1. **Name of the medicinal product**

Mezvite Multivitamin Syrup

2. Qualitative and quantitative composition

Each 10ml contains

L-lysine_____ 40mg
L-Histidine_____5.00mg
Vitamin D3_____ 300IU
Vitamin E_____ 10.00mg
Vitamin C_____ 60.00mg
Vitamin B1_____ 12.00mg
Vitamin B2_____ 3.00mg
Vitamin B3_____ 20.00mg
Vitamin B6_____ 5.00mg
Folic Acid _____ 200mcg
Vitamin B12_____ 10.00mcg
Biotin_____ 8.00mcg
Pantothenic Acid_____ 3.00mg
Iron_____ 10.00mg
Zinc _____ 6.00mg
Copper_____ 100.00mg
Manganese _____ 1.00mg
Iodine_____ 120.00mg

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Syrup

A brownish coloured syrup

4. Clinical particulars

4.1 Therapeutic indications

Multivitamin Syrup is indicated for the prevention of vitamin deficiencies and for the maintenance of normal growth and health during the early years of infancy and childhood; multivitamin supplement.

4.2 Posology and method of administration

Dosage

Adult: 10ml to be taken twice daily

Children: 3-6 years: 5ml to be taken twice daily

Children: 7-12 years: 10ml to be taken once or twice daily

Administration

Method of administration:

Oral

Do not exceed recommended dose.

4.3 Contraindications

Mezvite Multivitamin Syrup must not be used in:

- hypersensitivity to the active substances or to any of the excipients listed in section 6.1

- hypervitaminosis from any vitamin contained in this formulation,

4.4 Special warnings and precautions for use

Multivitamins are not recommended for the treatment of severe specific deficiencies of vitamins and minerals. While taking the multivitamins, both protein and energy are also required to provide complete nutrition in the daily diet. No other vitamins, minerals or supplements should be taken with this preparation except under medical supervision.

Do not take on an empty stomach.

Do not exceed the stated dose.

Keep out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions between specific vitamins in Mezvite Multivitamin Syrup and other agents should be managed accordingly.

Such interactions include:

• Antiplatelet agents (e.g., aspirin): Vitamin E can add to the inhibition of platelet function

• Certain anticonvulsants (e.g., phenytoin, carbamazepine, phenobarbital, valproate): Can cause folate, pyridoxine and vitamin D deficiencies

• Certain antiretroviral agents: Decreased vitamin D levels have been associated with, e.g., efavirenz and zidovudine. Decreased formation of the active vitamin D metabolite has been associated with protease inhibitors.

• Chloramphenicol: Can inhibit the haematological response to vitamin B12 therapy

• Ethionamide: Can cause pyridoxine deficiency

• Levodopa: The content of pyridoxine may interfere with the effects of concurrent levodopa therapy.

• Pyridoxine antagonists, including cycloserine, hydralazine, isoniazid, penicillamine, phenelzine: Can cause pyridoxine deficiency

• Theophylline: Can cause pyridoxine deficiency

• Vitamin K antagonists (e.g., warfarin): Enhanced anticoagulant effect by vitamin E

4.6 Fertility, pregnancy and lactation

Mezvite Multivitamin Syrup formula may be administered during pregnancy and lactation at the recommendation of the physician.

4.7 Effects on ability to drive and use machines

There is no information on the effects of Mezvite Multivitamin Syrup on the ability to operate an automobile or other heavy machinery.

4.8 Undesirable effects

Generally multivitamin and multimineral are well tolerated by the body. Sometimes, reactions could occur, but they disappear rapidly after continuous and regular use. Ascorbic Acid (C), Nicotinamide, Pyridoxine (B6), Riboflavin (B2) & Thiamine (B1) These water-soluble vitamins are generally nontoxic compounds with a wide margin of safety, the excess amounts being rapidly excreted in the urine.

4.9 Overdose

Seek emergency medical attention. Most commonly reported, symptoms of Vitamins & amino acid overdose include nausea and vomiting.

5. Pharmacological properties

5.1 Pharmacodynamic properties

(i) Pharmaco-therapeutic group: Multivitamins and other minerals, incl. combinations
(ii) ATC code: A11AA03

Mechanism of action: Mezvite Multivitamin Syrup is L-Lysine and L-Histidine, & Vitamins and minerals Syrup. The pharmacokinetics of the active substances would not be different from those naturally derived by food orally.

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

Lysine are amino acids which are important for growth.

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 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.

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 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.

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.

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.

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 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 H (d-Biotin)

Biotin is a co-enzyme for carboxylation during the metabolism of proteins and carbohydrates.

Pantothenic Acid

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.

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.

Zinc

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.

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.

Iodine (Potassium Iodide)

Iodine is an essential constituent of the thyroid hormones.

5.2 Pharmacokinetic properties

The pharmacokinetics of the active substances would not be different from those naturally derived by food orally.

The following account describes the absorption and fate of each of the active constituents of Mezvite Multivitamin Syrup

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 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.

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 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).

Nicotinamide

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

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.

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 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 H (d-Biotin)

Following absorption, biotin is stored in the liver, kidney and pancreas.

Pantothenic acid

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.

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.

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.

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.

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

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Methyl paraben
Propyl paraben
Sodium benzoate
Sucrose
Liquid glucose
Sodium saccharine
Propylene glycol
Colour caramel
Orange flavour
Purified water
Ethanol

6.2 Incompatibilities

No major incompatibilities are known.

6.3 Shelf life

Unopened: 2 years.

6.4 Special precautions for storage

Do not store above 30° C

6.5 Nature and contents of container

200ml amber colour glass bottle capped with 25mm ropp cap, packed in a mono carton.

6.6 Special precautions for disposal and other handling

Not applicable.

7. manufactured by

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