Summary of Product Characteristics

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# VITACAP

## 1. Name of the Medicinal Product

Vitacap

## 2. Qualitative and Quantitative Composition

Each soft gelatin capsule contains:

| | | |
|---|---|---|
| Vitamin A | 5000 | IU |
| Vitamin D3 | 400 | IU |
| Vitamin E | 15 | mg |
| Vitamin C (Ascorbic acid) | 75 | mg |
| Vitamin B1 (Thiamine mononitrate) | 5 | mg |
| Vitamin B2 (Riboflavin) | 5 | mg |
| Vitamin B6 (Pyridoxine hydrochloride) | 2 | mg |
| Vitamin B3 (Nicotinamide) | 45 | mg |
| Vitamin B12 | 5 | mcg |
| Folic acid | 1 | mg |
| D-panthenol | 5 | mg |
| Ferrous fumarate (Providing Iron 16.43 mg) | 50 | mg |
| Zinc sulphate (Providing Zinc 20.24 mg) | 50 | mg |
| Iodine (as Potassium Iodide) | 0.15 | mg |
| Copper (as Copper Sulphate) | 1 | mg |
| Manganese (as Manganese Sulphate) | 1 | mg |
| Calcium (as Dibasic Calcium Phosphate) | 20.62 | mg |
| Phosphorus (as Dibasic Calcium Phosphate) | 15.93 | mg |

For full list of excipients, see section 6.1

## 3. Pharmaceutical Form

Capsule, soft

Yellowish brown oily suspension filled in oblong, opaque brown color soft gelatin capsule with the word “VITACAP” white color imprinted

## 4. Clinical Particulars

### 4.1 Therapeutic indications

Prevention and treatment of multivitamin and mineral deficiency.

### 4.2 Posology and method of administration

**Posology**

Adults and the Elderly

One capsule daily, preferably taken one hour after meals. Do not exceed the stated dose. The capsule should be swallowed whole with water.

Children under 12 years of age

Vitacap are not recommended for this age group.

**Method of administration**

Oral Administration.

### 4.3 Contraindications

Hypercalcaemia, haemochromatosis and other iron storage disorders.
Avoid taking this product if you have allergy to any component of this product. Consult your healthcare professional before use.

### 4.4 Warnings & Precautions

Whilst taking Vitacap 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 take Vitacap on an empty stomach. Do not exceed the stated dose. Keep out of the reach of children. If symptoms persist, consult your doctor.

Important warning: Contains iron. Keep out of the reach and sight of children, as overdose may be fatal.

Patients with thyroid disorders should seek medical advice before taking Vitacap. An allowance should be made for vitamins or minerals obtained from other sources.

**Warnings according to Notification of the Ministry of Public Health**

- The product may accumulate in the body and cause toxicity. Therefore, it should not be used in excess of the prescribed dosage or used for a long period of time.
- Use this product as directed by healthcare professional only.

**4.5 Interaction with other medicinal products and other forms of interaction**

Ingredient in Vitacap may decrease the absorption of phenytoin, bisphosphonates, levodopa, levothyroxine, penicillamine, quinolones and tetracycline so it should separate dose at least 2 hours from each other's.

**4.6 Fertility, pregnancy and lactation**

Pregnant and lactation women should consult your healthcare professional before use.

**4.7 Effects on ability to drive and use machines**

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

**4.8 Undesirable Effects**

Some gastrointestinal disturbances including nausea, vomiting, bloating and other abdominal discomfort have been reported.

**4.9 Overdose & Treatment**

No case of overdosage in recommended dose has been reported.
Any symptoms which may be observed due to the ingestion of large quantities of Vitacap will be due to the fat soluble vitamin content. 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. In severe cases, after a latent phase, relapse may occur after 24 - 48 hours, manifest by hypotension coma and hepatocellular necrosis and renal failure.

<u>Treatment</u>

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 µmol/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 maximum 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.

## 5. Pharmacological Properties

### 5.1 Pharmacodynamics properties

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

Vitamin A

Vitamin A plays an important role in the visual process. It is isomerised to the 11-cis isomer and subsequently bound to the opsin to form the photoreceptor for vision under subdued light. One of the earliest symptoms of deficiency is night blindness which may develop into the more serious condition xerophthalmia. Vitamin A also participates in the formation and maintenance of the integrity of epithelial tissues and mucous membranes. Deficiency may cause skin changes resulting in a dry rough skin with lowered resistance to minor skin infections. Deficiency of Vitamin A, usually accompanied by protein-energy malnutrition, is linked with a frequency of infection and with defective immunological defence mechanisms.

Vitamin D

Vitamin D is required for the absorption of calcium and phosphate from the gastro-intestinal tract and for their transport. Its involvement in the control of calcium metabolism and hence the normal calcification of bones is well documented. Deficiency of Vitamin D in children may result in the development of rickets.

Vitamin $B_1$ (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 lactate 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 $B_2$ (Riboflavine)

Riboflavine is phosphorylated to flavine mononucleotide and flavine adenine dinucleotide 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 $B_6$ (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 $B_{12}$ (Cyanocobalamin)

Vitamin $B_{12}$ 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 $B_{12}$ 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.

