SUMMARY PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product:

FERICOR SYRUP

(Iron, Folic Acid and Cyanocobalamin Syrup)

2. Qualitative and Quantitative Composition:

Each 5 ml contains:
Ferric Ammonium Citrate USP: 234.29 mg
(equivalent to elemental Iron 41.0 mg)
Folic Acid BP: 1.5 mg
Cyanocobalamin BP: 50 mcg
Flavoured Syrupy Base: q. s.
Colour: Erythrosine and Caramel
Appropriate overages of vitamins added to compensate loss on storage

For a full list of excipients, see section 6.1

3. Pharmaceutical Form:

Syrup

Brown coloured syrupy liquid with Flavoured odour.

4. Clinical Particulars

4.1 Therapeutic indications:

- Iron deficiency anemia due to chronic blood loss, hook-worm infestation, inadequate intake of iron, etc.
- Dimorphic anemia due to deficiency of Iron, Folic Acid and/or Vitamin B12 (Cyanocobalamin)
- Anemia of pregnancy and lactation.
- Tonic in general weakness, lack of appetite, rundown conditions and convalescence.
- Post surgery and other debilitated states.

4.2 Posology and method of administration:

For ORAL use only

One tablespoonful (For therapeutic use) twice a day after meals will treat and maintain the average uncomplicated case of anaemia.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

Symptoms of iron intolerance.

4.4 Special warning and precautions for use:

Warnings: Prolonged administration in excess of the recommended dose as prescribed by the physician (one tablespoonful twice per day) may result in iron overload. Iron overloading and toxicity may occur in patients receiving both oral and parenteral administration of iron.

Special Precautions: Iron salts should not be given to patients receiving repeated blood transfusions or to patients with anaemias not produced by iron deficiency unless iron deficiency is also present. Care should be taken when given to patients with iron storage or iron-absorption diseases, haemoglobinopathies or existing gastro-intestinal disease.

4.5 Interaction with other medicinal products and other forms of Interactions

Iron salts and tetracycline absorption is diminished if taken concomitantly by mouth. Iron salts should be administered 3 hours before or 2 hours after the tetracycline. Concomitant ingestion of antacids and tea will also decrease the absorption of iron salts.
Iron salts may reduce the effects of Penicillamine. Quinolone anti-infective agent absorption is diminished if taken concomitantly by mouth with iron salts. Oral preparations should not be administered within two hours of quinolone agents.

4.6 Fertility, Pregnancy and lactation:

Pregnancy
Iron, Folic Acid and Cyanocobalamin Syrup can be used during pregnancy if clinically indicated.

Lactation
No adverse effects of Iron, Folic Acid and Cyanocobalamin Syrup have been shown in breastfed infants of treated mothers. Iron, Folic Acid and Cyanocobalamin Syrup can be used during breast-feeding if clinically indicated.

4.7 Effects on ability to drive and use machines.

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Side effects:

Some patients affected with pernicious anaemia may not respond to orally administered Vitamin B12 with Intrinsic Factor Concentrate and there is no known way to predict which patients will respond or which patients may cease to respond. Periodic examinations and laboratory studies of pernicious anaemia patients are essential and recommended.
Folic acid may obscure pernicious anaemia in that the peripheral blood picture may revert to normal while neurological manifestations may remain progressive. Haematinic syrup should not be relied on to correct the serious folic acid deficiency characterising sprue or the

malabsorption syndromes. In these conditions therapeutic amounts of folic acid should be administered.
Excessive doses of iron preparations may lead to toxicity in children. Adverse effects of iron administered in therapeutic doses may include gastro-intestinal discomfort, diarrhoea, vomiting, and constipation. Side-effects may be reduced by taking the medication with or immediately after food. As a result of iron therapy stools may become darkened or black in colour. Symptoms which may not appear for several hours include epigastric pain, diarrhoea, vomiting and haematemesis. Circulatory failure may follow if the diarrhoea and haemorrhage are severe. Hours or days later, after apparent recovery, metabolic acidosis, convulsions and coma may occur. If the patient survives, symptoms of acute liver necrosis may develop and may lead to death due to hepatic coma.

Reporting of suspected adverse reactions:
Healthcare professionals are requested to report any suspected adverse reactions to the National Regulatory Agents.

4.9 OVERDOSAGE

If any symptoms of intolerance occur the drug should be temporarily or permanently discontinued.

In acute poisoning desferrioxamine should be administered under the direction of a physician but preferably should not be administered during the 1st trimester of pregnancy. Alternatively, and preferably in the treatment during pregnancy and lactation empty the stomach by inducing emesis using a 1 to 5 % solution of sodium bicarbonate lavage. Fluid loss should be replaced by the I.V. administration of compound sodium lactate injection or Sodium Chloride and dextrose injection.

A dose of as little as 1g of iron should be considered toxic in children. Speed is essential here to block the absorption of iron.

5. Pharmacological Properties:

5.1 Pharmacodynamic Properties:

Pharmacotherapeutic group: Haematinics

ATC-code: B03AE01

Ferric Ammonium Citrate:
Ferric Ammonium Citrate contains between 16.5 % and 18.5 % of iron. It exerts haematinic action by being an essential constituent of haemoglobin. It is necessary for the oxidative process of living tissues. Ferric ammonium citrate is given by mouth as a source of iron for iron-deficiency anaemia. Ferric salts have not been preferred over ferrous salts as the ferric ion first requires reduction to ferrous form in the intestinal lumen. The bio-availability of iron from ferric salts is 3 to 4 times less than that of ferrous form. Ferric ammonium citrate (18 % elemental iron) is the most commonly used ferric salts.

