SUMMARY OF PRODUCT CHARACTERISITICS

1. Name of the Finished Pharmaceutical Product

1.1 Proprietary Name: KRISHAT MULTIVITAMIN and MINERALS With ALOE VERA SOFT GELATIN CAPSUILES

2. Qualitative and quantitative compositions:

Each softgel capsule contains:

Vitamin A (As Palmitate) BP 1000 I.U., Vitamin B1 BP 1mg, Vitamin B2 BP 1mg, Vitamin B6 BP 1.34mg, Vitamin B12 BP 1mcg, Vitamin D3 BP 200 I.U., Calcium Pantothenate BP 1mg, Nicotinamide BP 15 mg, Calcium (From Anhydrous Calcium Hydrogen Phosphate BP) 50 mg, Phosphorous (From Anhydrous Calcium Hydrogen Phosphate BP) 38.75 mg, Potassium (From Potassium Sulphate BP) 1 mg, Copper (from Copper Sulphate BP) 0.01 mg, Magnesium (From Magnesium Sulphate BP) 0.5 mg, Manganese (From Manganese Sulphate Monohydrate BP) 0.01 mg, Zinc (From Zinc Sulphate BP) 0.15 mg, Aloe Vera 5 mg.

'For full list of excipients, see section 6.1

1.2. Pharmaceutical dosage form: Soft gelatin capsules.

3. Description:

14 mm oblong shaped, brown coloured oblong shaped soft gelatin capsule filled with yellow coloured medicine.

4. Clinical particulars:

4.1. Therapeutic indications:

A supplement to improve overall nutritional health during pregnancy and lactating period. Soft gelatin capsules provides optimum levels of 15 essential nutrients including Zinc. Which are important for pregnancy. It improve vitality of the body helps in countering fatigue. Combination of antioxidants helps in strengthening immune system and helps to maintain overall good health.

It is used as everyday dietary supplementary for patients suffering from minerals and vitamin deficiencies, loss of concentration, exhaustion in physical as well as mental anxiety cases, swift exhaustion and decreased performance. 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. 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. As a therapeutic nutritional adjunct in convalescence from illness, e.g. where anorexia or cachexia exists and following chemo- or radiotherapy. As a therapeutic nutritional adjunct in convalescence from surgery, e.g. where nutritional intake continues to be inadequate. 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. As a therapeutic nutritional adjunct where food intolerance exists, e.g. exclusion diets. As an adjunct in synthetic diets, e.g. in phenylketonuria, galactosaemia and ketogenic diets. Aloe vera may help lower cholesterol and blood sugar and ease heartburn, Immunomodulatory and anti-inflammatory activities.

4.2. Posology and method of administration:

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

Capsules are not recommended for this age group.

4.3. Contra-indications:

Hypercalcaemia, haemochromatosis and other iron storage disorders. Hypersensitivity to the active substance(s) or to any of the excipients. This product capsules contain soya bean oil. Patients allergic to peanut or soya should not take this medicine. High dose of aloe Vera belly pain, kidney damaged and electrolyte imbalance.

4.4. Special warning and precautions for use:

Whilst taking soft gelatin Capsules 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 soft gelatin Capsules 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.

If person is taking medicines to lower blood sugar, aloe Vera could lower blood sugar too much, if nausea, belly pain and diarrhea symptoms may persist inform your physician.

4.5. Interaction with other drugs, other forms of interactions:

Interaction with other drugs have been found by physicians , taking medicines for Blood thinner, diabetic drugs, Digoxin ,stimulant laxative and diuretic drugs using then consult with physician first.

4.6. Use in pregnancy and lactation:

Not applicable.

4.7. Effects on ability to drive and operate machine:

Not applicable.

4.8. Undesirable effects:

Undesirable effects are listed by MedDRA System Organ Classes.

