LINDAFER

Instructions for the medicinal product

Trade name: Lindafer.
International Nonproprietary Name: Ferrous Fumarate + Folic Acid + Vitamin C + Cyanocobalamin + Zinc Sulphate Monohydrate.
Dosage form: Capsules.
Composition: Each hard gelatin capsule contains:

Ferrous Fumarate	BP	305 mg;
Folic Acid	BP	0.75 mg;
Vitamin C (as coated)	BP	75 mg;
Cyanocobalamin	BP	5 mcg;
Zinc Sulphate Monohydrate	BP	5 mg.

Pharmacotherapeutic group: Heamatinic.
ATC Classification: B03AE02.
Pharmacologic property:
Pharmacodynamics:
Ferrous fumarate - Iron is an essential constituent of the body, and is necessary for haemoglobin formation and for the oxidative processes of living tissues. Iron and iron salts should be given for the treatment or prophylaxis of iron deficiency anaemias.
Soluble ferrous salts are most effective by mouth. Ferrous fumarate is an easily absorbed source of iron for replacement therapy. It is a salt of ferrous iron with an organic acid and is less irritant to the gastro-intestinal tract than salts with inorganic acids.
Folic Acid a member of the vitamin B family that stimulates the hematopoietic system. After conversion into co-enzyme forms it is concerned in single carbon unit transfers in the synthesis of purines, pyrimidines and methionine. Folic Acid is used in the treatment and prevention of folate deficiencies and megaloblastic anemia.
Ascorbic Acid - In humans, an exogenous source of ascorbic acid is required for collagen formation and tissue repair. Vitamin C is a co-factor in many biological processes including the conversion of dopamine to noradrenaline, in the hydroxylation steps in the synthesis of adrenal steroid hormones, in tyrosine metabolism, in the conversion of folic acid to folinic acid, in carbohydrate metabolism, in the synthesis of lipids and proteins, in iron metabolism, in resistance to infection, and in cellular respiration. Vitamin C may act as a free oxygen radical scavenger. The usefulness of the antioxidant properties of vitamin C in reducing coronary heart disease were found not to be significant.
Vitamin B12 (Cyanocobalamin) refers to a group of water-soluble vitamins. It has high biological activity. Vitamin B12 is necessary for normal hematopoiesis (promotes maturation of erythrocytes). Involved in the processes of transmethylation, hydrogen transport, synthesis of methionine, nucleic acids, choline, creatine. Contributes to the accumulation in erythrocytes of compounds containing sulfhydryl groups. Has a beneficial effect on liver function and the nervous system. Activates the coagulation of blood in high doses causes an increase in the activity of thromboplastin and prothrombin.
Zinc Sulphate Monohydrate is an essential trace element involved in many enzyme systems. Severe deficiency causes skin lesion, alopecia, diarrhoea, increased susceptibility to infections and failure to thrive in children. Symptoms of less severe deficiency include distorted or absent perceptions of taste and smell and poor wound healing.
Pharmacokinetics:
Ferrous Fumarate - Iron, as a constituent of haemoglobin, plays an essential role in oxygen transport. It is also present in the muscle protein myoglobin and in the liver. Deficiency of iron leads to anaemia.
Folic Acid - is absorbed mainly from the proximal part of the small intestine. Folate polyglutamates are considered to be deconjugated to monoglutamates during absorption. Folic acid rapidly appears in the blood where it is extensively bound to plasma proteins. Some folic acid is distributed in body tissues, some is excreted as folate in the urine and some is stored in the liver as folate.
Vitamin C (Ascorbic acid) - is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues. Ascorbic acid in excess of the body's needs is rapidly eliminated in the urine and this elimination is usually accompanied by a mild diuresis.
Cyanocobalamin - is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study showed it was quickly taken up by the intestinal mucosa and held there for 2 3 hours. Peak concentrations in the blood and tissues did not occur until 8 - 12 hours after dosage with maximum concentrations in the liver within 24 hours. Cobalamins are stored in the liver, excreted in the bile and undergo enterohepatic recycling. Part of a dose is excreted in the urine, most of it in the first eight hours.
Zinc Sulphate (Zinc) - is poorly absorbed from the gastro-intestinal tract. It is widely distributed throughout the body. It is excreted in the faeces with traces appearing in the urine.
Indications for use:
- As a therapeutic nutritional adjunct where the intake of vitamins and minerals is suboptimal, e.g. in the presence of organic disease such as malignancy and immune deficiency syndromes, such as AIDS.
- As a therapeutic nutritional adjunct in conditions where the absorption of vitamins and minerals is suboptimal, e.g. malabsorption, inflammatory bowel disease and fistulae, short bowel syndrome and Crohn's disease, and where concurrent medication decreases vitamin and mineral absorption.
- As a therapeutic nutritional adjunct in convalescence from illness, e.g. where anorexia or cachexia exists and following chemo- or radio-therapy.
- As a therapeutic nutritional adjunct in convalescence from surgery, e.g. where nutritional intake continues to be inadequate.
- As a therapeutic nutritional adjunct for patients on special or restricted diets, e.g. in renal diets and where several food groups are restricted in therapeutic weight reducing diets.
- As a therapeutic nutritional adjunct where food intolerance exists, e.g. exclusion diets.
- As an adjunct in synthetic diets, e.g. in phenylketonuria, galactosaemia and ketogenic diets.

