1.3

PRODUCT INFORMATION

1.3.1 Summary of Product Characteristics (SmPC)

COMMON TECHNICAL DOSSIER (CTD) – Module 1

HAEMARON (Iron, Zinc and Vitamins Capsules)

SUMMARY OF THE PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE MEDICINAL PRODUCTS

HAEMARON (Iron, Zinc and Vitamins Capsules)

2. QUALITY AND QUANTITATIVE COMPOSITION

Each Capsule Contains:

Ferrous Fumarate	BP 150mg
Thiamine Nitrate	BP 1mg
Pyridoxine Hydrochloride	BP 1mg
Folic Acid	BP 2mg
Zinc Sulfate Monohydrate	USP 15mg

For the full list of excipients please refer section 6.1 below

3. PHARMACEUTICAL FORM

Red / red coloured "1" size capsules with 'HAEMARON / HAEMARON' printed on the capsule shells containing brown granular powder.

4. CLINICAL PARTICULARS

4.1 Therapeutics Indications

Haemaron is indicated in the following:

a) Management of iron deficiency anaemia.
b) Anaemia due to blood loss in worm infestation, surgery, delivery and menstruation.
c) Anaemia due to febrile illness like malaria, typhoid and influenza.
d) In symptoms like weakness, lack of concentration, lassitude, pallor, tiredness caused by depletion of iron stores in the body.
e) For speedy recovery from illness, convalescence, for growing children and for the elderly with the problems of poor ingestion.

4.2 Posology and method of administration

One capsule a day or as directed by the physician.

Method of administration: Oral - Swallow the capsule whole with a glass of water

4.3 Contraindication

Hypersensitivity to any of the B group vitamins contained in this preparation.

Patients with known lactose intolerance.

Known Hypersensitivity to any of the components Contraindicated in patients with pernicious anaemia and in the rare instance of hypersensitivity to Folic acid. Hemochromatosis and hemosiderosis are contraindications to iron therapy.

4.4 Special warning and precaution for use

If symptoms have not shown any improvement during that time, or you are concerned, please consult your doctor. Use with caution in patients with renal impairment. Iron preparations should be used with caution in patients with erythropoietic protoporphyria. Iron preparations colour the faeces black, which may interfere with tests used for detection of occult blood in the stools.

4.5 Interaction with other medicinal products and other forms of interaction

i. Iron and tetracyclines reduce the absorption of each other. Iron reduces absorption of zinc, and absorption of oral iron is reduced by zinc.

ii. Iron reduces the absorption of penicillamine, fluoroquinolones, levodopa, carbidopa, entacapone, bisphosphonates, and levothyroxine.

iii. Absorption of iron is reduced with calcium, magnesium and other mineral supplements, bicarbonates, carbonates, zinc and trientine and impaired by antacids, cholestyramine, tea, eggs or milk, but may be increased by ascorbic or citric acid.

iv. Chloramphenicol delays plasma iron clearance, incorporation of iron into red blood cells and interferes with erythropoiesis.

v. Reduced hypotensive effect of methyldopa.

vi. Serum levels of anticonvulsant drugs may be reduced by the co-administration of folate e.g. folic acid possibly reduces the plasma concentration of phenobarbital, phenytoin and primidone.

vii. Absorption of folic acid is possibly reduced by sulfasalazine.

viii. Concomitant use of folic acid with raltitrexed should be avoided.

ix. Pyridoxine may antagonise effects of L-dopa unless the patient is receiving a peripheral Dopa-decarboxylase inhibitor

4.6 Pregnancy, Lactation and Fertility

Administration of drugs during the first trimester of pregnancy requires careful assessment of the potential risks versus the benefits to be gained and should not be administered unless clearly indicated.

No adverse effects of ferrous Fumarate have been shown in breastfed infants of treated mothers. Ferrous Fumarate can be used during breast feeding if clinically indicated.

4.7 Effects on ability to drive and use machine

None stated.

4.8 Undesirable effects

If large amount of drug has taken then the following adverse reaction will occur.

Iron: Side effects may include nausea, vomiting, diarrhoea, constipation and other gastro-intestinal disturbances and may be minimised by taking the product with or after food or by starting with a small dose and increasing gradually.

Haemosiderosis may occur as a result of excessive or mistaken therapy.

Folic Acid: Rarely, folic acid may cause allergic reactions and gastrointestinal disturbances.

Thiamine: No toxic effects noted for humans after oral administration. However, since B Vitamins are interdependent, excess of one may produce deficiency of others.

Pyridoxine: Sensory and motor impairment. Dependency on high doses, leading to deficiency symptoms when one returns to normal amounts.

Zinc: Large amount of Zinc will cause gastrointestinal irritation, vomiting, adverse changes in HDL/LDL cholesterol ratios, impaired immunity. Nausea, anaemia, bleeding in stomach, premature birth and stillbirth, abdominal pain, fever. Can aggravate marginal copper deficiency. May produce atherosclerosis.

4.9 Overdose

Treatment is primarily supportive and symptomatic; however induced emesis, gastric lavage, or activated charcoal may be useful. Chelating agents such as calcium disodium EDTA may be useful.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Iron is a haematinic essential for satisfactory erythropoiesis during haemoglobin synthesis.

A daily dose of iron and folic acid is recommended for the prevention of iron and folic acid deficiencies during pregnancy.

