

SUMMARY PRODUCT CHARACTERISTICS

1. Name of the Medicinal Product:

FERICOR (Iron, Vitamins and Mineral Capsules)

2. Quality and Quantitative Composition

Each hard gelatin capsule contains:

Ferrous Fumarate BP 305 mg

(equivalent to elemental Iron 100 mg)

Folic Acid BP 0.75 mg

Cyanocobalamin BP 5 mcg

Ascorbic Acid BP 75 mg

Zinc Sulfate Monohydrate BP 5 mg

Excipients q.s.

For a full list of excipients, see section 6.1

3. Pharmaceutical Form:

Capsule.

Size “0”, Hard Gelatin Capsules having brown cap and brown body containing greenish brown powder.

4. Clinical Particulars

4.1 Therapeutic indications:

1. As a therapeutic nutritional adjunct where the intake of vitamins and minerals is suboptimal, e.g. in the presence of organic disease such as malignancy and immune deficiency syndromes, such as AIDS.
2. As a therapeutic nutritional adjunct in conditions where the absorption of vitamins and minerals is suboptimal, e.g. malabsorption, inflammatory bowel disease and fistulae, short bowel syndrome and Crohn's disease, and where concurrent medication decreases vitamin and mineral absorption.
3. As a therapeutic nutritional adjunct in convalescence from illness, e.g. where anorexia or cachexia exists and following chemo- or radio-therapy.
4. As a therapeutic nutritional adjunct in convalescence from surgery, e.g. where nutritional intake continues to be inadequate.

5. As a therapeutic nutritional adjunct for patients on special or restricted diets, e.g. in renal diets and where several food groups are restricted in therapeutic weight reducing diets.
6. As a therapeutic nutritional adjunct where food intolerance exists, e.g. exclusion diets.
7. As an adjunct in synthetic diets, e.g. in phenylketonuria, galactosaemia and ketogenic diets.

4.2 Posology and method of administration:

As Directed by Physician

Oral

4.3 Contraindications

Haemochromatosis and other iron storage disorders.

4.4 Special warning and precautions for use:

Ferikor Capsules should be used as a vitamin and mineral source in conjunction with an energy providing diet suitable for individual patient requirements. No other vitamins, minerals or supplements should be taken with this preparation except under medical supervision.

Do not exceed the stated dose. Keep out of the reach of children.

Important warning: Contains iron. as overdose may be fatal

4.5 Interaction with other medicinal products and other forms of Interactions

Not known

4.6 Fertility, Pregnancy and lactation:

Ferikor Capsules can be given to pregnant and lactating women, provided the product is administered with the approval of their clinician.

4.7 Effects on ability to drive and use Machines:

None anticipated

4.8 Side effects:

Not known

Reporting of suspected adverse reactions:

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

4.9 OVERDOSAGE

No cases of overdosage due to Fericor therapy have been reported. If iron overdosage is suspected, symptoms may include nausea, vomiting, diarrhoea, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycaemia and metabolic acidosis may also occur. Treatment should be implemented immediately.

5. Pharmacological Properties:

5.1 Pharmacodynamic Properties:

The following account summarises the pharmacological effects of the vitamins and minerals in Fericor Capsules and describes the conditions caused by deficiency of these.

Iron

Iron, as a constituent of haemoglobin, plays an essential role in oxygen transport. It is also present in the muscle protein myoglobin and in the liver. Deficiency of iron leads to anaemia.

Folic Acid

Folic acid is reduced in the body to tetrahydrofolate which is a co-enzyme for various metabolic processes, including the synthesis of purine and pyrimidine nucleotides and hence in the synthesis of DNA. It is also involved in some amino acid conversion and in the formation and utilisation of formate. Deficiency of folic acid leads to megaloblastic anaemia.

Vitamin B12 (Cyanocobalamin)

Vitamin B12 is present in the body mainly as methyl cobalamin and as adenosyl cobalamin and hydroxocobalamin. These act as co-enzymes in the trans methylation of homocysteine to methionine; in the isomerisation of methylmalonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B12 interferes with haemopoiesis and produces megaloblastic anaemia.

