Vitafer

Sustained release Capsules of Ferrous Sulphate with Folic Acid

Composition:
Each capsule contains:
Ferrous sulphate BP 150 mg (in time release-form) (Elemental Iron 45 mg approx.)
Folic Acid BP 500 mcg

Pharmacology:
Ferrous sulphate:
In healthy individuals, incorporation of iron from the diet is finely balanced to replenish losses and meet specific requirements for growth and reproduction. In men and non-menstruating women daily loss of iron are about 1 mg; in menstruating women this is increased to 2mg. Obligatory losses, apart from menstruation, result from loss of nails, desquamated skin, and hair and in feces and urine. In pregnancy and lactation mean losses are about 3mg. Infants are born with stores of iron and human milk can meet requirements for the first 4-6 months of life. Thereafter, about 1mg per day is needed.

Normally less than 10% of iron in the diet is absorbed and generally the 15-20 mg of total iron in Western diets is sufficient to meet adult requirements. Inorganic and heme iron are chiefly absorbed in the upper jejunum and duodenum, where luminal conditions, including the influence of gastric secretions and acid, facilitate bioavailability. Many components of the diet influence absorption by formation of soluble or insoluble complexes of iron and by actions on the oxidation state of elemental iron.

Folic acid:
After conversion into coenzyme forms it is concerned in single carbon unit transfers in the synthesis of purines, pyrimidines, and methionine.

Folic acid, after conversion to 5,6,7,8-tetrahydrofolate polyglumate, functions as a coenzyme in single carbon unit transfer. Thus in purine synthesis it donates formate (-CHO) to form carbons 2 and 8 of the purine nucleus. In pyrimidine synthesis it donates the 5-methyl group of thymidylate as a Methylene (-CH2-) group. It mediates de novo synthesis of methyl groups and this methyl is transfered to homocysteine to form methionine. Sources of single units include formate, serine, and histidine.

Therapeutic group: Source of Iron

Indications:
Vitafer is a haematinic preparation of prophylaxis of iron and folic acid deficiency during pregnancy.

Dosage and Administration:
The drug is administered by oral route.
1 capsule a day throughout pregnancy and lactation
Children: As directed by the physician.

Contraindications:
- Ferrous sulphate:
- Primary (idiopathic) or secondary iron storage disease
- Anemias associated with ineffective erythropoiesis, marrow hypoplasia, sideroblastic change, uncomplicated vitamin B_{12} or folate deficiency
- Intestinal disease
- Active rheumatoid arthritis
- Previous hypersensitivity
- Known idiosyncrasy to commonly used excipients
- Porphyria cutanea tardia
- Uncontrolled parathyroid disease.

Folic acid:
Untreated cobalamin deficiency
Addisonian pernicious anemia or other vitamin B12 deficiency.
Malignant disease.

Precautions:
Since Iron preparations interfere with absorption of oral tetracycline antibiotics, these products should not be taken within two hours of each other. Iron salts should not be given to patients receiving repeated blood transfusions or to patients with anaemias not produced by iron deficiency unless iron deficiency is also present. Care should be taken when given to patients with iron-storage or iron-absorption diseases, haemoglobinopathies, or existing gastro-intestinal disease.

Drug interactions:
Iron preparations interact with certain chelates of medical importance: diphosphonates, antacids and the tetracycline antimicrobials. Oral iron should not be given concurrently with tetracyclines. The bioavailability of iron is reduced by simultaneous ingestion of antacids: these form insoluble co-precipitates within the lumen. Aluminium hydroxide, calcium or magnesium hydroxide as well as carbonates, silicates and alginate-rich preparations interact strongly with medicinal iron in this way.

Use in pregnancy:
Oral iron preparations, given as prophylaxis against iron deficiency in pregnancy, are safe. In pregnancy aggravation of reflux symptoms and constipation can be troublesome. The particular importance of safe storage of iron capsules supplied to pregnant women with young children cannot be overemphasized. Large doses of iron given parentally to pregnant animals are teratogenic. Parental iron should thus be avoided in early pregnancy and only administered in the last two trimesters if there are proper indications of risk or evidence of severe iron deficiency.

There are a few data about the appearance of administered iron in maternal milk. At present, administration of iron in therapeutic doses to lactating women appears to be safe for breast-fed infants.

Adverse Effects:
Occasional gastrointestinal discomfort (such as nausea) may be minimized by taking meals. Iron containing medication may occasionally cause constipation or diarrhea.

A few subjects have been become sensitized to folic acid, and administration has been followed within an hour by an itchy skin eruption, malaise, and brochospasm. When given long term to patients with cobalamin deficiency, the drug can precipitate a neuropathy.

Overdose, signs, symptoms and treatment:
Large quantities of iron salts are toxic and fatal accidental ingestion in children is well recognized. In adults, deaths are rare and are nearly always the result of suicidal intent. In children ingestion of 1-2 g iron may be fatal.

Gastric lavage or induction of vomiting should be undertaken and further absorption of iron prevented by lavage with 1% sodium bicarbonate, depending on the size of the patient. Additional treatment of acture iron poisoning includes management of dehydration, acidosis and shock.

Storage: Store below 30°C. Protect from light. Keep all medicines away from children.

Presentation: 10 capsules in a blister. 3 such blisters in a carton.

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