

FERTONIC TABLET

FERTONIC-F SYRUP

FERTONIC SYRUP

COMPOSITION:

FERTONIC-F Syrup

Each 5ml contains:

Iron (III) Hydroxide Polymaltose Complex eq. to Elemental Iron..... 100mg
Folic Acid.....0.35mg
(Innovator's Specification)

FERTONIC Syrup

Each 5ml contains:

Iron (III) Hydroxide Polymaltose Complex eq. to Elemental Iron.....50mg
(Innovator's Specification)

FERTONIC Tablet

Each chewable tablet contains:

Iron (III) Hydroxide Polymaltose Complex eq.to Elemental Iron.....100mg
(Innovator's specification)

DESCRIPTION:

The Iron (III) hydroxide polymaltose comolex (IPC) is a water-soluble iron oxide, macromolecular complex of polynuclear iron (III) hydroxide that has distinct advantages over conventional iron preparations. As opposed to conventional iron salts that contain iron in ferrous form, iron polymaltose complex contains iron in ferric form. Ferrus releases an electron in the gastrointestinal tract before converting into ferric form. This electron is responsible for the formation of free radicals. Since iron is present in ferric form in iron polymaltose complex, so free radical do not form. This is the reason for its better safety profile as compared to ferrous salts. The bioavailability of IPC is better than ferrous iron. It produces less gastric irritation than ferrous iron.

Iron deficiency is particularly frequent during pregnancy and lactation, the content of folic acid is according to the WHO guideline. Folic acid, also known as folate or Vitamin B9, is a member of the B vitamin family and an essential cofactor for enzymes involved in DNA and RNA synthesis. Folic acid is particularly important during phases of rapid cell division, such as infancy, pregnancy, and erythropoiesis, and plays a protective factor in the development of cancer. As humans are unable to synthesize folic acid endogenously, diet and supplementation is necessary to prevent deficiencies. Inadequate folate levels can result in a number of health concerns including cardiovascular disease, anemia, cognitive deficiencies, and neural tube defects (NTDs). Folic acid is an important vitamin for the development of the unborn child.

MODE OF ACTION:

The drug is absorbed in the small intestine, primarily in the duodenum and jejunum. Absorption occurs via a controlled, active mechanism. No passive diffusion takes place, which ensures that practically no unbound (to transferrin) iron reaches the blood. The absorbed iron is primarily stored in the liver as ferritin (protein used for iron storage) and subsequently

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made available to the body for various functions, primarily for incorporation into the red blood cells hemoglobin, thereby transporting oxygen in the blood.

Folic acid, as it is biochemically inactive, is converted to tetrahydrofolic acid and methyltetrahydrofolate by dihydrofolate reductase. These folic acid congeners are transported across cells by receptor-mediated endocytosis where they are needed to maintain normal erythropoiesis, synthesize purine and thymidylate nucleic acids, interconvert amino acids, methylate tRNA, and generate and use formate. Using vitamin B12 as a cofactor, folic acid can normalize high homocysteine levels by remethylation of homocysteine to methionine via methionine synthetase.

INDICATIONS:

Iron hydroxide polymaltose comolex is primarily indicated for the prevention & treatment in conditions like iron deficiency, iron deficiency anaemia, Macrocytic anaemia and for prevention of folic acid deficiency during pregnancy and lactation. It can also be given in adjunctive therapy as an alternative drug of choice in anoxic seizures, cough. The liquid formulation is especially for the prophylactic therapy of iron deficiency to cover the recommended daily dietary allowances for children adolescents & during pregnancy & lactation.

DOSEAGE & ADMINISTRATION:

Fertonic Tablet

Adults & nursing women:

1-3 tablets daily for manifest iron deficiency and one tablet daily for latent iron deficiency.

Fertonic Syrup

Adults and children over 12 years of age:

For prevention of anemia: 1-2 teaspoonfuls daily.

For treatment of anemia: 2-4 teaspoonfuls daily.

Children's dosage:

For prevention of anemia: 1 mg (0.1 ml)/kg body weight daily.

Do not exceed a daily dosage of 15 mg for infants up to 2 years of age.

For treatment of anemia: up to 2 mg (0.2 ml)/kg body weight 3 times daily.

Fertonic-F Syrup

Adults

5 mL 2 to 3 times daily.

Children

5 mL 1 to 2 times daily.

