

ITEM #2465a

NDC 64980-105-03

FoliTab™ 500

Controlled-Release Iron With Vitamin C and Folic Acid to assist in the absorption of iron.

Rx only

PRESCRIBING INFORMATION

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

DESCRIPTION

FoliTab™ 500 caplets are a hematinic for oral administration containing iron in a controlled-release dose form, Vitamin C for enhancement of iron absorption, and Folic Acid.

One caplet provides:

*Ferrous Sulfate.....525 mg
(equivalent to 105 mg of elemental iron)
Vitamin C (as Ascorbic Acid).....500 mg
Folic Acid.....800 mcg
*In controlled release dose form.

Inactive Ingredients: Croscarmellose Sodium, Dicalcium Phosphate, FD&C Blue #1 Lake, FD&C Blue #2 Lake, FD&C Red #40 Lake, FD&C Yellow #6 Lake, Hypromellose, Magnesium Silicate, Magnesium Stearate, Microcrystalline Cellulose, Mineral Oil, Polyethylene Glycol, Polyvinylpyrrolidone, Stearic Acid and Titanium Dioxide.

CLINICAL PHARMACOLOGY

When oral iron is administered between meals it is absorbed most efficiently. Traditional iron preparations frequently cause gastric irritation when taken on an empty stomach. Studies with iron in controlled release form have indicated that relatively little of the iron is released in the stomach, gastric intolerance occurs infrequently, and hematologic response is consistent with that obtained from immediate release ferrous sulfate.

Iron is found in the body principally as hemoglobin. It is stored in the liver, spleen, and bone marrow in the form of ferritin. Concentrations of plasma iron and the total iron-binding capacity of plasma vary greatly in different physiological conditions and disease states.

Vitamin C (Ascorbic Acid) plays a role in anemia therapy. It augments the conversion of folic acid to its active form, folinic acid. In addition, Vitamin C promotes the reduction of ferric iron in food to the more readily absorbed ferrous form. Severe and prolonged Vitamin C deficiency is associated with an anemia that is usually hypochromic but occasionally megaloblastic in type.

Iron and folic acid are absorbed in the proximal small intestine, particularly the duodenum. While folic acid is absorbed maximally and rapidly at this site, iron is absorbed in a descending gradient from the duodenum distally.

Folic acid, after absorption, is rapidly converted into its metabolically active forms. Half of the folic acid stored in the body is found in the liver. It is also concentrated in spinal fluid. Approximately two-thirds is bound to plasma protein.

The percentage of absorption of food folates averages about 10%, except for the folates ingested in egg yolk, liver and yeast.

INDICATIONS AND USAGE

Non-pregnant Adults: For the treatment of iron deficiency and prevention of concomitant folic acid deficiency.

Pregnant Females: For the prevention and treatment of iron deficiency and to supply a maintenance dosage of folic acid.

CONTRAINDICATIONS

Contraindicated in patients with pernicious anemia and in the rare instance of hypersensitivity to folic acid. Hemochromatosis and hemosiderosis are contraindications to iron therapy.

PRECAUTIONS

Anemia is a manifestation that requires appropriate investigation to determine its cause or causes. Folic Acid alone is unwarranted in the treatment of vitamin B12 deficiency states, such as pernicious anemia. Folic Acid, especially in doses above 100 mcg daily, may obscure pernicious anemia in that hematological remission may occur while neurological manifestations remain progressive. Concomitant parenteral therapy with vitamin B12 may be necessary for adequate treatment of

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(continued)

patients with a deficiency of vitamin B12.

Pernicious anemia is rare in women of childbearing age, and the likelihood of its occurrence along with pregnancy is reduced by the impairment of fertility associated with vitamin B12 deficiency. In older patients and those with conditions tending to lead to vitamin B12 depletion, serum B12 levels should be regularly assessed during treatment.

Drug Interactions: Absorption of iron is inhibited by magnesium trisilicate and antacids containing carbonates. Since oral iron products interfere with absorption of oral tetracycline antibiotics, these products should not be taken within two hours of each other. Iron absorption may also be inhibited by the ingestion of milk or eggs.

Carcinogenesis: Adequate data are not available on long-term potential for carcinogenesis in animals and humans.

Pregnancy: Pregnancy Category A. Studies in pregnant women have not shown that the ingredients in the FoliTab™ 500 Caplet formula increase the risk of fetal abnormalities if administered during pregnancy. If this drug is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, however, FoliTab™ 500 caplets should be used during pregnancy only if clearly needed.

Nursing Mothers: Folic acid and ascorbic acid are excreted in breast milk.

ADVERSE REACTIONS

Rarely, controlled-release iron produces gastrointestinal reactions, such as diarrhea or constipation. Administering the dose with meals will minimize these effects in the iron-sensitive patient. Allergic sensitization has been reported with both oral and parenteral administration of folic acid.

OVERDOSAGE

Signs and symptoms of iron toxicity, which may be delayed because the iron is in a controlled release form, may include pallor and cyanosis, vomiting of blood, diarrhea, passage of dark-colored stool, shock, drowsiness and coma. In overdose, efforts should be made to hasten the elimination of the caplets ingested. An emetic should be administered as soon as possible, followed by gastric lavage if indicated. Immediately following emesis, a large dose of a saline cathartic should be used to speed passage through the intestinal tract. X-ray examination may then be considered to determine the position and number of caplets remaining in the gastrointestinal tract.

DOSAGE AND ADMINISTRATION

Adults, including Pregnant Females: The recommended dose is one caplet daily on an empty stomach.

HOW SUPPLIED

FoliTab™ 500 maroon caplets embossed with CPC2465 are supplied in packages of 30 caplets each containing 3 child resistant blisters of 10 caplets.

Rx only

Store below 77°F (25°C). Protect from light to avoid tablet color changes.

Distributed by:
Rising Pharmaceuticals, Inc.
Allendale, NJ 07401

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