Innovative Microencapsulated Technology

Ferfer Gro®

Fast Acting Iron+ Vitamin C & B12

Quickly dissolves in the mouth

Food Supplement

SUPPLEMENT

Each 0.82g sachet contains:
Elemental Iron.....10 mg
Vitamin C.....30mg
Vitamin B12.....0.9mcg
(PharmEvo Specs.)

DESCRIPTION

Ferfer Gro is a food supplement for children above 3 years containing iron pyrophosphate microencapsulated in liposomal form with essential, vitamins including Vitamin C and Vitamin B12. Ferfer Gro directly dissolves in the mouth without the need for water. The technology of liposomal microencapsulation, allows daily iron supplementation without any of the typical side effects of conventional oral iron supplements, such as heartburn, diarrhea, constipation, nausea and discolouring of the mucous membranes and of the stools, which increases patient compliance. It has no metallic taste or smell, does not discolour mucous membrane and has excellent tolerability. Besides the excellent tolerability, microencapsulated iron allows a greater and more rapid absorption of iron which raises hemoglobin and ferritin levels rapidly.

PHARMACOLOGICAL PROPERTIES

Mechanism of action

Ferfer Gro is a multi-ingredient supplement containing micro-encapsulated iron pyrophosphate (to form liposomes), vitamin C and vitamin B12 which are valuable for the control of nutritional deficiencies or increased organic needs of iron. The iron aids in the formation of hemoglobin and red blood cells and vitamin C improves the absorption of iron. Vitamin B12, along with all the other components, helps to reduce fatigue and strain.

THERAPEUTIC USES

FerFer Gro is as daily iron supplement for children above 3 years of age with vitamin B12 and Vitamin C for iron deficiency condition, in the periods of rapid growth & with increased physical and mental activity. Iron promotes growth processes, supports immune system function and prevents fatigue. Strenuous physical activity increases the demand for iron. Iron deficiencies result in the loss of appetite, which can cause deficiencies of essential vitamins and minerals.

RDAs for Iron

Age	Male	Female	Pregnancy	Lactation
Birth to 6 months	0.27 mg*	0.27 mg*		
7–12 months	11 mg	11 mg		
1–3 years	7 mg	7 mg		
4–8 years	10 mg	10 mg		
9–13 years	8 mg	8 mg		
14–18 years	11 mg	15 mg	27 mg	10 mg
19–50 years	8 mg	18 mg	27 mg	9 mg
51+ years	8 mg	8 mg		

RDAs for Vitamin B12

Age	Male	Female	Pregnancy	Lactation
0–6 months*	0.4 mcg	0.4 mcg		
7–12 months*	0.5 mcg	0.5 mcg		
1–3 years	0.9 mcg	0.9 mcg		
4–8 years	1.2 mcg	1.2 mcg		
9–13 years	1.8 mcg	1.8 mcg		
14+ years	2.4 mcg	2.4 mcg	2.6 mcg	2.8 mcg

RDAs for vitamin C

Age	Male	Female	Pregnancy	Lactation
0–6 months	40 mg*	40 mg*		
7–12 months	50 mg*	50 mg*		
1–3 years	15 mg	15 mg		
4–8 years	25 mg	25 mg		
9–13 years	45 mg	45 mg		
14–18 years	75 mg	65 mg	80 mg	115 mg
19+ years	90 mg	75 mg	85 mg	120 mg
Smokers	Individuals who smoke require 35 mg/day more vitamin C than nonsmokers			

*Adequate Intake

DOSAGE AND ADMINISTRATION

1 -2 sachets daily or as prescribed by physician as per the level of deficiency.

CONTRAINDICATIONS

- Hypersensitivity to iron salts, Ascorbic acid (Vitamin C) or any form of Vitamin B12.
- Hemosiderosis, hemochromatosis, or anemias other than iron-deficiency anemia (due to iron component)
- Hyperoxaluria (due to Vitamin C component)

WARNINGS AND PRECAUTIONS

- Do not exceed the recommended daily dose.
- Keep out of reach of children to prevent accidental overdose.
- Pregnant or breast feeding women should consult healthcare professional before use.
- Food supplements are not intended as substitutes for a varied diet and a healthy lifestyle.
- It contains aspartame, a source of phenylalanine. It contains polyols and due to its excessive consump -tion may cause laxative effects.
- Iron supplements must not be administered to patients receiving repeated blood transfusions; concomitant parenteral iron; haemochromatosis and other iron overload syndromes.
- Administer with caution in patients with haemolytic anaemia, haemoglobinopathies, iron storage or iron absorption diseases, existing gastrointestinal disease.
- Before starting treatment, it is important to exclude any underlying cause of the anaemia (e.g. gastric erosion, colonic carcinoma).
- Please consult your pharmacist/ doctor if symptoms persist/ worsen.
- Accidental overdose of iron containing products is a leading cause of fatal poisoning in children under the age of six (6) years. In case of accidental overdose, call a doctor or refer to healthcare facility immediately.
- Iron salts should be used with caution in active peptic ulcer disease and inflammatory bowel disease particularly ulcerative colitis because iron salts can cause GI irritation. Caution is also needed in intestinal strictures and diverticulitis.
- Iron salts should be used with caution in the elderly as there may be a risk of fecal impaction.
- Large doses of Vitamin C may cause hemolysis in patients with G6PD deficiency. However, this product contains only 30 mg of Vitamin C.
- Vitamin B12 may cause hypokalemia and should also be used with caution in patients with Polycythemia Vera.

