SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of finished pharmaceutical product:

IROFAS SYRUP

2. Qualitative and quantitative composition:

a) Qualitative Composition

Product / Generic Name : IROAFS SYRUP

Label Claim **:** Each 5 ml contains:
Iron (III) hydroxide polymaltose
Eq. to elemental iron…..... 50 mg
Folic Acid BP .....2 mg
Ascorbic Acid BP .....100 mg

b) Quantitative Composition

Product / Generic Name : IROAFS SYRUP

Label Claim **:** Each 5 ml contains:
Iron (III) hydroxide polymaltose
Eq. to elemental iron….....50 mg
Folic Acid BP .....2 mg
Ascorbic Acid BP.....100 mg

M. L. No. **:** RAJ/ No. 1639

Batch Size **:** 26,266 Bottles (3940.0 Liters)

S. No.	Name of Substance
1.	Iron (III) Hydroxide Polymaltose eq. to elemental Iron
2.	Folic Acid BP*
3.	Ascorbic Acid**
4.	Xanthan Gum
5.	Liquid Sorbitol
6.	Liquid Glucose
7.	Sodium Benzoate
8.	Sodium Methyl Hydroxybenzoate
9.	Sodium Propyl Hydroxybenzoate
10.	Disodium Edetate
11.	Saccharin Sodium
12.	Essence Raspberry No. 1
13.	Colour Ponceau-4 R Supra
14.	Sodium Hydroxide Pellets
15.	Sodium Hydroxide Pellets***
16.	Purified water

3. Pharmaceutical form:

Oral Syrup

4. Clinical particulars:

4.1 Therapeutic indications:

•Curative treatment of asiderotic anaemia (minimum 4 to 6 months of treatment in association with an etiologic treatment).

•Preventive treatment of iron-deficiency in exposed subjects: pregnant women, unbalanced food diets (old patients, vegetarians, vegetaliens, mental anorexia), chronic bleeding.

•Megaloblastic anaemia by lack of folic acid.

•Chronic disorder of intestinal absorption (malabsorption, celiac disease, strong digestive resection).

•Lack of folate: malnutrition, chronic alcoholism.

4.2 Posology and method of administration:

Adults and children over 2 years old

Adults: Treatment: 10 ml syrup to be taken 2-3 times/ day. After hemoglobin becomes normal, come back with the supplementation in meal 3 to 6 months.

Children: Supplement in meal: Children below 12 months: 3-6 mg/kg/day in 1 or 2 intakes during at least 4 to 6 months in association with etiologic treatment.

Children from 1 -10 years old: 6-10 mg/ kg/ day iron equivalent to 5 - 10 ml syrup.

The intake is based on the iron dosage in the body

Pregnant women: 10 ml syrup to be taken 1-2times/ day

4.3 Contraindications:

- Martial overload.
- Isolated use in vitamin B12 deficiency.
- Sensitivity to one of the components.
- Megaloblastic anaemia without diagnosis.

4.4. Special warnings and precautions for use:

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.

Precautions of use

IROFAS treatment requires first a causal diagnostic.

In order to avoid administering albendazole during early pregnancy, women of childbearing age should initiate treatment during the first week of menstruation or after a negative pregnancy test.

4.5 Interaction with other finished pharmaceutical products and other forms of interactions:

Iron absorption is impaired when associated with anti-acidity stomach drugs.

• The concomitant 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 ciprofloxacine and ofloxacine.

• Some food components like phytines (coming from cereals) or phosphates 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 phenytoine.

•Barbiturics, cycloserine and oral contraceptives induce a decrease in the plasma concentration in folic acid.

•Folic acid antagonists such as methotrexate, pyrimethamine, trimethoprime and triamterene can induce anaemia.

•Folic acid has an antagonist action with sulfamides.

• Some tuberculostatic drugs can interfere with folic acid action.

4.6 Use during pregnancy and lactation:

IROFAS does not represent any risk for pregnant and breastfeeding women at prescribed doses.

