Rx ONLY ADULTS ONLY

This product information is intended for physicians and is the entire product information. NO OTHER INFORMATION, WHETHER ORAL OR IN WRITING, SHOULD BE RELIED UPON!

NDC 52747-306-70

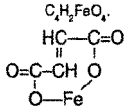
Hemocyte-F® Tablets

DESCRIPTION: Each tablet contains:

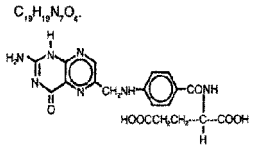
Iron (Ferrous Fumarate, anhydrous)	324 mg
(Provides approximately 106 mg of elemental iron)	
Folic Acid	1 mg

Inactive ingredients: FD&C Blue #2 Aluminum Lake, FD&C Red #40 Aluminum Lake, FD&C Yellow #6 Aluminum Lake, Hypromellose, Magnesium Stearate, Maltodextrin, Microcrystalline Cellulose, Polyethylene Glycol, Polyvinyl Alcohol, Sodium Starch Glycolate, Talc, Titanium Dioxide.

Ferrous Fumarate: 2-Butenediac acid, (E)-, iron (2+) salt, is a hematinic which occurs as a reddish orange to red-brown, odorless powder. It may contain soft lumps that produce a yellow streak when crushed. It is slightly soluble in water and very slightly soluble in alcohol. Its solubility in dilute hydrochloric acid is limited by the separation of fumaric acid. Its molecular formula and chemical structure follows: $C_4H_2FeO_4$.



Folic Acid: N - [4 - [[(2 - amino - 1, 4 - dihydro - 4-oxo - 6 - pteridinyl) methyl] aminol benzoyl] - 1 glutamic acid, is a vitamin (hematopoietic) which occurs as a yellow, yellowish-brownish, or yellowish orange, odorless, crystalline powder which is very slightly soluble in water, insoluble in alcohol, acetone, chloroform, or ether. It dissolves readily in dilute solutions of alkali hydroxides and carbonates, and is soluble in hot, 3 N hydrochloric acid and in hot, 2 N sulfuric acid, yielding very pale yellow solutions. Its molecular formula and chemical structure follow: $C_{19}H_{19}N_7O_6$.



CLINICAL PHARMACOLOGY: This product is formulated to meet the needs of the patient requiring both iron and folic acid. Deficiencies of these ingredients are common during pregnancy. Ferrous fumarate contains approximately 33 percent elemental iron. The use of well tolerated ferrous fumarate provides a high level of elemental iron with a low incidence of gastric distress.

Ferrous Fumarate: A very common anemia is that due to iron deficiency. In most cases the response to iron salts is prompt, safe and predictable. Within limits the response is quicker and more certain to large doses of iron than to small doses. Iron is absorbed from the small intestine; however, the exact mechanism regulating the amount absorbed is still a matter of controversy. The proportion of dietary iron absorbed is greater in iron deficient anemic individuals. Iron is transported via the blood in which it is bound to transferrin, a beta-1-globulin. The iron from deteriorated red blood cells is reutilized. Under normal circumstances the loss of iron from the body is very small, about 1 mg per day for men and an additional average daily loss of 0.5 mg/ day by menstruating women. Iron is stored in the bone marrow, intestinal wall, liver and spleen, with the latter organs containing the largest amounts.

Folic Acid: Folic acid is one of the important hematopoietic agents necessary for proper regeneration of the blood-forming elements and their function. Folic acid is a precursor of a large family of compounds which serve as coenzymes in carbon transfer reactions. These reactions are required for synthesis of purine and pyrimidine bases, inter-conversion of glycine and serine, biosynthesis of methionine methyl groups and degradation of histidine. Additionally, folic acid increases jejunal glycolytic enzymes and is involved in the desaturation and hydroxylation of long-chain fatty acids in the brain. A deficiency in folic acid results in megaloblastic anemia.

INDICATIONS AND USAGE: For the treatment of iron deficiency anemia and folate deficiency anemia. Hemocyte-F is indicated in pregnancy for the prevention and treatment of iron deficiency and to supply a maintenance dosage of folic acid.

Warnings: Accidental overdose of iron- containing products is the 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.

Warnings: Folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemmias where Vitamin B_{12} is deficient.

CONTRAINDICATIONS: Hemocyte-F is contraindicated in patients with known hypersensitivity to any of its ingredients. Also, all iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis, or hemolytic anemias. Pernicious anemia is a contraindication, as folic acid may obscure its signs and symptoms.

PRECAUTIONS: General: Anemia is a manifestation that requires appropriate investigation to determine its cause or causes. No single regimen fits all cases, and the status of the patient observed in follow-up is the final criterion for adequacy of therapy. Periodic clinical and laboratory studies are considered essential. Blood examinations including hemoglobin and hematocrit should be done at the usual intervals to make certain therapy is adequate. Use with care in the presence of peptic ulcer, regional enteritis and ulcerative colitis. Folic acid, especially in doses above 0.1 mg-0.4 mg daily, may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestations remain progressive.

Usage in Pregnancy: Before Hemocyte-F is prescribed for megaloblastic anemia in pregnancy, appropriate diagnostic exclusion of Addisonian pernicious anemia, (due to faulty or blocked absorption for Vitamin B_{12}, or extrinsic factor, on either a genetic, immunological or surgical basis), should be carried out.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: No clinical studies have been performed in patients 65 and over to determine whether older persons respond differently from younger persons. Dosage should always begin at the low end of the dosage scale and should consider that elderly persons may have decreased hepatic, renal, or cardiac function, and of concomitant disease.

ADVERSE REACTIONS: Ferrous fumarate has been implicated in some instances of gastrointestinal disturbances, including abdominal cramps, diarrhea, constipation, heartburn, nausea and vomiting. Reducing the dose and administering it with meals will minimize these effects in the sensitive patient. Increasing fiber in the diet can relieve constipation. Iron may turn stools black. This is a harmless effect that is a result of unabsorbed iron. Allergic sensitization has been reported following oral administration of folic acid.

OVERDOSAGE: Iron: Signs and Symptoms: Acute overdosage of iron may cause nausea and vomiting and, in severe cases, cardiovascular collapse and death. Other symptoms include pallor and cyanosis, melena, shock, drowsiness and coma. The estimated lethal dose of orally ingested elemental iron is 300 mg per kg of body weight. Hemocyte-F should be stored beyond the reach of children to protect against accidental iron poisoning. Keep this and all drugs out of the reach of children.

Treatment: For specific therapy, exchange transfusion and chelating agents should be used. For general management, perform gastric lavage with sodium bicarbonate solution or milk, administer intravenous fluids and electrolytes and use oxygen.

DOSAGE AND ADMINISTRATION: Usual adult dose is one tablet taken orally daily or as prescribed by a physician.

HOW SUPPLIED: Hemocyte-F are maroon film coated round tablets debossed with "US" logo on one side. Hemocyte-F are supplied in child resistant unit dose packs of 100 tablets and 30 tablets.

Boxes of 100 NDC 52747-306-70, Boxes of 30 NDC 52747-306-30

Dispense in a tight, light resistant container as defined in the USP/NF with a child resistant closure. Store at controlled room temperature 15°-30°C (59°-86°F). Keep in a cool, dry place.

Rx only.

Made in USA exclusively for US Pharmaceutical Corporation, Decatur GA 30035 USA.

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