PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
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1. NAME OF THE MEDICINE

TONY FERGUSON MULTIVITAMIN (film-coated tablets)

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

L-Glutamine	200,00 mg
L-Phenylalanine	115,50 mg
Ascorbic Acid (Vitamin C)	60,00 mg
Nicotinamide (Vitamin B3)	35,00 mg
Citrus x aurantium L.	30,00 mg
[fruit, extract providing 35 % citrus bioflavonoids]	
Magnesium Oxide	50,00 mg
Providing Magnesium (elemental)	30,00 mg
Calcium Pantothenate	20,00 mg
Providing Pantothenic Acid (Vitamin B5)	18,30 mg
Pyridoxine Hydrochloride	20,00 mg
Providing Pyridoxine (Vitamin B6)	16,50 mg
Riboflavin (Vitamin B2)	15,00 mg
Thiamine Hydrochloride	15,00 mg
Providing Thiamine (Vitamin B1)	13,40 mg
Ferrous Fumarate	21,34 mg
Providing Iron (elemental)	7,00 mg
Copper Glycinate	13,00 mg
Providing Copper (elemental)	1,30 mg
Zinc Sulphate Hepta-Hydrate	55,00 mg
Providing Zinc (elemental)	12,50 mg
Beta-Carotene	1,00 mg
Providing 83,30 RAE	
Chromium Picolinate	1,61 mg
Providing Chromium (elemental)	200,00 µg
Folic Acid	200,00 µg
Potassium Iodide	0,2 mg
Providing Iodine (elemental)	150,00 µg
Biotin (Vitamin H)	100,00 µg

Phytomenadione (Vitamin K1)	60,00 µg
Cyanocobalamin (Vitamin B12)	4,00 µg
Selenium Glycinate 0,2 %	1,50 mg
Providing Selenium (elemental)	3,00 µg
Colecalciferol (Vitamin D3)	200 IU
Dl-Alpha-Tocopherol Acetate	20,00 mg
Providing Dl-Alpha-Tocopherol (Vitamin E)	10 IU

Sugar free.

For full list of excipients, see section 5.1.

2. PHARMACEUTICAL FORM

Film-coated tablets.
Oblong, concave beige-coloured film-coated tablets.

3. CLINICAL PARTICULARS

3.1 Therapeutic indications

TONY FERGUSON MULTIVITAMIN is a complementary medicine that supports the maintenance of good health.

3.2 Posology and method of administration

Posology

Adults 18 years and older: Take 1 tablet daily in the morning with food, or as recommended by a healthcare provider.

Not suitable for children.

Swallow the tablet whole and do not chew or crush.

Do not exceed the recommended dose.

Method of administration

For oral use. To be taken with food.

3.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 5.1.
- Patients who are pregnant, breastfeeding, or who are intending on becoming pregnant.

3.4 Special warnings and precautions for use

- TONY FERGUSON MULTIVITAMIN contains phenylalanine.

- Use with caution in patients with any medical conditions or who are taking any other medications.
- Use with caution in patients who are following a low protein diet.
- Use with caution in patients who are tobacco smokers or who have a cardiovascular disease.
- Use with caution in patients using blood thinners or statins to lower their cholesterol (see section 3.5).
- Use with caution in patients who have a kidney disorder and/or diabetes.
- Use with caution in patients with schizophrenia.

3.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed on TONY FERGUSON MULTIVITAMIN. Not all possible interactions are indicated in this leaflet.