Infants

Begin with 2.5 mL daily and gradually increase to 5 mL daily.

PHARMACOKINETICS:

After administration, the maximum absorption capacity is reached already after 30 minutes and continuously increasing absorption can be observed over 24 hours. The non-absorbed iron is excreted via

the stool.

Folic acid is administered orally and parenterally. Folic acid congeners are extensively bound to plasma proteins and are distributed throughout the body including the CSF. They also appear in breast milk. After administration of small doses, reduction and methylation of folic acid to methyl tetrahydrofolate occurs in the liver. Following large doses, folic acid may appear unchanged in the plasma. Active forms of folic acid are reabsorbed through enterohepatic recirculation. Folic acid is eliminated primarily renally as metabolites. When body stores become saturated, excess folic acid is excreted unchanged in the urine.

PRECAUTIONS:

Absorption of iron is hampered when used concomitantly with calcium or chloramphenicol. One should also be careful while giving IPC with antacids which decrease the absorption of iron. Iron can reduce the bioavailability of methyl dopa, bisphosphonates and fluoroquinolones.

In case of anaemia due to infection or malignancy, the substituted iron is stored in the reticulo-endothelial system from which it is mobilized and utilized only after correcting the primary disease. Discontinue iron salts if symptoms of intolerance appear. Occasional gastrointestinal (GI) discomfort, as nausea may occur which can be minimized by taking it with meals.

Before using Iron (III) hydroxide polymaltose complex / folic Acid, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug.

Administration of Folic acid alone is improper therapy for pernicious anemia and other megaloblastic anemia in which vitamin B12 is deficient.

- Avoid alcohol consumption, especially if having alcoholic cirrhosis.
- Folic acid in doses above 0.1 mg daily may obscure the diagnosis of pernicious anemia.
- Risk of obscuring the diagnosis of pernicious anemia.

SIDE EFFECTS:

The severe or irreversible adverse effects of Iron hydroxide polymaltose comolex, which give rise to further complications include Convulsions, Hepatic failure.

Iron hydroxide polymaltose comolex produces potentially life-threatening effects, which include anaphylactic reactions, circulatory collapse, and Circulatory collapse which are responsible for the discontinuation of Iron Hydroxide Poly Maltose Complex therapy.

The signs and symptoms that are produced after the acute over dosage of Iron hydroxide polymaltose comolex include vomiting, tachycardia, diarrhea, convulsions, coma, drowsiness, drowsiness, metabolic acidosis, hypoglycemia, abdominal pain, epigastric pain, hyperventilation, restlessness, GI

hemorrhage, cyanosis, hypotensive collapse, hemorrhagic gastroenteritis, hepatic failure, coagulation disorder, Haemochromatosis, endocrine dysfunction.

The symptomatic adverse reactions produced by Iron hydroxide polymaltose comolex are more or less tolerable and if they become severe, they can be treated symptomatically, these include dizziness, nausea, diarrhea, constipation, sweating, epigastric discomfort, flushing, taste disturbance, nausea and vomiting, heart burn, GI irritation, sense of repletion, dizziness, Black color faces, tooth discoloration, local inflammation, joint & muscle pain.

DRUG INTERACTIONS:

Polysaccharide iron complex should be used with caution with medications like ciprofloxacin, levofloxacin, moxifloxacin, minocycline, doxycycline, levothyroxine, ibandronate, and alendronate. Polysaccharide iron complex can slow down the absorption of such medications and may reduce their therapeutic effects.

CONTRAINDICATIONS:

Fertonic/Fertonic-F is contraindicated in conditions like

Hypersensitivity to any component of product

- Hemochromatosis.
- Hemolytic anaemia.
- Haemochromatosis.
- Haemosiderosis.
- Hemoglobinopathy.
- Inflammatory bowel disease.
- Blood transfusion.
- Sivero-acrostic anemia.
- Thalassemia.

STORAGE & INSTRUCTIONS:

Store between 15-25°C.

Protect from heat, sunlight and moisture.

Keep away from the reach of children.

To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED:

FERTONIC Tablet 100mg

10's, 30's tablets.

FERTONIC Syrup

60ml, 120ml

FERTONIC-F Syrup

60ml, 120ml

خوراک و طریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو 15-25°C ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔

دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:

PHARMA SOL
PRIVATE LIMITED
549, Sundar Industrial Estate,
Lahore, Pakistan.