Vitamin C (Ascorbic Acid)

Vitamin C cannot be synthesised by man therefore a dietary source is necessary. It acts as a cofactor in numerous biological processes including the hydroxylation of proline to hydroxyproline. In deficiency, the formation of collagen is, therefore, impaired. Ascorbic acid is important in the hydroxylation of dopamine to noradrenaline and in hydroxylations occurring in steroid synthesis in the adrenals. It is a reducing agent in tyrosine metabolism and

by acting as an electron donor in the conversion of folic acid to tetrahydrofolic acid is indirectly involved in the synthesis of purine and thymine. Vitamin C is also necessary for the incorporation of iron into ferritin. Vitamin C increases the phagocytic function of leucocytes; it possesses anti-inflammatory activity and it promotes wound healing. Deficiency can produce scurvy. Features include swollen inflamed gums, petechial haemorrhages and subcutaneous bruising. The deficiency of collagen leads to development of thin watery ground substances in which blood vessels are insecurely fixed and readily ruptured. The supportive components of bone and cartilage are also deficient causing bones to fracture easily and teeth to become loose. Anaemia commonly occurs probably due to Vitamin C's role in iron metabolism.

Zinc (Zinc Sulphate)

Zinc is a constituent of many enzymes and is, therefore, essential to the body. It is present with insulin in the pancreas. It plays a role in DNA synthesis and cell division. Reported effects of deficiency include delayed puberty and hypogonadal dwarfism.

5.2 Pharmacokinetic Properties

The following account describes the absorption and fate of each of the active constituents of Ferikor Capsules.

Ferrous Fumarate (Iron)

Iron is absorbed chiefly in the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach and if the iron is in the ferrous state as in ferrous fumarate. In iron deficiency, absorption is increased and, conversely, it is decreased in iron overload. Iron is stored as ferritin.

Folic Acid

Folic acid is absorbed mainly from the proximal part of the small intestine. Folate polyglutamates are considered to be deconjugated to monoglutamates during absorption. Folic acid rapidly appears in the blood where it is extensively bound to plasma proteins. Some folic acid is distributed in body tissues, some is excreted as folate in the urine and some is stored in the liver as folate.

Vitamin B12 (Cyanocobalamin)

Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. Vitamin B12 is taken up by the intestinal mucosa and held there for 2 - 3 hours.

Peak concentrations in the blood and tissues occur 8 - 12 hours after dosage with maximum concentrations in the liver within 24 hours. Cobalamins are stored in the liver, excreted in the bile and undergo enterohepatic recycling. Part of a dose is excreted in the urine, most of it in the first eight hours.

Vitamin C (Ascorbic Acid)

Ascorbic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in The body tissues. Ascorbic acid in excess of the body's needs is rapidly eliminated in the urine.

5.3 Preclinical safety Data:

None stated.

6. Pharmaceutical Particulars:

6.1 List of excipients:

Sr. No.	Ingredients	Specification
1.	Cellulose Acetate Phthalate	BP
2.	Starch	BP
3.	Dicalcium Phosphate	BP
4.	Sodium Lauryl Sulphate	BP
5.	Purified Talc	BP
6.	Magnesium Stearate	BP
7.	Isopropyl Alcohol	BP
8.	Dichloromethane	BP
9.	EHG Capsule 0 (Brown/Brown)	IH

6.2 Incompatibilities:

Not known.

6.3 Shelf life:

24 Months

6.4 Special precautions for storage:

Store below 25°C in a dry place. Protect from light.

Keep medicine out of reach of children.

6.5 Nature and contents of container:

Primary Packing: 10 Capsules to be packed in a ALU- ALU Blisters.

Secondary Packing: Such 3 blisters are placed in printed carton along with pack insert.

6.6 Special Precaution for Disposal and other handling:

None

7. Marketing Authorization Holder:

Company name: Signature Healthcare Limited

Address : The Eco Green Business Center (TILISI)
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Email : exports@corallab.com

Website : www.corallab.com

8. Marketing Authorization Numbers
CTD13442

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

07/05/2026

10. Date of revision of the text:

07/05/2026