- Antibiotics: concomitant intake of magnesium, iron or zinc with antibiotics can decrease the absorption of quinolone and tetracycline antibiotics.
- Anticoagulant/antiplatelet medications: selenium may have antiplatelet effects and may increase the risk of bleeding if used with anticoagulant or antiplatelet medications. Vitamin E may inhibit platelet aggregation and antagonize the effects of vitamin K-dependent clotting factors, thereby increasing the risk of bleeding when used concomitantly with anticoagulant/antiplatelet medications.
- Aminoglycoside antibiotics: concomitant intake of aminoglycoside antibiotics and magnesium may increase the risk for neuromuscular weakness.
- Amiodarone: taking iodine with amiodarone might cause excessively high iodine levels.
- Anticonvulsants: glutamine may antagonize the effects of anticonvulsant medications.
- Antithyroid medications: iodine might alter the effects of antithyroid medications.
- Atorvastatin: vitamin D might reduce the absorption of atorvastatin.
- Baclofen: concomitant intake of phenylalanine may reduce the intestinal absorption of baclofen.
- Bisphosphonates: magnesium and iron can decrease absorption of bisphosphonates.
- Calcipotriene: concomitant use of vitamin D with calcipotriene increases the risk for hypercalcaemia.
- Carbamazepine: niacinamide might increase the levels and adverse effects of carbamazepine.
- Cephalexin: zinc may decrease cephalexin levels by chelating with cephalexin in the gut and preventing its absorption.
- Dolutegravir: iron may decrease levels of dolutegravir by reducing its absorption when taken concomitantly.
- Estrogens: vitamin C may increase the blood levels of estrogens.
- Insulin: concomitant use of chromium and insulin can increase the risk of hypoglycaemia.
- Levodopa: phenylalanine, particularly in high doses, can reduce the effectiveness of levodopa. Magnesium can reduce the bioavailability of levodopa/carbidopa. Iron may decrease levodopa levels by reducing its absorption.
- Levothyroxine: iron may decrease levothyroxine levels by reducing its absorption when taken concomitantly.
- Lithium: concomitant use of iodine with lithium may have additive hypothyroid effects.
- Methyldopa: iron may decrease methyldopa levels by reducing its absorption when taken concomitantly.
- Methotrexate: folic acid might reduce the efficacy of methotrexate as a cancer treatment when taken concomitantly.
- Penicillamine: iron and zinc may decrease penicillamine levels by reducing its absorption.

- Phenobarbital: folic acid may antagonistic effects on phenobarbital and increase the risk for seizures.
- Primidone: niacinamide might increase the levels and adverse effects of primidone. Folic acid may have antagonistic effects on primidone and increase the risk for seizures.
- Ritonavir: zinc modestly reduces the levels of ritonavir.
- Sulfonylureas: magnesium increases the systemic absorption of sulfonylureas, increasing their effects and side effects.
- Warfarin: vitamin K can antagonize and reverse the therapeutic effects of warfarin. Using vitamin E with warfarin might increase the risk of bleeding.

3.6 Fertility, pregnancy and lactation

Patients who are pregnant or breastfeeding or who are intending to become pregnant should not take TONY FERGUSON MULTIVITAMIN.

3.7 Effects on ability to drive and use machines

Patients should take caution before performing activities requiring their attention, until they are reasonably certain that TONY FERGUSON MULTIVITAMIN does not adversely affect their performance.

3.8 Undesirable effects

TONY FERGUSON MULTIVITAMIN is generally well tolerated.

Gastrointestinal disorders

Frequency unknown: nausea, constipation, heartburn, belching, bloating, flatulence, vomiting, diarrhoea, gastrointestinal pain, decreased or loss of appetite, dry mouth.

Endocrine disorders

Frequency unknown: hypoglycaemia.

Metabolism and nutrition disorders

Frequency unknown: decreased serum folic acid concentrations.

Nervous system disorders

Frequency unknown: headache, vertigo, paresthesia, somnolence.

Psychiatric disorders

Frequency unknown: anxiety, insomnia, hypomania, irritability, mood changes.

Renal and urinary disorders

Frequency unknown: bright yellow urine.

Reproductive system and breast disorders

Frequency unknown: breast soreness or enlargement.

Skin and subcutaneous tissue disorders

Frequency unknown: skin reactions, photosensitivity, iododerma.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

3.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

Treatment of overdose is symptomatic and supportive.

4. PHARMACOLOGICAL PROPERTIES

4.1 Pharmacodynamic properties

Class and category: Category D 34.12 Multiple Substance Formulation

L-Glutamine
A source of amino acids involved in muscle protein synthesis.

Phenylalanine
A source of essential amino acids involved in muscle protein synthesis and the maintenance of good health.

