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What is *IROFAS Syrup* used for

IROFAS Syrup contains Iron (III) Hydroxide Polymaltose Complex, Folic Acid and Ascorbic Acid. It is used for treatment of latent Iron deficiency and Iron deficiency anaemia.

How *IROFAS Syrup* works

IROFAS Syrup is involved in the formation and functioning of red blood cells.

Before you use *IROFAS Syrup*

-When you must not use it

- If you are allergic to iron or any of the ingredients in *IROFAS Syrup*.
- If you are having hemosiderosis, hemochromatosis, thalassemia, sideroblastic anaemia, chronic haemolysis, or lead-induced anaemia.
- If you are receiving repeated blood transfusions.

Do not use this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using *IROFAS Syrup*.

-Before you start to use it

Please make sure you have understood the explanation given by your doctor or pharmacist before taking this medicine. Speak to your doctor/pharmacist if you have one of following conditions:

- If you are under epileptic treatment.
- If you have hemosiderosis, hemochromatosis, thalassemia, sideroblastic anaemia, chronic haemolysis, or lead-induced anaemia.

-Taking other medications

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription, herbal medicines, dietary supplements or vitamins. This is especially important if you take one of the following medicines:

- other ferrous preparations
- anti-acidity stomach drugs
- tetracycline
- levodopa
- methyl dopa
- penicillamine
- fluoroquinolones like ciprofloxacin and ofloxacin
- ethanol
- phenytoin
- barbiturics
- cycloserine
- oral contraceptives
- methotrexate
- pyrimethamine
- trimethoprim
- triamterene
- sulfamides
- tuberculostatic drugs
- zinc supplements

Pregnancy and breast-feeding
IROFAS Syrup does not represent any risk for pregnant and breastfeeding women at prescribed doses.

How to use *IROFAS Syrup*

-How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Using this medicine:

- Take this medicine by oral route only.
- Always shake the bottle thoroughly before use.
- Use the 10 ml cup in the pack to measure the dose.

Precaution should be taken while taking *IROFAS Syrup* with some food components like phytines (coming from cereals) or phosphates can generate insoluble compounds with iron. An excessive consumption of tea also can inhibit the absorption of iron.

The recommended dose for Manifestation of Iron deficiency:

Adult, nursing women & children >12 yr.: 10-20 mL daily
1-12 yr.: 5-10 mL daily
Infant up to 1 yr.: 2.5-5 mL daily
Pregnant women: 20-30 mL daily

The recommended dose for Latent Iron deficiency:

Adult, nursing women & children >12 yr.: 5-10 mL daily
1-12 yr.: 2.5-5 mL daily
Pregnant women: 10 mL daily

IROFAS Syrup should be taken before meals. Based on the daily dose, *IROFAS Syrup* can also be given in divided doses.

-When to use it

Use as directed by your doctor or pharmacist.

-How long to use it

Continue taking *IROFAS Syrup* for as long as your doctor recommends.

-If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

-If you use too much (overdose)

If you (or someone else) accidentally take too much of *IROFAS Syrup*, you should tell your doctor at once or contact the nearest accident and emergency department.

While you are using it

-Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *IROFAS Syrup*.

Tell your doctor immediately if you become pregnant while taking this medication.

-Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *IROFAS Syrup* to anyone else, even if they have the same symptoms or condition as you.

-Things to be careful of

Driving and using machines

None known

Side effects

Like all medicines, *IROFAS Syrup* can cause side effects, although not everybody gets them. Tell your doctor or pharmacist if you notice any of the following side effects:

- constipation
- nausea or rarely vomiting
- stool a black colour

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Consumer -> Reporting -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of *IROFAS Syrup*

-Storage

Store below 30°C.

Keep the medicine out of reach of children.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Dark brown syrupy liquid.

-Ingredients

- Active ingredient(s)
 - Iron III Hydroxide
 - Polymaltose
 - Folic Acid
 - Ascorbic Acid
- Inactive ingredient(s)
 - Xanthan gum
 - Liquid Sorbitol
 - Liquid Glucose
 - Sodium Benzoate
 - Sodium Methyl Hydroxybenzoate
 - Sodium Propyl Hydroxybenzoate
 - Disodium Edetate
 - Saccharin Sodium
 - Essence Raspberry
 - Colour Ponceau-4 R Supra
 - Sodium Hydroxide (Pellets)
 - Purified water

-MAL number: MAL19086011X

Manufacturer

Gracure Pharmaceuticals Ltd.
E-1105, Industrial Area,
Phase-III Bhiwadi,
Alwar (Rajasthan),
India.

Product Registration Holder

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