

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!

**ADULTS  
ONLY**

A hematinic for iron deficiency anemia.

NDC 52747-307

# Hemocyte®

**DESCRIPTION:** Each tablet contains:

Ferrous Fumarate (anhydrous) 324 mg

Each tablet is equivalent to about 106 mg of Elemental Iron.

**PHARMACOLOGY:** Ferrous Fumarate is an anhydrous salt of a combination of Ferrous Iron and Fumaric Acid, containing 33% iron by weight. The acute toxicity in experimental animals is low. It is also well tolerated clinically. However, gastrointestinal tolerance to all iron preparations seems to be primarily a function of the total amount of elemental iron per dose and of psychological factors, rather than the form in which iron is administered.

Being a ferrous salt, it is more efficiently absorbed than ferric forms. Iron absorption is maximal in the duodenum unlike Ferrous Sulfate, which must be protected against oxidation through coating. The Hemocyte® (Ferrous Fumarate) Tablet is not enteric coated and is superior to enteric coated or sustained-release preparations that are apt to pass beyond the duodenum and would therefore be poorly absorbed. Calculation of Dose should be in terms of elemental iron and three doses ranging from 50-100 mg of elemental iron is usually adequate.

**INDICATIONS:** The treatment of iron deficiency anemia, which may occur due to increased need for iron, a deficient intake of iron, or an excessive loss of iron.

**CONTRAINDICATIONS:** All iron compounds are contraindicated in patients with hemosiderosis, hemochromatosis and hemolytic anemias.

**WARNING: Iron is toxic, when overdoses are ingested by children, severe reactions, including fatalities have resulted. As with every drug, pregnant or nursing women should seek the advice of a health professional before using this product. Keep out of the reach of pediatric patients. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.**

**PRECAUTIONS:** Existing gastrointestinal diseases, i.e. peptic ulcers, regional enteritis, ulcerative colitis may be aggravated causing the iron not to be absorbed and therefore be ineffective in patients with steatorrhea or those with a partial gastrectomy. It is important to determine and treat the underlying cause of the anemia, in addition to the administration of Hemocyte® (Ferrous Fumarate). Indefinite administration of iron should be avoided.

**SIDE EFFECTS:** Gastrointestinal disturbance (anorexia, nausea, diarrhea, constipation) occur occasionally but are usually mild and subside with continuation of therapy and physician encouragement. Although the absorption of iron is best when taken between meals, occasional G. I. disturbances may be controlled by giving Hemocyte® (Ferrous Fumarate) shortly after meals. Too few data are available to permit dosage recommendations for infants and children.

**DOSAGE AND ADMINISTRATION:** Adults, 1 tablet twice daily, between meals, orally.

**TIME AND DURATION:** The hematologic response to orally administered iron is initiated by reticulocytosis of 2% to 10% depending on the severity of the anemia, beginning five to ten days after initiation of therapy. A rise in hemoglobin value is observable at the end of the second week. When therapy is adequate, hemoglobin value increases 0.1 to 0.2 gm per 100ml of blood a day and usually becomes normal in two months. However, to improve body iron stores, treatment may be continued for 3 to 12 months, after the hemoglobin has returned to normal. If no satisfactory response is noted after 3 weeks of therapy, consideration should be given to (1) whether dosage recommendations have been followed, (2) blood loss is occurring simultaneously, (3) whether there are complicating causes, such as infection, defects in absorption or utilization, (4) whether diagnosis of iron-deficiency anemia was correct.

**WARNING: Do not administer to pediatric patients. Do not exceed recommended dosage. Keep this and all drugs out of reach of pediatric patients. If you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Observe iron warnings on child proof blister package.**

SUPPLIED: In boxes of 30's NDC 52747-307-30 and 100's NDC 52747-307-70.

Keep tightly closed. Store at room temperature between 15°- 30°C (59°- 86°F)

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