

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

TONY FERGUSON B-COMPLEX (tablets)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:	
Brewer's Yeast (<i>Saccharomyces cerevisiae</i>)	10,00 mg
Vitamin B3 (as Nicotinamide)	3,00 mg
Vitamin B1 (as Thiamine Hydrochloride)	1,00 mg
Vitamin B2 (as Riboflavin)	1,00 mg
Vitamin B5 (as Calcium-D-Pantothenate)	1,00 mg
Vitamin B6 (as Pyridoxine)	1,00 mg

Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

Round, biconvex light yellow to brown coloured tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

TONY FERGUSON B-COMPLEX is a health supplement that may help to:

- Supports the nervous system and psychological function.
- Contributes to normal mental performance and cognitive function.
- Supports normal energy-yielding metabolism.
- Contributes to the reduction of tiredness and fatigue.
- Contributes to the synthesis and metabolism of some neurotransmitters.

- Supports the maintenance of good health.

4.2 Posology and method of administration

Posology

Adults and children 6 years and older:

Take two tablets daily, or as recommended by a healthcare provider.

Do not exceed the recommended daily dosage.

Method of administration

For oral use.

4.3 Contraindications

- Hypersensitivity to any of the active substances listed in section 2 or to any of the excipients listed in section 6.1.
- Patients with Crohn's disease or an immune-compromised condition (e.g. AIDS, lymphoma, patients undergoing long-term corticosteroid treatment).

4.4 Special warnings and precautions for use

- Patients should take special care with TONY FERGUSON B-COMPLEX if they are currently taking any medication or if they are suffering from a medical condition.
- Patients should discontinue using TONY FERGUSON B-COMPLEX if symptoms of digestive upset (e.g. diarrhoea) occur, worsen and/or persist beyond 3 days.
- Patients should consult a healthcare provider prior to use if they have fever, vomiting, bloody diarrhoea, or severe abdominal pain.
- Patients should consult a healthcare provider prior to use if they have peptic ulcer disease or gallbladder disease.

4.5 Interaction with other medicines and other forms of interaction

Brewer's Yeast

- **Antidiabetes medications:** concomitant use may increase the risk of hypoglycaemia.
- **Antifungal medications:** concomitant use may decrease the effectiveness of brewer's yeast.
- **Lithium:** concomitant use may have additive effects and side effects.
- **Monoamine oxidase inhibitors (MAOIs):** concomitant use may increase the risk of hypertensive crisis and hypertension.

Nicotinamide

- **Anticoagulant or antiplatelet medications:** nicotinamide may have additive effects when used concomitantly with anticoagulants or antiplatelet medications.

- **Carbamazepine:** nicotinamide might increase the levels and adverse effects of carbamazepine.
- **Primidone:** nicotinamide may increase the levels and adverse effects of primidone.

Thiamine

No known interactions.

Riboflavin

No known interactions.

Pantothenic Acid

No known interactions.

Pyridoxine

No known interactions.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that TONY FERGUSON B-COMPLEX does not adversely affect their performance.

4.8 Undesirable effects

TONY FERGUSON B-COMPLEX is generally well tolerated.

Gastrointestinal disorders

Frequency unknown: gastrointestinal discomfort, flatulence, nausea, vomiting, heartburn, abdominal pain, loss of appetite, diarrhoea, anal irritation.

Metabolic and nutrition disorders

Frequency unknown: decreased serum folic acid concentrations.

Nervous system disorders

Frequency unknown: headache, paresthesia, somnolence.

Renal and urinary disorders

Frequency unknown: bright yellow urine.

Reproductive system disorders

Frequency unknown: breast soreness or enlargement.

Skin and subcutaneous tissue disorders

Frequency unknown: photosensitivity.

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 requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Class and category: Category D 34.12 Multiple Substance Formulation. Complementary Medicine: Health Supplement.

Brewer's Yeast

Source of B-vitamins and protein.

Vitamin B3

A factor in the maintenance of good health. Helps to metabolise carbohydrates, fats and proteins. Contributes to normal growth and development.

Vitamin B1

Helps to metabolise carbohydrates, fats and proteins. Contributes to the normal function of the nervous system, heart, and psychological function.

Vitamin B2

Contributes to the function of the nervous system and the reduction of tiredness and fatigue. Supports the maintenance of skin, mucous membranes, vision, the metabolism of iron and tissue formation.

Vitamin B5

Contributes to the normal synthesis and metabolism of steroid hormones, vitamin D and some neurotransmitters.

Vitamin B6

Supports normal energy-yielding metabolism, homocysteine metabolism, and glycogen metabolism. Contributes to the regulation of hormonal activity. Support the immune system function. Supports the nervous system and psychological function.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on TONY FERGUSON B-COMPLEX.

Brewer's Yeast

Pharmacokinetic studies not available.

Vitamin B3

Niacinamide (Vitamin B3) is rapidly absorbed from the gastrointestinal tract and converted to the coenzymes: nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP) in all tissues of the body. Excess niacinamide is excreted in the urine.

Vitamin B1

Thiamine (vitamin B1) is absorbed in the small intestine and distributed into the skeletal muscle, the heart, the liver, the kidneys and the brain. Thiamine and its metabolites are excreted in the urine.

Vitamin B2

Riboflavin (vitamin B2) is readily absorbed from the gastrointestinal tract and is widely distributed in the body. It is excreted in the urine.

Vitamin B5

Pantothenic acid (Vitamin B5) is the precursor of coenzyme A (CoA) and is excreted in the urine.

Vitamin B6

Pyridoxine (Vitamin B6) is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the urine.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Povidone

Microcrystalline cellulose

Di-calcium phosphate
Croscarmellose sodium

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 months.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

White 175 ml PET container with a white screw-on cap.
Pack size: 100 tablets.

6.6 Special precautions for disposal

No special requirements.

7. 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

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.