Vitamin C
Is an antioxidant and helps in the development and maintenance of bones, cartilage, teeth and gums, as well as connective tissue formation.

Vitamin B3
Helps the body to metabolise carbohydrates, fats and proteins. Contributes to normal growth and development. Is a factor in the maintenance of good health.

Citrus Bioflavonoids
A source of antioxidants for the maintenance of good health.

Magnesium
Contributes to normal energy-yielding metabolism, the normal functioning of the nervous system, as well as to normal electrolyte balance. Contributes to the reduction of tiredness and fatigue and is a factor in the maintenance of good health.

Vitamin B5
Helps the body to metabolise carbohydrates, fats and proteins. Contributes to tissue formation and is a factor in the maintenance of good health.

Vitamin B6
Contributes to normal cysteine synthesis. Contributes to the normal function of the immune system, psychological function, and to the regulation of hormonal activity. Is a factor in the maintenance of good health.

Vitamin B2
Helps the body to metabolise carbohydrates, fats and proteins. Contributes to tissue formation and is a factor in the maintenance of good health.

Vitamin B1
Helps the body to metabolise carbohydrates, fats and proteins. Contributes to normal growth and is a factor in the maintenance of good health.

Iron
Helps to form red blood cells and helps in their proper function. Iron is factor in the maintenance of good health.

Copper
Helps to produce and repair connective tissue and form red blood cells. Copper is a factor in the maintenance of good health.

Zinc
Helps with cognitive tissue formation, maintains healthy skin and immune function as well as good health in growing children.

Beta-Carotene
Contributes to the maintenance of eyesight, skin, membranes and immune function. Contributes to the development and maintenance of bones and teeth. Maintains and supports healthy vitamin A levels.

Chromium
Contributes to normal macronutrient metabolism, normal blood glucose levels, and helps the body to metabolise carbohydrates and fats.

Folic Acid
Helps the body to metabolise proteins and form red blood cells, and is a factor in the maintenance of good health.

Iodine
Contributes to the normal production of thyroid hormones and normal thyroid function, and is a factor in the maintenance of good health.

Vitamin A
Contributes to the maintenance of eyesight, skin, membranes and immune function. Contributes to the development and maintenance of bones and teeth. Is a factor in the maintenance of good health.

Biotin
Helps the body to metabolise carbohydrates, fats and proteins. Is a factor in the maintenance of good health.

Vitamin K1
Contributes to the maintenance of normal bones and is a factor in the maintenance of good health.

Vitamin B12
Helps to metabolise carbohydrates, fats and proteins. Contributes to normal red blood cell formation and is a factor in the maintenance of good health.

Selenium
Contributes to the protection of cells from oxidative stress, normal spermatogenesis, thyroid function and immune function, and is a factor in the maintenance of good health.

Vitamin D
Helps in the development and maintenance of bones and teeth. Is a factor in the maintenance of good health.

Vitamin E
Is an antioxidant for the maintenance of good health and is a factor in the maintenance of good health.

4.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on TONY FERGUSON MULTIVITAMIN.

The vitamins and minerals in TONY FERGUSON MULTIVITAMIN are well absorbed from the gastrointestinal tract and are widely distributed to all tissues in the body.

5. PHARMACEUTICAL PARTICULARS

5.1 List of excipients

Core:

Di-Calcium Phosphate
Microcrystalline Cellulose
Povidone
Magnesium Stearate

Film-Coating:

Aqueous hydroxypropyl methylcellulose (HPMC)

5.2 Incompatibilities

Not applicable.

5.3 Shelf Life

24 months.

5.4 Special precautions for storage

Store at or below 25 °C.
Store in a dry place away from direct sunlight and moisture.
Keep tablets in the container until required for use.

5.5 Nature and contents of container

White PET container with a white screw cap lid.
Pack size: 30 or 60 tablets.

5.6 Special precautions for disposal

No special requirements.

6. HOLDER OF CERTIFICATE OF REGISTRATION

Tony Ferguson Weightloss SA (Pty) Ltd.
686 Carradale Crescent
Cedar Creek Estate
Needwood Ext. 8
Broadacres, Johannesburg
South Africa
2191

7. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

8. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.