PROFESSIONAL INFORMATION

Scheduling Status: S0

1. Proprietary Name

Multi Vita-Mineral

2. Qualitative and Quantitative Composition

Each capsule contains the composition as per table 2.1 below.

2.1 Composition

Each white capsule contains	
Beta-carotene providing elemental vitamin A 90 ug	900 ug
Lynside® Forte B100 EU (S. cerevisiae enriched with B vitamins)	56.3 mg
of which Vitamin B1 (Thiamine)	0.3 mg
of which Vitamin B2 (Riboflavin)	0.3 mg
of which Vitamin B3 (Nicotinamide)	3.8 mg
of which Vitamin B5 (D-Calcium pantothenate)	1.4 mg
of which Vitamin B6 (Pyridoxine HCl)	0.4 mg
of which Vitamin B8 (Biotin)	12.4 ug
of which Vitamin B9 (Folic acid)	50.7 ug
of which Vitamin B12 (Cyanocobalamin)	0.6 ug
Vitamin C (Malpighia glabra) Acerola cherry extract providing elemental Vitamin C 25 mg	100 mg
Vitamin D (as Vita-Algae D™) providing elemental Vitamin D3 5 ug	1.5 mg
Vitamin E Acetate providing Vitamin E 5 mg	10 mg
Vitamin K (as MenaQ7® Pharmapure)	30 ug
Calcium (as AlgaeCal® organic algae) providing elemental calcium 31 mg	110 mg
Choline bitartrate providing elemental Choline 44 mg	275 mg
Chromium picolinate providing elemental Chromium 6.3 ug	50 ug
Copper glycinate amino acid chelate providing elemental Copper 0.5 ug	4.5 ug
Ascophyllum nodosum (Kelp) providing elemental iodine 9.6 ug	75 ug
Magnesium (as *S. cerevisiae*) providing elemental Magnesium 24 mg	120 mg
Manganese glycinate providing elemental Manganese 0.5 mg	5 mg
Molybdenum amino acid chelate providing elemental Molybdenum 4 ug	20 ug
Selenomethionine (as Selenium SeLECT™) providing elemental selenium 12.5 ug	2.5 mg
Zinc (Lynside® Forte ZN100K) providing elemental Zinc 2.5 mg	25 mg

Excipients: milled rice flour, vegetarian capsules.

2.2 Sugar Free.

2.3 For full list of excipients see section 7.1.

3. Pharmaceutical form

White size 0 capsules containing light brown free-flowing powder.

4. Clinical Information

4.1 Indications for Use

Indicated where a deficiency in the active ingredients may exist. May contribute to overall health.

4.2 Method of Administration and Posology

4.2.1 Administration

Orally.

4.2.2 Posology

Adults and children over 18 only.

Take 2 capsules daily.

Take capsules with a sufficient quantity of water.

Do not chew the capsules swallow whole.

Take capsules at approximately the same time every day.

4.3 Contraindications

Not recommended for individuals who are hypersensitive (allergic) to any of the ingredients contained in the product.

4.4 Special Warnings and Precautions

Not recommended for individuals who are under the age of 18. If the patient experiences any gastrointestinal symptoms while using this product, discontinue use.

4.5 Interactions

S. cerevisiae: Major risk of interactions with MAOIs. Moderate risk of interactions with antidiabetic drugs and lithium.

Magnesium: Moderate risk of interactions with aminoglycoside antibiotics, antacids, bisphosphonates, calcium channel blockers, digoxin, ketamine, quinolone antibiotics, skeletal muscle relaxants, sulfonylureas, and tetracycline antibiotics. Major risk of interactions with levodopa/carbidopa.

Zinc: Moderate risk of interactions cephalexin, cisplatin, integrase inhibitors, penicillamine, quinolone antibiotics, ritonavir, and tetracycline antibiotics.

Acerola cherry: Moderate risk of interactions with alkylating agents and antitumour antibiotics.

Manganese: Moderate risk of interactions with antipsychotic drugs, quinolone antibiotics and tetracycline antibiotics.

Copper: Moderate risk of interactions with penicillamine.

Vitamin E: Moderate risk of interactions with alkylating agents, anticoagulant drugs, antitumour antibiotics, cyclosporine, cytochrome P450 3A4 substrates, selumetinib and warfarin.

Chromium: Moderate risk of interactions with antidiabetic drugs, insulin, and levothyroxine.

Vitamin K: Major risk of interactions with warfarin.