Thiamine is a vitamin with antioxidant, erythropoietic, cognition-and mood-modulatory, anti atherosclerotic, putative ergogenic, and detoxification activities. Thiamine protect against lead-induced lipid peroxidation in rat liver and kidney. Thiamine deficiency results in selective neuronal death in animal models. The neuronal increased free radical production, suggesting that oxidative stress may play an important early role in brain damage associated with thiamine deficiency. Thiamine intracellular glucose metabolism and it is thought that thiamine inhibits the effect of glucose and insulin on arterial smooth muscle cell proliferation. Inhibition of proliferation may also promote atherosclerosis. Endothelial cells in culture have been found to have a decreased proliferative rate and delayed migration in response conditions. Thiamine has been shown to inhibit this effect of glucose on endothelial cells.

Vitamin B6 (Pyridoxine) is a water-soluble vitamin used in the prophylaxis and treatment of vitamin B6 deficiency and peripheral neuropathy in those receiving hydrazide, INH). Vitamin B6 has been found to lower systolic and diastolic blood pressure in a small group of subjects with essential hypertension. Hypertension atherosclerosis and coronary heart disease. Another study showed pyridoxine hydrochloride to inhibit ADP- or epinephrine-induced platelet aggregation and levels and increase HDL-cholesterol levels, again in a small group of subjects. Vitamin B6, in the form of pyridoxal 5'-phosphate, was found to protect vascular culture from injury by activated platelets. Endothelial injury and dysfunction are critical initiating events in the pathogenesis of atherosclerosis.

Zinc - Normal growth and tissue repair depend upon adequate zinc levels. Zinc acts as an integral part of several enzymes important to protein and carbohydrate metabolism. . Severe zinc deficiency is associated with growth retardation, primary hypogonadism, skin disease, disturbances of taste and smell, and impaired immunity, with increased susceptibility to infection.

5.2 Pharmacokinetic properties

Folic acid is rapidly absorbed, mainly from the proximal part of the small intestine.

Iron: For absorption of iron, the iron must be separated from any organic material such as protein. In almost all cases any ferric iron must be changed to ferrous iron. This change is accomplished in the presence of acid- either hydrochloric acid, normally found in stomach or Vitamin C (Ascorbic acid). The absorption occurs mainly in upper part of the small intestine.

Once iron has been absorbed, the blood stream carries it throughout the body bound to the protein carrier transferrin. It will be released from blood for various functions e.g. for the use in synthesis of respiratory enzymes and other vital cellular contents that require iron and mainly in the manufacture of haemoglobin for red blood cells. Approximately 1000 mg of iron is stored in the body at any one time, 30% is in the liver, 30% in the bone marrow and rest is in the spleen and muscles.

Thiamine: It is thought that the mechanism of action of thiamine on endothelial cells is related to a reduction in intracellular protein glycation by redirecting the glycolytic the transport form of the vitamin, while the active forms are phosphorylated thiamine derivatives. There are five known natural thiamine phosphate derivatives: (ThMP), thiamine diphosphate (ThDP), also sometimes called thiamine pyrophosphate (TPP), thiamine triphosphate (ThTP), and the recently discovered adenosine triphosphate (AThTP), and adenosine thiamine diphosphate. Each derivative has unique functions; however, most are involved as coenzymes.

Pyridoxine: Vitamin B6 is the collective term for a group of three related compounds, pyridoxine (PN), pyridoxal (PL) and pyridoxamine (PM), and their phosphorylated derivatives, phosphate (PNP), pyridoxal 5'-phosphate (PLP) and pyridoxamine 5'-phosphate (PMP). Although all six of these compounds should technically be referred to vitamin B6 is commonly used interchangeably with just one of them, pyridoxine. Vitamin B6, principally in its biologically active coenzyme form pyridoxal 5'-phosphate, wide range of biochemical reactions, including the metabolism of amino acids and glycogen, the synthesis of nucleic acids, hemoglobin, sphingomyelin and other synthesis of the neurotransmitters serotonin, dopamine, nor epinephrine and gamma-amino butyric acid (GABA).

Zinc: Absorption: Zinc is incompletely absorbed from the small bowel, with between 10 and 40% of an ingested dose absorbed. Numerous dietary components can interfere with zinc

absorption, particularly phytates and fibre, which bind to zinc, resulting in poorly absorbed zinc complexes.

Distribution

Approximately 60% of circulating zinc is bound to albumin and roughly 30% is bound to macroglobulin. The majority of zinc is stored in the liver and kidney, chiefly intracellularly, and bound to metalloproteins.

Elimination

In adults, it has been estimated that approximately 0.5 to 1.0 mg/day is secreted in the biliary tract and excreted in the stool, while 0.5 to 0.8 mg/day is excreted in the urine.

5.3 Preclinical safety data

None stated

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Liquid Paraffin, Thiourea, Disodium Edetate, Purified Talc, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Anhydrous Calcium Hydrogen Phosphate, Lactose Monohydrate, Light Kaolin, Colloidal Anhydrous Silica and Magnesium Stearate.

6.2 Incompatibilities

None

6.3 Shelf Life

30 months

6.4 Special Precautions for storage

Store below 30°C in a dry place. Protect from light.

6.5 Nature and contents of container

Nature: Blister pack (Printed Aluminum blister foil/ PVC clear film)

Contents of container: 3 x 10’s & 12 x10’s

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7. ADDRESS OF THE MANUFACTURER

M/s. FOURRTS (INDIA) LABORATORIES PVT.LIMITED,
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8. Marketing Authorization Number:

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9. Date of first Authorization / Renewal of the authorization:

Renewal of Authorization: 06.09.2018

10. Date of revision of the text:

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