FERROLIFE

Instructions
on medical use of the drug

Trade name of the drug: Ferrolife.
International nonproprietary name: Iron polymaltose complex, folic acid, cyanocobalamin, zinc sulfate.
Dosage form: Capsules for oral administration.
Composition*: Each capsule contains:*
Iron (III) hydroxide polymaltose complex
eq, elemental iron ..... ……..120 mg;
Folic acid ..... 1,5 mg;
Cyanocobalamin BP (vitamin B12)…….....15 mcg;
Zinc sulfate monohydrate BP ....61,8 mg.
Excipients: v.d.k.
ATX code: B03AD04.
Pharmacotherapeutic group: Antianemic drugs. Hematopoiesis stimulants. Iron supplements. Ferric iron preparations for oral administration.
Pharmacological properties:
Pharmacodynamics:
Polymaltose iron complex: Ferrolife contains polymaltose iron complex, which is a non-ionic source of iron. Due to its rapid absorption, high level of iron utilization, and effective production of hemoglobin using MPC, Ferrolife becomes an ideal drug for the treatment of iron deficiency anemia. Bioavailability Iron polymaltose is equivalent to ferrous salt. This leads to rapid utilization of iron introduced in hemoglobin synthesis and replenishment of iron stores. Slower absorption increases the safety profile of MPCs. After 3 months of treatment, both MPC and ferrous iron salts give the same results.
Ferrolife is used to correct iron deficiency anemia and nutritional anemia, which occur especially during pregnancy and lactation. Being non-ionic iron, Ferrolife does not release iron free radicals, unlike other iron salts. This may prevent poisoning due to unintentional overdose. There are no foods or medications known to interact with or interfere with iron absorption, so Ferrolife may be taken before or after meals.
Folic acid is one of the B vitamins necessary for DNA synthesis. Folic acid deficiency is an important cause of anemia. The need for folic acid increases during pregnancy. Folic acid is very important for the prevention of many chronic diseases and neural tube defects in newborns.
Zinc sulfate monohydrate is vital for many biological functions such as immune resistance, wound healing, digestion, reproduction and physical growth.
Vitamin B12 plays a key role in the normal functioning of the brain and nervous system, as well as in hematopoiesis. It is involved in the metabolism of every cell of the human body, especially affecting the synthesis and regulation of DNA.
Pharmacokinetics:
After ingestion, iron is absorbed in the form of ferrous iron. The conversion of ferric iron to divalent iron is promoted by hydrochloric acid. Iron is transported through transferrin. When the body's iron stores are high, ferric iron combines with apoferritin to form ferritin.
Ferritin is an iron storage protein. About 80% of the iron in the blood plasma goes to the erythroid brain. Iron excretion is minimal. Only a small amount of iron is lost when cells in the intestinal lining shed, and trace amounts are excreted in urine, sweat, and bile.
Once iron deficiency is confirmed, oral iron therapy can be given. Generally, oral iron therapy is prescribed unless the patient has severe anemia, malabsorption syndrome, gastrectomy, or the patient exhibits side effects of oral iron therapy.

Indications for use: *used for the treatment of iron deficiency conditions in the following cases:*

- treatment of iron deficiency without anemia and iron deficiency anemia (IDA) various genesis and latent iron deficiency;
- prevention of iron deficiency;
- increased need for iron (pregnancy, lactation, donation, period of intensive growth, vegetarianism, old age);
- with a clinical need for rapid replenishment of iron reserves in the body;
- when IDA occurs after surgery (posthemorrhagic anemia).

