Haema-Caps®

Integrated formula for prevention and treatment of iron deficiency anemia

COMPOSITION:
Each Soft gelatin capsule contains:

Active Ingredients:

Ferrous fumarate	350 mg.	Vitamin E (D-Alpha Tocopheryl acetate)	5 mg.
Eq. to 115 mg Fe		Calcium gluconate	75 mg.
Folic acid	2 mg.	Manganese Chloride Tetrahydrate	9 mg.
Vitamin B12	7.5 mcg	Eq. to 2.5 mg Mn	
Vitamin B1 (Thiamin HCL)	15 mg.	Copper Sulphate Pentahydrate	9.8 mg.
Vitamin B2 (Riboflavin Phosphate)	2.75 mg	Eq. to 2.5 mg Copper	
Eq. to 2 mg Riboflavin		Safflower oil	270 mg.
Vitamin B6 (Pyridoxine Hcl)	10 mg.	Eq. to 200 mg Linoleic acid	
Calcium Ascorbate Dihydrate	60 mg	Linseed oil	90 mg.
Eq. to 50 mg Ascorbic acid		Eq. to 45 mg Linolenic acid	
Vitamin D3 (Colecalciferol)	400 I.U.	Taurine	15 mg.

Inactive Ingredients
Lecithin, Soybean oil, Hydrogenated Soybean oil, yellow Bees wax & Lactose Monohydrate
Composition of capsule shell: Dry substance of anidrisorb 85/70, Glycerin, Gelatin, Ethylvanillin, Iron Oxide Red, Iron Oxide Black.
Pharmaceutical form: Soft gelatin capsule

