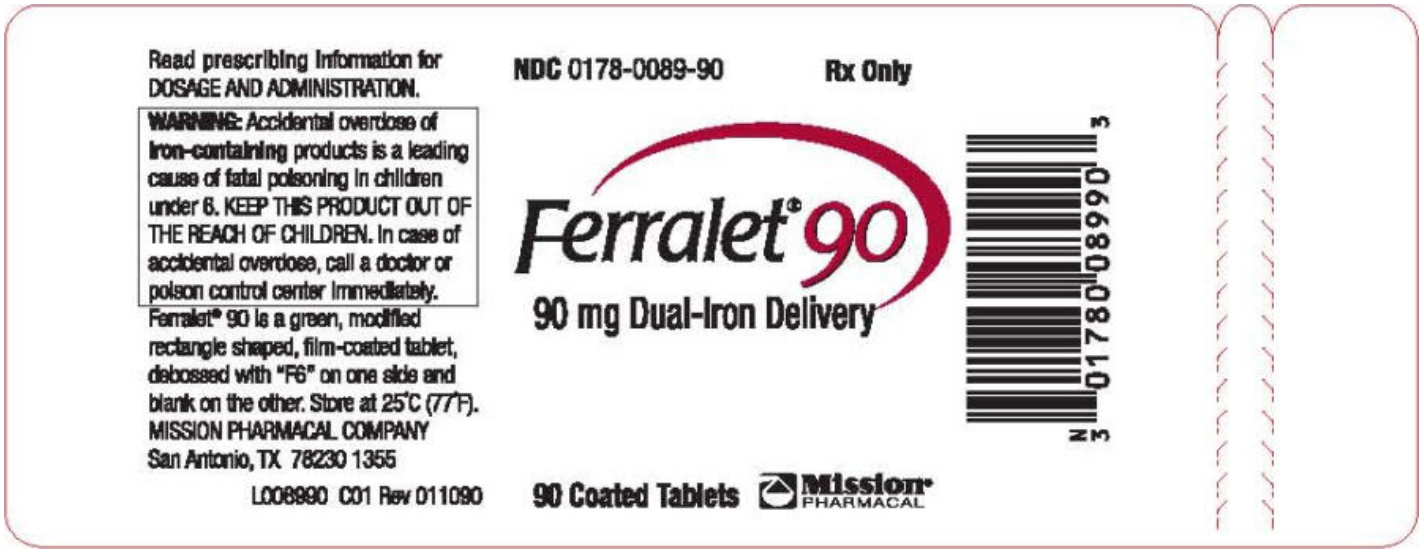
NDC 0178-0089-90

Rx Only

Ferralet® 90
90 mg Dual-Iron Delivery

90 Coated Tablets

Mission ®
PHARMACAL



FERRALET 90

iron, folic acid, cyanocobalamin, ascorbic acid, and docusate sodium tablet, film coated

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0178-0089
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
IRON (UNII: E1UOL152H7) (IRON - UNII:E1UOL152H7)	IRON	90 mg
FOLIC ACID (UNII: 935E97BOY8) (FOLIC ACID - UNII:935E97BOY8)	FOLIC ACID	1 mg
CYANOCOBALAMIN (UNII: P6YC3EG204) (CYANOCOBALAMIN - UNII:P6YC3EG204)	CYANOCOBALAMIN	12 ug
ASCORBIC ACID (UNII: PQ6CK8PD0R) (ASCORBIC ACID - UNII:PQ6CK8PD0R)	ASCORBIC ACID	120 mg
DOCUSATE SODIUM (UNII: F05Q2T2JA0) (DOCUSATE - UNII:M7P27195AG)	DOCUSATE SODIUM	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
POVIDONE (UNII: FZ989GH94E)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
MAGNESIUM SILICATE (UNII: 9B9691B2N9)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
POLYETHYLENE GLYCOL (UNII: 3WQ0SDW1A)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
ETHYL VANILLIN (UNII: YC9ST449YJ)	

Product Characteristics			
Color	green	**Score**	no score

Shape	RECTANGLE (modified)	**Size**	9mm
Flavor		**Imprint Code**	F6
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0178-0089-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	06/23/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/04/2010	

Labeler - Mission Pharmacal Company (008117095)

Registrant - Mission Pharmacal Company (927726893)

Establishment

Name	Address	ID/FEI	Business Operations
Mission Pharmacal Company		927726893	manufacture(0178-0089)

Revised: 9/2017 Mission Pharmacal Company