4.6 Pregnancy and Lactation

The safety in pregnancy and breastfeeding has not been established.

4.7 Effects on ability to drive and use machinery.

No known effect.

4.8 Side Effects

Generally, well tolerated when used as advised. Side effects may include mild gastrointestinal disturbances, such as nausea, diarrhoea, constipation, indigestion, bloating, metallic taste in the mouth, and flatulence.

5 Pharmacological Classification

Category D: 33.7 Multiple substance formulation.

Complementary Medicine.

6 Pharmacokinetic Properties

Beta-Carotene

Absorption: intact beta-carotene is absorbed in the intestine, and it seems that it is better absorbed from supplements than food. Compared to synthetic supplements, absorption from food is only 5% to 30%, due to the complexes it forms with protein and fibre. These complexes are broken down when food is heated. Absorption and conversion of beta-carotene to vit A is dependent on the individual's vitamin A status, beta-carotene stores and the total amount of beta-carotene ingested. Most of the beta-carotene is converted to all-trans-beta-carotene in the intestine.

Metabolism: Beta-carotene is converted to Vit A in the intestinal mucosa and in the liver. A high intake of beta-carotene does not result in Vitamin A toxicity, because the portion of beta-carotene that is converted to vit A decreases with an increased beta-carotene intake.

Distribution: Carotenoids are carried on low-density lipoproteins. 10% to 25% of carotenoids in the tissues are beta-carotene cis isomers.

Excretion: Beta-carotene is excreted in the faeces.

Vitamin C

Absorption: absorption of vit C decreases as the dose increases and is well absorbed at lower dosages. A 30 mg oral dose leads to an 87% absorption and only 80% of a 100 mg dose is absorbed. The vit C transporter, SVCT1 that is sodium dependant, is responsible for the transport of Vit C from the intestines into the blood. With increased dosages of Vit C, the renal excretion increases and the bioavailability decreases.

Excretion: Vit C is mostly excreted in the urine.

Vitamin D:

Absorption: Cholecalciferol and ergocalciferol are two forms of Vit D that are well absorbed. 25-hydroxyvitamin D serum levels are the best measure of Vit D status. The bioavailability of Vit D from supplements appears to be equivalent to that of fortified food.

Distribution: dietary Vit D and Vit D produced in the skin follow different transport paths. Vit D produced in the skin is transported on a Vit D binding protein, DBP. Dietary Vit D is transported by chylomicron, that distributes Vit D to the peripheral tissue, and if it is not absorbed by the peripheral tissue, it is transported to the liver.

Metabolism: the active metabolite, calcitriol is formed by Hydroxylation of ergocalciferol and cholecalciferol as both are inert. Vit D hydroxylation first takes place in the liver and the hydroxylation of Vit D to calcitriol takes place in the kidneys. People that suffer from chronic liver failure may require forms of Vit D that do not require hydroxylation e.g., calcitriol or calcifediol. Disorders such as tuberculosis, sarcoidosis, and histoplasmosis disturb vit D metabolism. In addition to the kidneys, Vit D is converted to calcitriol by activated macrophages that are trapped in the pulmonary alveoli and granulomatous inflammation, this may lead to an increased risk of hypercalcemia.

Excretion: Diabetes, HIV and cancer may cause Vit D to clear more rapidly.

Selenium:

Absorption: the major source of Selenium is from the diet. Depending on food source, 80% of Selenium is absorbed. Selenium -enriched yeast has a much higher bioavailability than inorganic selenium. L- Selenomethionine is absorbed more efficiently than parselenium. Selenomethionine has twice the bioavailability of selenium as selenite.

Distribution: the highest level of Selenium will be found in the kidneys. Selenium crosses the intestinal barrier from the GIT, reaches the blood and is then distributed to the different tissues of the body, including the skin, which allows for selenium to be metabolized and presented in active form.

Metabolism: at times of selenium deficiency the brain retains selenium to a greater extent.

Excretion: Selenomethionine has shown to have a greater excretion than selenite. Selenium that is obtained from either food or supplements is excreted in the urine.

Zinc:

Absorption: bioavailability is depended on the zinc status. If zinc intakes are low or there is a zinc deficiency, absorption will increase. Zinc is mostly absorbed in the jejunum as the best absorption takes place in an acidic environment. People with a reduced stomach acid would benefit from a zinc acetate as it is absorbed over a wide pH range. Diets high in phytate result in lower bioavailability of zinc. Zinc absorption may be improved with an addition of a protein source as vegetarian diets result in a lower absorption of zinc.

