ROTAFER PLUS

COMPOSITION
Capsule contains
Active ingredients:
iron (III) hydroxidepolymaltose complex 50 mg
zinc gluconate 50 mg
folic acid 0.35 mg
vitamin B₁ (thiamine hydrochloride) 2 mg
vitamin B₂ (riboflavin) 1 mg
vitamin B₆ (pyridoxine hydrochloride) 2 mg

PHARMACOLOGICAL PROPERTIES

Rotafer Plus is a combination drug or iron, zinc and B vitamins.
Iron in the drug has the structure of Fe³⁺ hydroxidepolymaltose complex. Multinuclear centers of Fe³⁺ hydroxide are surrounded on the outside with numerous noncovalently linked polymaltose molecules, thus creating a complex with total molecular weight of 50000 Dalton. The complex is so large that its diffusion across intestinal mucous membranes is about 40 times inferior than that of Fe²⁺ hexahydrate. This macromolecular complex is stable, it does not release iron in the form of free ions and has a structure similar to that of a natural iron and ferritin compound. Due to such similarity Fe³⁺ ions penetrate from intestine into blood only by way of active absorption which explains the impossibility of overdose (and intoxication) of the drug, in contrast with ordinary iron salts, absorption of which proceeds according to the concentration gradient.
The absorbed iron depots in the ferritin-bound form predominantly in liver. Later it is included into hemoglobin in the bone marrow. Iron in the Fe³⁺-hydroxide polymaltose complex does not possess pro-oxidant properties (inherent to ordinary Fe²⁺ salts), which leads to a decrease in oxidation of low density lipoproteins (LDL) and very low density lipoproteins (VLDL).
Administration of the drug quickly compensates for the deficit of iron in the body, stimulates erythropoiesis, and restores hemoglobin level.
Zinc is an important element of human body, which is mainly found in erythrocytes as zinc metalloenzyme carbonic anhydrase, and to a lesser extent in plasmain α-2-macroglobulin-bound form. It is present in more than 70 enzymes that catalyze key stages of DNA, RNA and protein synthesis. The substance markedly influences the processes of tissue growth and maturation, produces positive effect in mental and physical retardation in children. It stabilizes cell membranes, influences regeneration processes and neurotransmission, potentiates the effect of insulin, stimulates hair growth, produces immunomodulating effect on T-cell component of immune system, and increases factors of non-specific immune defense. It is a strong antioxidant and is effective in treatment of acne and alopecia.
Folic acid is a B vitamin which participates in major biological processes, particularly in DNA, RNA and protein synthesis. In pregnancy folic acid averts development of neural tube defects in the fetus. Folate deficiency results in development of megaloblastic anemia. Folic acid deficit may lead to interruption of pregnancy, premature birth, and mental disability of the child.

Vitamin B₁ (thiamine hydrochloride) is an important active compound. As a result of phosphorylation processes in the body it converts to cocarboxylase which is a coenzyme of numerous enzymatic reactions. The substance takes an important part in carbohydrate, protein and lipid metabolism, as well as in the processes of conduction of synaptic excitation. It protects cell membranes against toxic effect of peroxidation products.

Vitamin B₂ (riboflavin) is a catalyst of cell respiration and visual perception; it takes an important part in DNA formation and promotes processes of tissue regeneration (including that of skin cells).

Vitamin B₆ (pyridoxine hydrochloride) in a phosphorylated form is part of enzymes participating in the processes of decarboxylation and transamination of amino acids, as well as in lipid metabolism. The substance is necessary for normal functioning of peripheral nervous system and central nervous system (CNS).

**PHARMACOKINETICS**

Due to the complex formula of the drug performance of pharmacokinetic studies is impossible.

**THERAPEUTIC INDICATIONS**

As part of complex therapy, symptomatic treatment of such diseases as:
- iron-deficient anemia of various genesis and latent deficiency;
- increased demand for iron (pregnancy, lactation, blood donation, intensive growth, vegetarianism, elderly age).

**DOSAGE AND ADMINISTRATION**

**Rotafer Plus** is administered per os.

Dosage and duration of the therapy depend on severity of iron deficiency. The daily dose can be administered once daily. The drug is taken during or just after meal and is followed with water.

Treatment of mild and moderate clinically apparent iron deficiency (iron-deficient anemia): 2 capsules/day for 3-5 months until blood hemoglobin is normal. After blood hemoglobin is normalized the supportive dose is prescribed upon the recommendation of the doctor.

Pregnant women should take 1-2 capsules daily until blood hemoglobin level is normal. Thereafter the therapy is continued at a dose of 1 capsule/day, at least until the delivery, for replenishment of iron reserves.

In therapy and prevention of latent iron deficiency, as part of complex therapy, patients should take 1 capsule daily.

**CONTRAINDICATIONS**

- hypersensitivity to any component of the drug;
- high body iron levels (e.g., in hemochromatosis, hemosiderosis);
- impairment of iron utilization (lead anemia, sideroblastic anemia, thalassemia);
- non-iron deficiency anemias (hemolytic anemia, megaloblastic anemia, anemia induced by vitamin B<sub>12</sub> deficiency);
- children under the age of 12 (due to absence of clinical data).

Administration with caution: in gastric and duodenal ulcers, inflammatory diseases of the intestine (enteritis, diverticulitis, ulcerative colitis, Crohn`s disease).

**SIDE EFFECTS**
Gastrointestinal system disorders: very rarely—signs of GT irritation (including sensations of fullness and pressure in epigastrium, nausea, constipation or diarrhoea). Stool may become dark due to excretion of unabsorbed iron (clinically irrelevant).
Other disorders: allergic reactions to folic acid.

**SPECIAL INDICATIONS**
Concomitant administration of other polyvitamin and mineral complexes is not recommended in order to avoid overdose.
The drug should be taken 1 hour before or 2 hours after ingestion of milk, dairy products, complex-forming agents (bicarbonates, carbonates, oxalates, phosphates, tetracyclines and copper).
Possibility of copper deficiency development should be considered in case of prolonged administration of zinc preparations. If treatment course exceeds 3-4 months, copper preparations should be prescribed.
Avoid consumption of ethanol-containing drinks.

**INFLUENCE ON ABILITY TO DRIVE AND OPERATE OTHER MECHANISMS**
There are no warnings regarding administration of the drug by drivers and people working with potentially dangerous mechanisms.

**PREGNANCY AND LACTATION**
If necessary, the drug can be used in pregnancy and lactation.

**PEDIATRIC USE**
No data on efficiency and safety of Rotafer Plus in children under 12 are available. Administration of the drug in this age group is not recommended.

**DRUG INTERACTIONS**
The drug should not be prescribed concomitantly with antacids containing salts of aluminium, magnesium and calcium, as these decrease absorption of iron.
Do not administer the drug simultaneously with injectable iron-containing preparations (GI absorption of iron decreases). Treatment with oral iron-containing drugs should be initiated at least 1 week after the last injection.
Iron reduces absorption of tetracycline preparations.
Pyridoxine decreases the therapeutic effect of levodopa.
Zinc reduces absorption of tetracyclines and copper and is pharmaceutically incompatible with salts of silver and lead, quinine and citral (forms poorly soluble compounds). Thiazide diuretics increase excretion of zinc in urine. Thiosemicarbazone and 5-fluorouracil act as antagonists of vitamin B₃ and decrease its efficiency. Antacids inhibit absorption of vitamin B₁. Long-term administration of high doses of folic acid may decrease concentration of vitamin B₁₂.

**OVERDOSE**
No reports of overdose have been made.