Contraindications:
- History of hypersensitivity to any of the constituents of the formulation;
- Thromboembolism;
- Erythremia;
- Erythrocytosis;
- Hemochromatosis;
- Hemosiderosis;
- Aplastic and hemolytic anemia;
- Hereditary porphyria cutanea tarda;
- Children under 12 years old.

Pregnancy and lactation:
During pregnancy, this medication should be used only when clearly needed. Discuss the risks and benefits with your doctor. This medication passes into breast milk. Consult your doctor before breast-feeding.
Dosage and directions for use:
Adults (persons over 12 years of age): 1 capsule daily, between meals, or as prescribed by a physician.
Do not exceed recommended dosage.
Do not administer to children under the age of 12.
Side-effects:
Gastrointestinal disturbances such as diarrhea, constipation, abdominal colic, heartburn, nausea and vomiting may be experienced by some patients.
Overdose:
Iron overdosage is an acute emergency requiring urgent medical attention. An acute intake of 75mg/kg of elemental iron is considered extremely dangerous in young children.
Symptoms:
Iron overdosage is an acute emergency requiring urgent medical attention. An acute intake of 75mg/kg of elemental iron is considered extremely dangerous in young children.
Symptoms: Initial symptoms of iron overdosage include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycemia and metabolic acidosis may occur. However, if overdosage is suspected, treatment should be implemented immediately. In severe cases, after a latent phase, relapse may occur after 24-48 hours manifested by hypotension, coma, hypothermia, hepatocellular necrosis, renal failure, pulmonary oedema, diffuse vascular congestion, coagulopathy and/or convulsions. In many cases, full recovery may be complicated by long-term effects such as hepatic necrosis, toxic encephalitis, CNS damage and pyloric stenosis.
Treatment: Administer an emetic. Gastric lavage may be necessary to remove drug already released into the stomach. This should be undertaken using a desferrioxamine solution (2g/l).
Desferrioxamine 5g in 50-100ml water should be introduced into the stomach following gastric emptying. In the presence of shock and/or coma with high serum iron levels (>142umol/l) immediate supportive measures plus IV infusion of desferrioxamine should be instituted.
The recommended dose of desferrioxamine is 5mg/kg/h by a slow IV infusion up to a maximum of 80mg/kg/24 hours. Hypotension may occur if the infusion rate is too rapid. Less severe poisoning: IM deferrioxamine 50mg/kg up to a maximum dose of 4g should be given. Serum iron levels should be monitored throughout.
Drug interactions:
Iron chelates with concomitantly administered tetracyclines, and absorption of both agents may be impaired, allow an interval of 2-3 hours if treatment with both drugs is necessary. Iron also chelates with acetohydroxamic acid reducing the absorption of both.
Absorption of iron may be reduced in the presence of antacids and proton pump inhibitors which reduce stomach acid. Iron absorption may also be reduced in the presence of food (e.g. tea, coffee, wholegrain cereals, eggs and milk), neomycin and cholestyramine. Bicarbonates, carbonates, oxalates, or phosphates, may impair the absorption of iron by the formation of insoluble complexes. Iron absorption may be increased by ascorbic or citric acid. Iron absorption may be reduced with calcium, oral magnesium salts and other mineral supplements, zinc and trientine. If treatment with both iron and trientine is necessary a suitable interval is advised. The response to iron may be delayed in patients receiving systemic chloramphenicol. Chloramphenicol delays plasma clearance of iron and incorporation of iron into red blood cells by interfering with erythropoiesis.
The hypotensive effect of methyldopa is reduced by iron.
Concomitant use of iron and dimercaprol should be avoided as toxic complexes may form.
Iron reduces the absorption of fluoroquinolones, levodopa, carbidopa, entacapone, bisphosphonates, penicillamine, thyroid hormones such as levothyroxine (give at least 2 hours apart), mycophenolate, and cefdinir. Iron possibly reduces the absorption of eltrombopag (give at least 4 hours apart).
Serum levels of anticonvulsant drugs may be reduced by the co-administration of folate e.g. folic acid possibly reduces the plasma concentration of phenobarbital, phenytoin and primidone.
Concomitant use of folic acid with raltitrexed should be avoided.
Absorption of folic acid is possibly reduced by sulfasalazine.
Cyancobalamin absorption may be reduced by Para-aminosalicylic acid, colchinine, biguanides, neomycin, cholestyramine, potassium chloride, methyldopa, and cimetidine.
Patients treated with chloramphenicol may respond poorly to this medicine.
Serum levels of cyancobalamin may be lowered by oral contraceptives.
These interactions are unlikely to have clinical significance.
Anti-metabolites and most antibiotics invalidate Vitamins B12 assays by microbiological techniques.
Cautions:
Stools may be coloured dark as with iron preparations.
In perinicious anaemia, folic acid in Lindafer may correct anaemia but aggravate neurological lesions.
Effects on ability to drive and use machine:
Does not affect ability to drive and to use machinery.
Presentation:
3x10 alu/ alu blister in carton box with instruction for use.
Storage:
Keep in dry place, protected from light at a temperature below 30°C. Keep out of reach of children.
Shelf life:
Labeled. Do not use after expiry date.
Distribution condition:
Non- prescribed medicine.