Directions for use and dosage:
Treatment of iron deficiency anemia in children over 12 years of age and adult patients: 1 capsule 2-3 times a day, daily, for 3 to 5 months until hemoglobin (Hb) levels normalize. After this, the drug must be continued to be taken. Maintenance therapy is carried out for at least another 4 weeks after achieving normal hemoglobin levels (1 capsule per day) in order to replenish iron reserves in the body.
Treatment of iron deficiency without anemia in children over 12 years of age and adult patients: prescribed according to 1 capsule per day for 1-2 months.
Treatment of iron deficiency anemia during pregnancy: 1 capsule 2-3 times a day, daily, until Hb levels normalize. After this, the drug must be continued until the end of pregnancy at the dosage used for iron deficiency without anemia in order to replenish iron reserves in the body and meet the increased need for iron during pregnancy.
Side effects:
Adverse reactions from taking iron supplements may include constipation, diarrhea, nausea, vomiting, dark stools, and abdominal

pain. Adverse reactions to iron therapy are usually short-lived. Allergic sensitization may occur after oral administration of folic acid. Adverse reactions such as nausea, upset stomach, heartburn, fever, chills, diarrhea, vomiting, gastrointestinal discomfort, persistent itchy rash, hypersensitivity reactions, loss of appetite may occur.

Warnings and precautions:

If you are pregnant, planning to become pregnant, or breastfeeding, you should consult your doctor or health care provider before using or continuing to use this drug. Do not exceed the recommended dose. The type of anemia and the cause must be determined before taking Ferrolife. Because anemia can be the result of a systemic disorder, such as recurrent blood loss, the underlying cause should be addressed if possible.

Contraindications :

• hypersensitivity to gallstones or to the components of the drug;
• children under 12 years of age;
• iron oversaturation, for example hemochromatosis, hemosiderosis;
• disorders of iron absorption, such as anemia caused by lead poisoning, sideroblastic anemia, thalassemia;
• use of the drug in the first trimester of pregnancy is contraindicated. The drug should be used in the second and third trimesters of pregnancy only when the potential benefit to the mother outweighs the potential risk to the fetus.
• bronchial asthma;
• infectious kidney diseases in the acute stage;
• uncontrolled hyperparathyroidism ;
• decompensated cirrhosis of the liver;
• anemia not caused by iron deficiency, such as hemolytic anemia or megaloblastic anemia caused by vitamin B12 deficiency, erythropoiesis disorders, bone marrow hypoplasia.

Overdose:

The clinical course of acute iron overdose can be variable. Initial symptoms may include abdominal pain, nausea, vomiting, diarrhea, tarry stools, melena, hematemia, hypotension, tachycardia, metabolic acidosis, hyperglycemia, dehydration, somnolence, pallor, cyanosis, fatigue, convulsions, shock, and coma.

Pregnancy and breastfeeding:

In controlled studies in pregnant women in the second and third trimesters of pregnancy, no undesirable effects of the drug on the mother and fetus were noted. During the first trimester of pregnancy, the drug should be used only if the potential benefit from using the drug in the mother outweighs the possible risk to the fetus.

Interaction with other drugs:

As a rule, interactions of Ferrolife with food or drugs are not observed or obvious, unlike what happens with iron salts. However, oral iron salt has been shown to exhibit the following interaction profile.
Antacids: absorption of iron in the gastrointestinal tract is reduced.
Ascorbic acid: enhanced absorption of iron in the gastrointestinal tract.
Chloramphenicol: Serum iron levels may be increased.
Cimetidine: Absorption from the gastrointestinal tract may be reduced.
Levodopa: decreased serum levels of levodopa.
Methyldopa: May reduce the effectiveness of methyldopa.
Quinolones: absorption of quinolones in the gastrointestinal tract is reduced.
Penicillamine: markedly reduced absorption of penicillamine in the gastrointestinal tract.
Tetracyclines: decreased absorption of both tetracyclines and iron salts.
Food: Eggs and milk interfere with iron absorption. Taking calcium and iron supplements with food reduces iron absorption by a third.

Release form:

Capsules No 30. 10 capsules in a blister pack. 3 contour-cell packages along with instructions for use are placed in a cardboard box.

Storage conditions:

Store in a dry place, protected from light, at a temperature not exceeding 25 °C.
Keep the drug out of the reach of children. Do not use the drug after the expiration date indicated on the blister and cardboard box.

Conditions for dispensing from pharmacies:

Without a doctor's prescription.

Made for:
MAXX PHARM LTD
London, Great Britain