PROFESSIONAL INFORMATION

Scheduling Status: S0

1. Proprietary Name

Immune Complex

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
Vitamin C (*Malpighia glabra*) Acerola cherry extract providing 50 mg elemental Vitamin C	200 mg
Vitamin D (as Vita-Algae D™) Providing elemental Vitamin D 5 ug	2.5 mg
Selenomethionine (as Selenium SeLECT™) Providing elemental Selenium 5 ug	5mg
Zinc (as Lynside® Forte ZN100K) Providing elemental Zinc 1 mg	10 mg
Olea europaea (Olive leaf) Leaf extract, as 50 mg of a 4:1 extract	200 mg
N-Acetyl-L-Cysteine Providing L-Cysteine	150 mg
Vitis vinifera (Grape) Seed extract standardised to 95% proanthocyanins	25 mg
Curcuma longa (Turmeric) Root extract standardised to 95% curcuminoids	10 mg

Excipients: vegetarian capsule, milled rice flour.

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

A combination product which contains vitamins, minerals, and antioxidants, which may assist with the reduction of inflammation, support immune function and aid in the maintenance of overall good health. It is indicated where a deficiency in one or more of the ingredients exists.

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 pregnant or breastfeeding.
Not recommended for individuals who are under the age of 18.
Take two hours before any other medication.

4.5 Interactions

Grape Seed Extract: Moderate risk of interactions with anti-coagulant medication, cyclosporine, cytochrome P450 substrates, midazolam (Dormicum) and phenacetin (Banned in most countries).
Acerola Cherry Extract: Moderate risk of interactions with alkylating agents and antitumour antibiotics.
Turmeric Extract: Moderate risk of interactions with alkylating agents, amlodipine (Norvasc), anticoagulant/antiplatelet drugs, antidiabetic drugs, antitumour antibiotics, cytochrome P450 3A4 substrates, sulfasalazine (Azulfidine), tacrolimus (Prograf), talinolol, tamoxifen (Nolvadex), topoisomerase I inhibitors and Warfarin (Coumadin).
Selenium: Moderate risk of interactions with anticoagulant/antiplatelet drugs, barbiturates, immunosuppressants and Warfarin (Coumadin).

4.6 Pregnancy and Lactation

Do not use in pregnancy and lactation.

4.7 Effects on ability to drive and use machinery.

No known effect.

4.8 Side Effects

No known side effects.

5 Pharmacological Classification

Category D: 33.7 Combination Product
Health Supplements

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 Vit 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 is 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. 80% of Selenium is absorbed depends on the food source. 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.

Olive Leaf:

Absorption of olive leaf extract, the following metabolites are found in the plasma, oleuropein and conjugated metabolites of hydroxytyrosol. The conjugated hydroxytyrosol metabolites make up 96% of olive phenolic metabolites in plasma. The mean time to peak for conjugated hydroxytyrosol was 64-80 minutes with clearance by 240 minutes.

Metabolism: Sulphated and glucuronidated metabolites of hydroxytyrosol and oleuropein are found in the plasma.

Excretion: Metabolites are found in the urine within 8 hours.

N-acetyl cysteine:

Absorption: The bioavailability is low, ranging from 4% to 10%.

Metabolism: Animal research suggests that it is metabolized to disulphides via deacetylation and oxidation.

Excretion: N-acetyl cysteine is excreted in the urine and has a renal clearance of 30%. The terminal half-life is about 6.25 hours. Patients with cirrhosis appear to have a slower plasma clearance and longer half-life.

Grape seed:

Absorption Proanthocyanidins and flavonoids from grape seed extract are absorbed and distributed into serum within two-three hours of ingestion.

Turmeric:

Absorption The oral bioavailability of curcumin is very low. When taken with food, black/white pepper (piperine) the absorption appears to increase. If taken in a capsule, liposomal formulation, nanoparticle powder or in phospholipid Complex or as a water dispersible turmeric extract.

Metabolism: Curcumin is metabolised in the liver and in the intestines, this contributes to low oral bioavailability. Curcumin is present in the plasma as glucuronide and sulphate conjugates, and the half-life is 6-24 hours.

Excretion: Curcumin is excreted in the faeces.

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/

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