4.7 Effects on ability to drive and use machines:

There is negligible influence on the ability to drive and use machines.

4.8 Undesirable effects:

Like all medicines, IROFAS can have side effects. Gastro-intestinal irritation and abdominal pain with nausea and vomiting are rare. Other effects include diarrhoea or constipation. The faeces of patients taking iron salts may be coloured black.

4.9 Overdose (symptoms, emergency procedures, antidotes).

If you have taken too much IROFAS, contact immediately your doctor, your pharmacist or the poison units. Folic acid and vitamin C are relatively non toxic substances. Symptoms of intoxication due to an overdosage of iron are the followings: diarrhoea, nausea, blood-stained vomiting and shock. Immediate transfer to hospital is required. The treatment in hospital is based on gastro-intestinal evacuation and the antidote is the deferoxamine with symptomatic reanimation.

5. Pharmacological properties:

5.1 Pharmacodynamic properties

Therapeutic Category	: Haematinics
ATC Code	
Iron (III) hydroxide Polymaltose	: B03 AC 02
Folic Acid BP	: B03 BB 01
Ascorbic Acid BP	: G01 AD 03

Iron(III)hydroxide Polymaltose is the main component of haemoglobin, which transports oxygen and carbon dioxide to and from the lungs.

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.

Ascorbic acid (vitamin C) is a water-soluble vitamin. In humans, an exogenous source of ascorbic acid is required for collagen formation and tissue repair by acting as a cofactor in the posttranslational formation of 4-hydroxyproline in -Xaa-Pro-Gly- sequences in collagens and other proteins. Ascorbic acid is reversibly oxidized to dehydroascorbic acid in the body. These two forms of the vitamin are believed to be

important in oxidation-reduction reactions. The vitamin is involved in tyrosine metabolism, conversion of folic acid to folinic acid, carbohydrate metabolism, synthesis of lipids and proteins, iron metabolism, resistance to infections, and cellular respiration.

5.2 Pharmacokinetic properties

Iron(III)hydroxide Polymaltose: none known

Folic Acid: Onset: Peak effect: Oral: 0.5-1 hr.

Absorption: Rapidly absorbed mainly from the duodenum and jejunum.

Distribution: Extensively bound to plasma protein. Principal site of storage is the liver.

Metabolism: Undergoes conversion in the plasma and liver to the metabolically active 5-methyltetrahydrofolate.

Excretion: Via urine (as unchanged drug and metabolites). Removed by haemodialysis.

Ascorbic Acid: Absorption: Oral: Readily absorbed; an active process thought to be dose dependent Distribution: Large

Metabolism: Hepatic via oxidation and sulfation

Excretion: Urine (with high blood levels)

5.3 Preclinical safety data.

Not known

6. Pharmaceutical particulars:

6.1 List of Excipients

S. No.	Excipients	Specifications
1.	Xanthan Gum	BP
2.	Liquid Sorbitol (Non- crystallizing)	BP
3.	Liquid Glucose	BP
4.	Sodium Benzoate	BP
5.	Sodium Methyl Hydroxybenzoate	BP
6.	Sodium Propyl Hydroxybenzoate	BP
7.	Disodium Edetate	BP

8.	Saccharin Sodium	BP
9.	Essence Raspberry No. 1	IHS
10.	Colour Ponceau- 4 R (Supra)	IHS
11.	Sodium Hydroxide (Pellets)	BP
12.	Purified water	BP

6.2 Incompatibilities

None.

6.3 Shelf life

36 Months from the manufacturing date.

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

1 x 150 ml Amber coloured PET Bottle packed in unit carton along with package insert.

7. Marketing authorisation holder.

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8. Number(s) in the national register of finished product pharmaceutical products.

GRA/IND/004

05588/07178/REN/2019

9. Date of the first authorisation/renewal of the authorisation.

14/03/2016

Jan 4, 2021

10. Date of revision of the text.

Not Applicable