LINDAFER

Instructions for the medicinal product

Trade name: Lindafer.
International Nonproprietary Name: Ferric Ammonium Citrate + Cyanocobalamin + Folic Acid.
Dosage form: Syrup.
Composition: Each 5 ml contains:
Ferric Ammonium citrate USP 235 mg;
Eq. to Iron 41 mg;
Vitamin B12 BP 50 mcg;
Folic Acid BP 1.5 mg.
Pharmacotherapeutic group: Heamatinic.
ATC Classification: B03AE01.
Pharmacologic property:
Pharmacodynamics:
Ferric Ammonium Citrate it is an essential constituent of hemoglobin, cytochrome, and other components of respiratory enzyme systems. Its chief functions are in the transport of oxygen to tissue (hemoglobin) and in cellular oxidation mechanisms. Depletion of Iron (Ferric Ammonium Citrate) stores may result in iron-deficiency anemia
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.
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.
Pharmacokinetics:
Well absorbed after oral administration. The average dietary intake of iron is 12 to 20 mg/day for males and 8 to 15 mg/day for females, however only 10% of this iron is absorbed (1 to 2 mg/day) in individuals with adequate iron stores in liver.
Vitamin B12 (Cyanocobalamin) absorbed from the gastrointestinal tract. The absorption of cobalamins from the gut is dependent upon the glycoprotein intrinsic factor. Cobalamins are transported rapidly into the blood bound to protein, known as transcobalamins. Cobalamins are stored in the liver and excreted in the bile. They are known to cross the placenta. Metabolized in the tissues, becoming a co-enzyme form - adenosylcobalamin which is the active form of cyanocobalamin.
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.
Indications for use:
- Treatment of iron deficiency anemia of different etiologies;
- Treatment of iron deficiency anemia, accompanied by folic acid deficiency.

Contraindications:
- A history of hypersensitivity to any of the constituents of the formulation;
- Thromboembolism;
- Erythremia;
- Erythrocytosis;
- Hemochromatosis;
- Hemosiderosis;
- Aplastic and hemolytic anemia;
- Hereditary porphyria cutanea tarda.

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. Should consult doctor before breast-feeding.
Dosage and directions for use:
Adults and children over 12 years: 15 - 25 ml per day after meals.
Children under 12 years : the usual therapeutic dose of Iron is 4-6 mg/kg of body weight per day, after meals or as directed by physician.
Recommended doses of Lindafer syrup for children under 12 years:
Children with weight 5-6 kg: recommended dose of iron 25 - 30 mg per day, 3 ml a day.
Children with weight 7-8 kg: recommended dose of iron 35 - 40 mg per day, 5 ml a day.
Children with weight 9-10 kg: recommended dose of iron 40 - 55 mg per day, 5 - 5.25 ml a day.
Children with weight 11-12 kg: recommended dose of iron 50 - 65 mg per day, 5.25 - 5.5 ml a day.
Children with weight 13-14 kg: recommended dose of iron 60 - 75 mg per day, 5.5 - 5.75 ml a day.
Children with weight 15-20 kg: recommended dose of iron 75 - 100 mg per day, 5.75 - 10.5 ml a day.
Children with weight 20-25 kg: recommended dose of iron 100 - 125 mg per day, 10.5 - 15 ml a day.
Children with weight 25-30 kg: recommended dose of iron 125 - 150 mg per day, 15 - 20 ml a day.
Side-effects:
Rarely, iron in therapeutic doses produces gastrointestinal reactions, such as diarrhea or constipation. Reducing the dose and administering it with meals will minimize these effects in the iron-sensitive patient.
In extremely rare instances, skin rash suggesting allergy has been noted following the oral administration of liver-stomach material. Allergic sensitization has been reported following both oral and parenteral administration of folic acid.
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: 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 interaction:
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, cefdinir and zinc. 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:
Do not take more than the recommended dose without checking with your doctor.
Lindafer syrup may discolor the stools. This is normal and not a cause for concern.
Lindafer may interfere with certain lab tests, including tests used to check for blood in the stool. Be sure your doctor and lab personnel know you are taking this medicine.
Care should be taken in patients who may develop iron overload, such as those with haemochromatosis, haemolytic anaemia or red cell aplasia.
Iron can lead to an increase in infectious disease morbidity in areas where bacterial infections are common. Iron deficiency protects against infection by creating an unfavorable environment for bacterial growth.
Failure to respond to treatment may indicate other causes of anaemia and should be further investigated.
The folic acid content is unlikely to mask pernicious anaemia should this condition be present; pregnancy during pernicious anaemia is very rare.
Presentation:
150 ml Amber color Glass bottle in a monocarton,measuring cup and instructions 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.