Cyanocobalamin
Cyanocobalamin is an essential constituent for growth, cell reproduction, hematopoiesis, and nucleoprotein and myelin synthesis. Cyanocobalamin is converted in to coenzyme B12 in the tissues which is essential for conversion of methylmalonate to succinate and synthesis of Methionine from homocystine. It is also associated with fat and carbohydrate metabolism and protein synthesis. Cells characterized by rapid division such as epithelial cells, bone marrow, and myeloid cells appear to have greatest requirement of Cyanocobalamin.

Folic Acid
Folic acid reduced by enzymes folate reductase and dihydrofolate reductase and forms dihydrofolic acid tetrahydrofolic acid respectively. Tetrahydrofolic acid acts as a coenzyme which mediates a number of one carbon transfer reactions by carrying a methyl group as an adduct. It involves a number of reactions such as 1) conversion of homocysteine to Methionine.
2) Synthesis of thymidylate which is an essential constituent of DNA from methylene-tetrahydrofolic acid.
3) Conversion of serine to glycine by tetrahydrofolic acid and forms methylene-tetrahydrofolic acid.
4) To introduce carbon units at position 2 and 8 during de novo purine synthesis requires formyl-tetrahydrofolic acid and methenyl-tetrahydrofolic acid. 5) Generation and utilization of "formate pool". 6) For mediating formino group transfer in histidine metabolism. Folic acid is required to maintain normal erythropoiesis and nucleoprotein synthesis.

5.2 Pharmacokinetic Properties

Ferric ammonium citrate:
Absorption: Ferric is converted into ferrous form and it is absorbed in ferrous form. It is poorly absorbed in healthy individuals (about 10 %) but in patients suffering from iron deficiency anaemia up to 60 % dose is absorbed.
Distribution: Transported in a transferrin bound form in to bone marrow for incorporation in to haemoglobin.
Metabolism: Iron liberated by destruction of haemoglobin is reused by the body.
Excretion: Excretion of iron is minimal. Loss usually occurs in nails, faeces, urine, hair, sweat, and bile.

Cyanocobalamin
Absorption: Absorbed irregularly after oral administration and absorption depends on Ca and intrinsic factor. It is also administered subcutaneously and intramuscularly.
Distribution: Distributed into liver, bone marrow, and other tissues. It crosses the placenta and appears in breast milk.
Metabolism: It is metabolized in liver.
Excretion: In normal dosage it is reabsorbed from bile and a minute portion is excreted through urine, but the extra drug is excreted through urine.

Folic Acid
Absorption: Well absorbed orally
Distribution: Widely distributed in the body and highest concentration is seen in liver. It appears in the CSF and breast milk.
Metabolism: Metabolized into N-methyl tetrahydrofolic acid in liver.

Excretion: Extra drug is excreted unchanged in urine. A small portion of folate is lost by a combination of urinary and fecal excretion and oxidative cleavage of molecule.

5.3 Preclinical safety Data:

No further relevant information other than that which is included in other sections of the Summary of Product Characteristics.

6. Pharmaceutical Particulars:

6.1 List of excipients:

Sr. No.	Ingredients	Specification
1.	Creshmer RH 40	BP
2.	Sucrose	BP
3.	Sodium Methyl Paraben	BP
4.	Sodium Propyl Paraben	BP
5.	Liquid Sorbitol (70 %)	BP
6.	Liquid Glucose	USP
7.	Colour Caramel	USP
8.	Colour Erythrosine Supra	IH
9.	Sodium Hydroxide Pellets	BP
10.	Orange Crush Oil 11024 A BP	BP
11.	Disodium Edetate	BP
12.	Purified Water	BP

6.2 Incompatibilities:

Not Applicable

6.3 Shelf life:

24 Months

6.4 Special precautions for storage:

Store below 30°C. Protect from light.

Keep medicine out of reach of children.

6.5 Nature and contents of container:

Primary Packing: 200 ml hemp up shape PET bottle.

Secondary Packing: Such 1 bottle packed in a carton along with pack insert.

6.6 Special Precaution for Disposal and other handling:

None

7. Marketing Authorization Holder and Manufacturing Site Address::

Marketing Authorization Holder:

Company name : Signature Healthcare Limited

Address : The Eco Green Business Center (TILISI)
OFF A 104 NAIROBI-NAKURU HIGHWAY,
Ngecha, Chunga Mali Road
P.O BOX 66172 00800, Nairobi.

Country : KENYA

Phone No : 00-254-020-2556185/2556225

Fax : 00-254-020-2555811

E-Mail: info@signaturehealthcareltd.com, mohamediftikharsaeed@gmail.com, info@signaturehealthcareltd.co.ke

Name and address of Manufacture:

(Company) Name: CORAL LABORATORIES LIMITED

Address : Plot No. 57/1 (16),
Bhenslore, Dunetha,
Nani Daman-396 210, INDIA.
Tel No. : + 91-260-2263923, + 91-260-2263489
Email : exports@corallab.com, daman@corallab.com
Website : www.corallab.com

8. Marketing Authorization Numbers

CTD13452

9. Date of first Registration /renewal of the Registration:

06.05.2026

10. Date of revision of the text:

06.05.2026