Vitamin E

Vitamin E deficiency has been linked to disorders such as cystic fibrosis where fat absorption is impaired. It is essential for the normal function of the muscular system and the blood.

Nicotinamide

The biochemical functions of nicotinamide as NAD and NADP (nicotinamide adenine dinucleotide phosphate) include the degradation and synthesis of fatty acids, carbohydrates and amino acids as well as hydrogen transfer. Deficiency produces pellagra and mental neurological changes.

Calcium (Dibasic Calcium Phosphate)

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 osteoporosis in the elderly.

Phosphorus (Dibasic Calcium Phosphate)

Phosphate plays important roles in the osteoblastic and osteoclastic reactions. It interacts with calcium to modify the balance between these two processes. Organic phosphate esters

play a key role in the metabolism of carbohydrates, fats and proteins and in the formation of 'high energy phosphate' compounds. Phosphate also acts as a buffer and plays a role in the renal excretion of sodium and hydrogen ions.

Pantothenic Acid (D-panthenol)

Pantothenic acid is incorporated into co-enzyme A and is involved in metabolic pathways involving acetylation which includes detoxification of drug molecules and biosynthesis of cholesterol, steroid hormones, mucopolysaccharides and acetylcholine. CoA has an essential function in lipid metabolism.

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.

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.

Copper (Copper Sulfate)

Traces of copper are essential to the body as constituents of enzyme systems involved in oxidation reactions.

Zinc (Zinc Sulfate)

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.

Manganese (Manganese Sulfate)

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.

Iodine (Potassium Iodide)

Iodine is an essential constituent of the thyroid hormones.

**5.2 Pharmacokinetic properties**

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

Vitamin A

Except when liver function is impaired, Vitamin A is readily absorbed. Vitamin A (retinol) is emulsified by bile salts and phospholipids and absorbed in a micellar form. Part is conjugated with glucuronic acid in the kidney and part is metabolised in the liver and kidney, leaving 30 to 50% of the dose for storage in the liver. It is bound to a globulin in the blood. Metabolites of Vitamin A are excreted in the faeces and the urine.

Vitamin D

The metabolism of ergocalciferol is similar to that of cholecalciferol. Cholecalciferol is absorbed from the gastro-intestinal tract into the circulation. In the liver, it is hydroxylated to 25-hydroxycholecalciferol, is subject to entero-hepatic circulation and is further hydroxylated to 1,25-dihydroxycholecalciferol in the renal tubule cells. Vitamin D metabolites are bound to specific plasma proteins.

Vitamin $B_1$ (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 $B_2$ (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 $B_6$ (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 $B_{12}$ (Cyanocobalamin)

Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin $B_{12}$ 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 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 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.

Nicotinamide (Nicotinic Acid Amide)

Nicotinic acid is absorbed from the gastro-intestinal tract, is widely distributed in the body tissues and has a short half-life.

Calcium (Dibasic Calcium Phosphate)

A third of ingested calcium is absorbed from the small intestine. Absorption of calcium decreases with age.

Phosphorus (Dibasic Calcium Phosphate)

The body contains from 600 - 800 g of phosphorus, over 80% of which is present in the bone as phosphate salts, mainly hydroxyapatite crystals. The phosphate in these crystals is available for exchange with phosphate ions in the extra-cellular fluids.

Pantothenic Acid (D-panthenol)

Pantothenic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues. About 70% of pantothenic acid is excreted unchanged in the urine and about 30% in the faeces.

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.

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 Sulfate (Copper)

Copper is absorbed from the gastro-intestinal tract and its major route of excretion is in the bile.

Zinc Sulfate (Zinc)

Zinc is poorly absorbed from the gastro-intestinal tract. It is widely distributed throughout the body. It is excreted in the faeces with traces appearing in the urine.

Manganese Sulfate (Manganese)

Manganese salts are poorly absorbed.

Potassium Iodide (Iodine)

Iodides are absorbed and stored in the thyroid gland as thyroglobulin. Iodides are excreted in the urine with smaller amounts appearing in the faeces, saliva and sweat.

**5.3 Preclinical safety data**

No data available.

## 6. Pharmaceutical Particulars

### 6.1 List of excipients

Vanilla, Lecithin, Vegetable oil, Beewax, Soyabean, Gelatin, Glycerin, Iron oxide red, Iron oxide black, Iron oxide yellow and Purified water

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf Life

Two years from manufacturing date.

### 6.4 Special precautions for storage

Store below 30°C in a dry place, away from direct sunlight.

### 6.5 Nature and contents of container

Blister of 10 Soft gelatin capsules packed in a carton.

### 6.6 Special precautions for disposal and other handling

No special requirements.

**Note:**

*Read the instructions carefully before use.*

*Do not use the product after the expiry date.*

*Do not use the product if there are any significant changes in appearance of the capsules.*

*Keep out of reach of children.*

**7. Marketing Authorization Holder**

**MEGA LIFESCIENCES Public Company Limited**

Samutprakarn, Thailand

**8. Marketing Authorization Number**

[.....]

**9. Date of First Authorization/Renewal of the Authorization**

DD/MM/YYYY

**10. Date of Revision of the Text**

MM/YY