Distribution: skeletal muscle and bone make up more 85% of the total zinc in the body.

Metabolism: Zinc is metabolised in the liver.

Excretion: Zinc is excreted in the faeces, with a small amount eliminated in the urine. Type 2 Diabetic patients and patients with congestive heart failure appear to have increased urinary zinc levels. During lactation, zinc excretion increases in breastmilk. The body compensates for this increased zinc demand, by increasing zinc absorption and by conserving endogenous zinc.

Vitamin E:

Absorption: Vit E is absorbed via passive diffusion and takes place in the small intestine. The absorption rate is dependent on qualities such as pancreatic function and level of inflammation of the individual patient.

Distribution: supplemental Vit E refers to alpha tocopherol. Alpha-tocopherol depends on alpha-TTP for distribution. Alpha -TTP is present in the brain, uterus, and placenta and possibly the spleen, lung, and kidney.

Metabolism: the metabolism of Vit E is not fully understood. It appears to be a substrate of cytochrome P-450 enzyme system.

Excretion: Vit E is eliminated mostly unchanged in the faeces. The water-soluble metabolites of Vit E are excreted in the urine.

Vitamin K

Absorption: the bile salts are required for the oral absorption of Vit K1 and Vit K2 but not Vit K4. Vit K1 is better absorbed from supplements than vegetables 5%- 10% from vegetables and 13% from supplements, from kale with added oil is about 5%. The absorption of Vit K depends on the type and form of food that it is contained in. The presence of fat may assist in the absorption of Vit K1.

Distribution: small amounts of Vit K are stored in body tissue, with adiposity it appears that a higher concentration of Vit K is stored in adipose tissue, resulting in reduced Vit K levels in the blood. The longer sidechain forms of Vit K2 (menaquinone) are transported with LDL and triacylglycerol-rich fractions of plasma lipoproteins, whereas the shorter chains of Vit K1 is only transported with the triacylglycerol fraction. The Vit K2 reaches the liver and many extrahepatic tissues and K1 is mainly cleared by the liver.

Metabolism: the pancreas, testes and arterial vessel walls convert Vit K1 into MK-4 form of vitamin K2

Excretion: Vit K1 (phytonadione) and menaquinone-4 and menaquinone-7 forms of vit K2, results in increased K3(menadione) excretion in the urine, at peak concentration 3 hours after intake. Both urine and faeces present with Vit K excretion.

Calcium:

Absorption: Calcium absorption depends on several factors, it is based on age, race, environmental conditions, and dietary conditions. People of African and Asian descent absorb calcium more efficiently than Caucasian people. In post-menopausal women, Calcium absorption is decreased, and excretion is increased. Elderly females have impaired intestinal response to vit D, this impairment can increase the negative calcium balance and bone loss.

Distribution: bones and teeth contain more than 99% of the calcium in the body. Calcium is mainly present in the bone as hydroxyapatite. The blood, extracellular fluid muscle and other tissue also contain calcium. The reserve source of calcium that is present in the bone can be mobilized to maintain extracellular calcium concentration.

Excretion Calcium is excreted in the urine and faeces. During late pregnancy and lactation, the excretion in the urine is decreased. Calcium supplementation increases urinary excretion. Calcium excretion is increased with individuals affected by osteoporosis. Calcium excretion in urine is decreased when intake of calcium is low and intake of protein is high.

7 Pharmaceutical Information

7.1 List of Excipients

Milled rice flour, vegetarian capsules.

7.2 Incompatibilities

None.

7.3 Shelf Life

24 months from date of manufacture.

7.4 Storage

Store in a cool dry place, between 15°C -25°C. Store in original container.

7.5 Presentation

60 white size 0 capsules packed in a 300 ml cylindrical white container with a lid and packaged.

7.6 Disposal and handling of product

All unused medication should be disposed of in accordance with local regulatory authority.

8. Holder of certificate of registration

FoodGrown™©
371 Angus Crescent
Northlands Business Park

North Riding
Gauteng
South Africa

9. Registration Number

Still to be allocated

10. Date of first authorisation

Still to be allocated

11. Date of review

New

12. Reference: https://naturalmedicines.therapeuticresearch.com/

APPLICANT DETAILS:

FoodGrown™©
371 Angus Crescent
Northlands Business Park
North Riding
Gauteng
South Africa
+27(0)87 265 4789

DATE OF PUBLICATION:

16 May 2023