For the use of Registered Medical Practitioners or a hospital or a laboratory only

IROFAS SYRUP

COMPOSITION:
Each 5 ml contains:

Iron (III) hydroxide polymaltose Eq to 50 mg Elemental Iron	
Folic Acid BP	2mg
Ascorbic Acid	100mg

Product Description :
Dark brown syrupy liquid.
Pharmacodynamics :
Iron (III) Hydroxide Polymaltose complex (IPC) is a complex of ferric hydroxide and isomaltose. It is highly water-soluble over a broad pH-range, thus facilitating the absorption in the gut.
Iron is indicated for the treatment or prevention of iron-deficiency anaemia. Iron deficiency and iron-deficiency anaemia can, if left untreated, have adverse effects on both physical and mental capacity and on performance. The goal of iron deficiency anaemia therapy is to supply sufficient iron to replenish haemoglobin and storage iron deficit.
Pharmacokinetics :
Iron is irregularly and incompletely absorbed from the gastrointestinal tract, the main sites of absorption being the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach and by some dietary acids (such as ascorbic acid) and occurs more readily when the iron is in the ferrous state or is part of the haem complex (haem-iron).
Absorption is also increased in conditions of iron deficiency or in the fasting state but is decreased if the body stores are overloaded. Normally only about 5 to 15% of the iron ingested in food is absorbed. Apart from haemorrhage, iron is mainly lost from the body in the faeces, urine, from skin, and sweat, but the total loss is very small. IPC is equally bioavailable as iron salts at comparable doses.
Indication : Treatment of latent Iron deficiency and Iron deficiency anaemia
Recommended Dose
Manifestation of Iron deficiency-
Adult, nursing women & children >12 yr.:1 0-20 mL daily
1-12 yr.: 5-10 mL daily
Infant up to 1 yr.: 2.5-5 mL daily
Pregnant women: 20-30 mL dail y
Latent Iron deficiency-
Adult, nursing women & children >12 yr.:5 -10 mL daily
1-12 yr.: 2.5-5 mL daily
Pregnant women: 10 m L daily
Irofas syrup should be taken before meals. Based on the daily dose, Irofas syrup can also be given in divided doses.
Route of Administration :
ORAL
Contraindications :
Irofas Syrup is contraindicated in case of
- Allergy to iron or any of the ingredients in Irofas Syrup
- hemosiderosis, hemochromatosis, thalassemia, sideroblastic anaemia, chronic haemolysis, or lead-induced anaemia.
- patients receiving repeated blood transfusions.

Warnings and Precautions :
The excessive and prolonged use or the combination with other ferrous preparations can induce iron intoxication.
This formulation must be administered with caution to epileptic patients under treatment.
Interactions with Other Medicaments :
Following precaution should be taken while taking Irofas Syrup:
- Iron absorption is impaired when associated with anti-acidity stomach drugs.
- The concomitment administration of tetracycline reduces the resorption (a suitable interval of 2 or 3 hours is therefore required between the intakes).
- Iron salts reduce the absorption and bioavailability of other drugs;among them the levodopa, the methyldopa, the penicillamine and fluoroquinolones like ciprofloxacin and ofloxacin.
- Some food components like phytines (coming from cereals) or phosphates can generate insoluble compounds with iron.
- Zinc salts can reduce absorption of iron.
- An excessive consumption of tea can inhibit the absorption of iron.
- The resorption of folic acid is reduced by ethanol and phenytoin.
- Barbiturics, cycloserine and oral contraceptives induce a decrease in the plasma concentration of folic acid.
- Folic acid antagonists such as methotrexate, pyrimethamine, trimethoprim and triamterene can induce anaemia.
- Folic acid has an antagonist action with sulfamides.
- Some tuberculostatic drugs can interfere with the folic acid action.

Pregnancy and Lactation :
Irofas Syrup does not represent any risk for pregnant and breastfeeding women at prescribed doses.
Side Effects
In addition to its desired action, this medication may cause some side effects, notably:
- It may cause constipation- to prevent this, plenty of water or juice and more dietary fibre should be taken.
- It may cause nausea or rarely vomiting
- It may give stool a black colour

Each person may react differently to a treatment. If one think this medication may be causing side effects (including those described here, or others), doctor or pharmacist should be consulted.
Symptoms and Treatment of Overdose :
Iron (III) hydroxide Polymaltose has a low toxicity. The preparation is well tolerated and has a minimal risk of accidental overdosing. Irofas syrup should not be used more than prescribed dose. Overdosage can cause acute iron overloading which may manifest itself as haemosiderosis. Iron overload refers to the gradual build up too much iron in the body. It is caused by the body's regulatory system failing to keep iron levels within healthy limits. For most people, iron overload is not a concern. However, it is a problem for those who are genetically predisposed to excessive absorption of iron from digestive tract. Early symptoms of iron poisoning may include stomach pain, nausea and vomiting. Gradually, the excess iron accumulates in internal organs, causing potential fatal damage to the brain and liver. Early recognition and treatment is crucial for a better outcome. If it is suspected that overdosing with Irofas syrup has been done, immediate visit to the emergency department of the closest hospital or nursing home is recommended. Carry medicine box, container or label with you to help doctors with necessary information.
Storage Condition :
Store below 30^0 C. Keep the medicine out of the reach of children.
Shelf Life :
36 months
ATC Code B03AE02 :
IRON, MULTIVITAMINS AND FOLIC ACID

NAME & ADDRESS OF MANUFACTURER
Gracure Pharmaceuticals Ltd.
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