Dosage and Administration:
One capsule daily, preferably after meals.
Clinical Pharmacology:
Pharmacodynamics
Vitamin B1 (Thiamine)
Thiamine (as the coenzyme thiamine pyrophosphate) is associated with carbohydrate metabolism. Thiamine pyrophosphate also acts as a co - enzyme in the direct oxidative pathway of glucose metabolism. In thiamine deficiency, pyruvic and lactic acids accumulate in the tissues. The pyruvate ion is involved in the biosynthesis of acetylcholine via its conversion to acetyl co-enzyme A, through a thiamine-dependent process. In thiamine deficiency, therefore, there are effects on the central nervous system due either to the effect on acetylcholine synthesis or to the lactatee and pyruvate accumulation. Deficiency of thiamine results in fatigue, anorexia, gastro-intestinal disturbances, tachycardia, irritability and neurological symptoms. Gross deficiency of thiamine (and other Vitamin B group factors) leads to the condition beri-beri.
Vitamin B2 (Riboflavine)
Riboflavine is phosphorylated to flavine mononucleotide and flavine adenine dinucleotidc which act as co-enzymes in the respiratory chain and in oxidative phosphorylation. Riboflavine deficiency presents with ocular symptoms as well as lesions on the lips and at angles of the mouth.
Vitamin B6 (Pyridoxine)
Pyridoxine, once absorbed, is rapidly converted to the co-enzymes pyridoxal phosphate and pyridoxamine phosphate which play an essential role in protein metabolism. Convulsions and hypochromic anaemia have occurred in infants deficient in pyridoxine.
Vitamin B12 (Cyanocobalamin)
Vitamin B12 is present in the body mainly as methylcobalamin and as adenosylcobalamin 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 anemia.
Vitamin C (Ascorbic Acid)
Vitamin C cannot be synthesized 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 lo become loose. Anaemia commonly occurs probably due to Vitamin C's role in iron metabolism.
Vitamin D
Vitamin D facilitates absorption and utilization of calcium and phosphorus protects against muscle, weakness, and is important in prevention and treatments of osteoporosis.
Vitamin E
Vitamin E deficiency has been linked to disorders such as cystic fibrosis where fat absorption is impaired. It is essential tor the normal function of the muscular system and the blood.
Calcium
Calcium is an essential body electrolyte. It is involved in the maintenance of normal muscle and nerve function and essential for normal cardiac function and the clotting of blood. Calcium is mainly found in the bones and teeth. Deficiency of calcium leads to rickets, osteomalacia in children and osleoporosis in the elderly.
Copper
Traces of copper are essential to the body as constituents of enzyme systems involved in oxidation reactions.
Manganese
Manganese is a constituent of enzyme systems, including those involved in lipid synthesis, the tricarboxylic acid cycle and purine and pyrimidine metabolism. It is bound to arginase of the liver and activates many enzymes.
Taurine
Taurine is an amino acid involved in bile formation; the liver converts bile acids into bile salts by conjugation with Taurine. It helps also in absorption of fat soluble vitamins.
Linoleic & Linolenic acids
They are essential fatty acids which combine with phosphates to form phospholipids which serve as structural components of cell membranes.
Pharmacokinetics:
The following account describes the absorption and fate of the active constituents of Haema-Caps.
Vitamin B1(Thiamine)
Thiamine is absorbed from the- gastro-intestinal tract and is widely distributed to most body tissues. Amounts in excess of the body's requirements are not stored but excreted in the urine as unchanged thiamine or its metabolites.
Vitamin B2 (Riboflavine)
Riboflavine is absorbed from the gastro-intestinal tract and in the circulation is bound to plasma proteins. It is widely distributed. Little is stored and excess amounts are excreted in the urine. In the body riboflavine is converted to flavine mononucleotide (FMN) and then to flavine adenine dinucleotide (FAD).
Vitamin B6 (Pyridoxine)
Pyridoxine is absorbed from the gastro-intestinal tract and converted to the active pyridoxal phosphate which is bound to plasma proteins. It is excreted in the urine as 4 - pyridoxic acid.
Vitamin B12 (Cyanocobalamin)
Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B12 showed it was quickly taken up by the intestinal mucosa and held there for 2 - 3 hours. Peak concentrations in the blood and tissues did not occur until 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 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 and this elimination is usually accompanied by a mild diuresis.
Vitamin E
Vitamin E is absorbed from the gastro-intestinal tract. Most appears in the lymph and is then widely distributed to all tissues. Most of a dose is slowly excreted in the bile and the remainder is eliminated in the urine as glucuronides of tocopheronic acid or other metabolites.
Folic Acid
Folic acid is absorbed mainly from the proximal part of the small intestine. Folale polyglutamales 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.
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 conditions of iron deficiency, absorption is increased and conversely, it is decreased in iron overload. Iron is stored as ferritin.
Copper Sulphate (Copper)
Copper is absorbed from the gastro-intestinal tract and its major route of excretion is in the bile.
Manganese
Manganese salts are poorly absorbed.
Indication:
Treatment of Iron Deficiency Anemia associated with increased demand of vitamins and minerals included in the formula.
Contraindications
- Hypersensitivity to active substances or to excipients.
- Hacmochromatosis and other iron storage disorders.
Precautions & Warnings
While taking **Haema-Caps®**, both protein and energy are also required to provide complete nutrition in the daily diet. No other vitamins, minerals or supplements with or without vitamin A should be taken with this preparation except under medical supervision. Do not exceed the staled dose. If symptoms persist, consult your doctor.
The product contains Lactose: Patients with rare hereditary problems of galactose intolerance, the Lapp lactose deficiency or glucose-galactose malabsorption should not take this medicine.
Drug Interactions
- Folic acid can reduce the plasma concentration of phenytoin.
- Oral iron, Calcium and Zinc sulphate reduce the absorption of tetracyclines.
Pregnancy & Lactation
Haema-Caps® may he administered during lactation at the recommendation of the physician. Not to be used during the first trimester of pregnancy.
Side effects
No undesirable effects due to **Haema-Caps®** have been reported and none can be expected if the dosage schedule is adhered to.
Overdose
No cases of overdosage due to Haema-Caps have been reported. Any symptoms which may be observed due to ingestion of large quantities of Haema-Caps will be due to the fat soluble vitamin content. If iron overdosage is suspected, symptoms may include nausea, vomiting, abdominal pain, haematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycaemia and metabolic acidosis may also occur. Treatment should be implemented immediately. In severe cases, after a latent phase, relapse may occur after 24 - 48 hours, manifested by hypotension coma and hepatocellular necrosis and renal failure.
Treatment
The following steps are recommended to minimise or prevent further absorption of the medication:
1. Administer an emetic
2. Gastric lavage may be necessary to remove drug already released into the stomach. This should be undertaken using desferrioxamine solution (2 g/l). Desferrioxamine 5 g in 50 - 100 ml water should be introduced into the stomach following gastric emptying. Keep the patient under constant surveillance to detect possible aspiration of vomitus; maintain suction apparatus and standby emergency oxygen in case of need.
3. A drink of mannitol or sorbitol should be given to induce small bowel emptying.
4. Severe poisoning: in the presence of shock and/or coma with high serum iron levels(> 142 umol/l), immediate supportive measures plus i.v. infusion of desferrioxamine should be instituted. The recommended dose of desferrioxamine is 5 mg/kg/h by slow i.v. infusion up to a maximuin of 80 mg/kg/24 hours. Warning: hypotension may occur if the infusion rate is too rapid.
5. Less severe poisoning: i.m. desferrioxamine 50 mg/kg up to a maximum dose of 4 g should be given.
6. Serum iron levels should be monitored throughout.
7. Any fluid or electrolyte imbalance should be corrected.
Pack
Carton Box containing 4 (AL/Colorless transparent PVC/PVDC) strips, each of 7 soft gelatin capsules + inner leaflet.
Storage
Store at temperature not exceeding 25°C, In dry place.
Shelf life: 2 Years.

Keep all medicaments out of reach of children

AMOUN

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AMOUN PHARMACEUTICAL CO. S.A.E.
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