Assessment of undesirable effects is based on the following frequency groupings:

Very common: ≥ 1/10

Common: ≥ 1/100 to <1/10

Uncommon: ≥ 1/1,000 to <1/100

Rare: ≥ 1/10,000 to <1/1,000

Very rare: <1/10,000

Not known: cannot be estimated from the available data

Immune system disorders	*Not known:* Hypersensitivity reaction (such as rash)
Gastrointestinal disorders	*Not known:* Gastrointestinal disturbances (such as nausea, vomiting and abdominal pain)

4.9. Overdoses:

Not applicable.

No cases of overdosage due to krishat multivitamin have been reported. Any symptoms which may be observed due to the ingestion of large quantities of krishat multivitamin capsules 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.

5. Pharmacological properties:

5.1. Pharmaco-kinetic properties:

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

Vitamin A

Except when liver function is impaired, Vitamin A is readily absorbed. β -carotene (as in soft gelatin Capsules) is Provitamin A and is the biological precursor to Vitamin A. It is converted to Vitamin A (Retinol) in the liver; 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.

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 (Calcium Hydrogen Phosphate)

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

Phosphorus (Calcium Hydrogen 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.

Calcium Pantothenate

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.

Copper Sulfate (Copper)

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

Magnesium Sulphate (Magnesium)

Magnesium salts are poorly absorbed from the gastro-intestinal tract; however, sufficient magnesium will normally be absorbed to replace deficiency states. Magnesium is excreted in both the urine and the faeces but excretion is reduced in deficiency states.

Potassium Sulfate (Potassium)

Potassium salts are absorbed from the gastro-intestinal tract. Potassium is excreted in the urine, the faeces and in perspiration. Urinary excretion of potassium continues even when intake is low.

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**.**

Aloe Vera

Epithelialisation also occurs at injured sites in the small intestine or colon. The main advantage of dietary acemannan is the attenuation of the digestive process, increasing satiety, and slowing the release of sugars from starches. In the colon, acemannan is digested by microbes into short-chain fatty acids that are absorbed and augment the sensation of satiety and confer a host of other health benefits.

5.2. Pharmaco-dynamic properties:

The following account summarises the pharmacological effects of the vitamins and minerals in soft gelatin Capsules 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.

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 (Calcium Hydrogen 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 (Calcium Hydrogen 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

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.

Copper (Copper Sulfate)

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

Magnesium (Magnesium Sulphate)

Magnesium is essential to the body as a constituent of skeletal structures and in maintaining cell integrity and fluid balance. It is utilised in many of the functions in which calcium is concerned but often exerts the opposite effect. Some enzymes require the magnesium ion as a co-factor.

Potassium (Potassium Sulfate)

Potassium is the principle cation of intracellular fluid and is intimately involved in the cell function and metabolism. It is essential for carbohydrate metabolism and glycogen storage and protein synthesis and is involved in transmembrane potential where it is necessary to maintain the resting potential in excitable cells. Potassium ions maintain intracellular pH and osmotic pressure.

Prolonged or severe diarrhoea may lead to potassium deficiency.

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.

Aloe Vera:

Aloe vera contains antioxidant vitamins A, C, and E, as well as B_1, B_2, B_3, choline, folic acid, and trace amounts of vitamin B_{12}. It also provides 7 essential and 9 non-essential amino acids, contributing to its nutritional value.

5.3. Pre-clinical safety data:

Not applicable.

6. Pharmaceutical particulars:

6.1. List of excipients:

Gelatin, Glycerin, Sorbitol, Methyl Paraben, Propyl Paraben, Ponceau 4R, Sunset yellow supra,

Brilliant blue, Titanium Dioxide Liquid paraffin, Colloidal anhydrous silica, BHT,BHA, Beeswax,

Hydrogenated vegetable oil, Soya lecithin, Refined Soybean Oil & Purified Water

6.2. Incompatibilities:

No.

6.3. Shelf-life:

Three 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:

The primary pack is 15 Capsules / Blister. The secondary pack is 2 x 15 capsules packed in one Mono-carton.

6.6 Special precaution for disposal and other handling

No special requirements.

7.0 Marketing authorization holder

Krishat Pharma Industries Limited

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