ADVERSE REACTIONS

Typical adverse reactions with iron supplements include heartburn, gastro-intestinal irritation, nausea, vomiting, bloating, epigastric pain, abdominal cramps, early satiety, loss of appetite, constipation, diarrhea, coloring of mucous membranes and of stools etc. The rate of these adverse effects is significantly reduced with Fefer Gro due to the presence of iron in microencapsulated liposomal form.
The low doses of Vitamin B12 and Vitamin C in Ferfer Gro (0.9 mcg and 30 mg respectively) are not associated with any adverse effects.

DRUG INTERACTIONS

- Absorption of oral iron is reduced by calcium, magnesium, zinc salts and tetracycline.
- Iron may reduce the absorption of other drugs such as quinolone antibiotics (give at least 2 hours apart), bisphosphonates, tetracyclines, levodopa, entacapone, eltrombopag. (administer at least 4 hours apart), mycophenolate, penicillamine, levothyroxine and zinc.
- There are no well- known interactions for Vitamins C and B12.

OVERDOSAGE

Iron is toxic to the GI system, cardiovascular system, and CNS. Specific mechanisms are unclear, but excess free iron is inserted into enzymatic processes and interferes with oxidative phosphorylation, causing metabolic acidosis. Iron also catalyzes free radical formation, acts as an oxidizer, and, when plasma protein binding is saturated, combines with water to form iron hydroxide and free H+ ions, compounding the metabolic acidosis. Coagulopathy may appear early because of interference with the coagulation cascade and later because of liver injury.
Toxicity depends on the amount of elemental iron that has been ingested. Children may show signs of toxicity with ingestions of 10-20 mg/kg of elemental iron.
Symptoms of iron poisoning occur in 5 stages; however, symptoms and their progression vary significantly. The severity of stage 1 symptoms usually reflects the overall severity of poisoning; late-stage symptoms develop only if stage 1 symptoms are moderate or severe. If no symptoms develop within the first 6 h after ingestion, risk of serious toxicity is minimal. If shock and coma develop within the first 6 h, the mortality rate is about 10%.

Treatment

The first step in treating a case of acute iron toxicity is to provide appropriate supportive care, with particular attention paid to fluid balance and cardiovascular stabilization. Vital signs and mental status of patients with iron overdose should be monitored. Serial serum iron levels, Complete blood counts and metabolic panel should be obtained
Initial treatment should also address the issue of preventing further absorption of iron by the GI tract by performing whole bowel irrigation with polyethylene glycol 1 to 2 L/h for adults or 25 to 40 mL/kg/h for children. Magnesium hydroxide antacids (5 mg magnesium hydroxide per gram of elemental iron ingested) decrease serum iron concentrations following a simulated overdose
All patients with more than mild gastroenteritis are hospitalized. Patients with severe toxicity (metabolic acidosis, shock, severe gastroenteritis, or serum iron level > 500 µg/dL) - treated with IV deferoxamine to chelate free serum iron. Deferoxamine may be administered intramuscularly or intravenously. The intramuscular route is not recommended because it is painful and less iron is excreted compared with the intravenous route. Deferoxamine is infused at rates up to 15 mg/kg/h IV, can be titrated up to a rate of 40 mg/kg/hour for patients with severe poisoning. Because both deferoxamine and iron poisoning can decrease BP, patients receiving deferoxamine require IV hydration. No clear end point of therapy is noted; however, indications for cessation include significant resolution of shock and acidosis. Infusion of deferoxamine for 6-12 hours has been suggested for moderate toxicity. For severe toxicity, administer deferoxamine for 24 hours. Because these end points are arbitrary, observe the patient for the recurrence of toxicity 2-3 hours after the deferoxamine has been stopped.
Hemodialysis is not effective in removing iron, but may be necessary to remove deferoxamine-iron complexes in patients with renal insufficiency. Consider exchange transfusion in those patients with a serum iron exceeding 1000 mcg/dL who clinically deteriorate despite supportive care and intravenous chelation therapy

PRESENTATION

FerFer Gro: Pack of 30 Sachets

INSTRUCTIONS

Use as advised by the physician.
Keep out of the reach of children.
Protect from light, heat and moisture.
Store below 30°C.
For suspected adverse drug reaction, report at reports@pharmevo.biz

DI- FERO 00 08/2023
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DRAP Company Enlistment Number : 00712
DRAP Product Enlistment Number : 00712.0004