PROFESSIONAL INFORMATION
TURBOVITE® FOCUS capsules

- Complementary Medicine.
- D.34.13 Complementary Medicines: Health Supplements – Other
- Health Supplements are intended only to complement health or supplement the diet. This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
S0

1. NAME OF THE MEDICINE
TURBOVITE® FOCUS (capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains:

Active ingredients	Per capsule	Per max daily dose (2 capsules)	% NRV# per max daily dose (2 capsules)
Panax ginseng [root extract]	53,34 mg	106,68 mg	*
Caffeine	50 mg	100 mg	*
L-Theanine	100 mg	200 mg	*
Vitamin B1 (thiamine hydrochloride)	1,2 mg	2,4 mg	200 %
Vitamin B2 (riboflavin)	2 mg	4 mg	308 %
Vitamin B3 (nicotinamide)	9 mg	18 mg	113 %
Vitamin B5 (calcium D-pantothenate)	3 mg	6 mg	120 %
Vitamin B6 (pyridoxine hydrochloride)	2,5 mg	5 mg	294 %
Vitamin B9 (folic acid)	250 µg	500 µg	125 %
Vitamin B12 (cyanocobalamin)	8 µg	16 µg	667 %
Biotin (D-biotin)	50 µg	100 µg	333 %
Vitamin C (ascorbic acid)	100 mg	200 mg	200 %
Magnesium (magnesium oxide)	42 mg	84 mg	20 %

Nutrient reference values for adults and children older than 4 years.
* NRV not established.

Turbovite® Focus capsules is sugar free.
CONTAINS CAFFEINE.
For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Capsule, hard gelatine
Turbovite® Focus capsules are purple, hard gelatine capsules.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Turbovite® Focus capsules is a health supplement indicated for the support of cognitive performance during times of stress and for the maintenance of healthy energy levels.

4.2 Posology and method of administration
The recommended daily dosage is
Adults 18 years and older:
One (1) capsule in the morning and one (1) capsule early afternoon, after meals, with a glass of water.
Advise the patient to not take dosage at the same time as other medications (see **INTERACTIONS**).

4.3 Contraindications
- Hypersensitivity to any of the ingredients of Turbovite® Focus capsules (see section **6.1 List of excipients**).
- Turbovite® Focus capsules contains nicotinamide, which is contraindicated in patients with liver disease or in patients with active peptic ulcer disease.
- Turbovite® Focus capsules contains vitamin B12, which is contraindicated in patients with cobalamin or cobalt hypersensitivity.

4.4 Special warnings and precautions for use
- Must not be given to patients with known hypersensitivity or allergy towards any of the ingredients. Patients should be advised to consult their medical practitioner if in doubt.
- Acute and chronic overdose increases the risk of side effects. Individuals receiving other vitamin or multivitamin preparations, any other medication, placed on a restricted diet, or those with conditions such as diabetes, glaucoma or detrusor instability should consult a healthcare professional before use of the product.
- Contains 100 mg caffeine per capsule. A cup of instant coffee contains approximately 80 mg of caffeine.
- Not suitable for children under the age of 18 years.
- Discontinue use two weeks prior to surgery.
- Use of caffeine may result in sleep deprivation.
- If the patient is of childbearing age, pregnant or breastfeeding see **4.6 Fertility, pregnancy and lactation**.
- Use with caution in people with diabetes or hypertension, as Panax ginseng may have an effect on blood sugar levels and blood pressure

Porphyria
Safety has not been established.

4.5 Interaction with other medicinal products and other forms of interactions

Active ingredients	Medicine	Description
Caffeine	Products containing caffeine	Avoid taking Turbovite® Focus capsules with health supplements or foods that contain caffeine or increase blood pressure
		(e.g. medication, coffee, tea, colas, cocoa, guarana, maté, bitter orange extract, synephrine, octopamine, ephedra, ephedrine).
Caffeine	Lithium	Patients taking lithium should use Turbovite® Focus capsules with caution as it contains caffeine which increases serum lithium concentrations.
Vitamin B6	Levodopa	Pyridoxine enhances the metabolism of levodopa, reducing its antiparkinsonism effects. However, this interaction does not occur when carbidopa is used in combination with levodopa.
Vitamin B12	Chloramphenicol	Chloramphenicol may delay or interrupt the reticulocyte response to vitamin B12. Therefore, blood counts need to be closely monitored if this combination can't be avoided.
Vitamin B9	Vitamin B12 deficiency	Patients should use Turbovite® Focus capsules with caution if they have a vitamin B12 deficiency, as vitamin B9 (Folic acid) could mask the deficiency.
Vitamin B9	Methotrexate	Folic acid supplementation may reduce the effectiveness of methotrexate in the treatment of acute lymphoblastic leukemia and theoretically, the efficacy in the treatment of other cancers.
Magnesium	Potassium sparing diuretics	Potassium sparing diuretics also have magnesium sparing properties. Increased magnesium levels could result with concomitant use of potassium sparing diuretics and supplementation.
Magnesium	Antibiotics	Turbovite® Focus capsules contains magnesium which may reduce the absorption of antibiotics. Oral antibiotics should be taken at least two (2) hours before, or four (4) hours after Turbovite® Focus capsules or similar supplements.
Panax ginseng	Antidepressants	Patients taking antidepressant medication, blood thinners or digoxin should use Turbovite® Focus capsules with caution.

4.6 Fertility, pregnancy and lactation
Pregnancy
It is not advisable to take Turbovite® Focus capsules during pregnancy as it contains caffeine and *Panax ginseng*. Caffeine crosses the placenta.
Breastfeeding
It is not advisable to take Turbovite® Focus capsules while breastfeeding as it contains caffeine and *Panax ginseng*.
Fertility
There are no known effects of Turbovite® Focus capsules on fertility.

4.7 Effects on the ability to drive and use machines.
Based on the side effect profile, Turbovite® Focus capsules should not affect the ability to drive or operate machinery.

4.8 Undesirable effects
Patients experiencing any side effects or sensitivity to any of the ingredients, should discontinue use.

System Organ Class	Frequency	Adverse Event
Immune system disorders	frequency unknown	Hypersensitivity reactions or anaphylaxis, symptoms include: difficulty breathing or swallowing, angioedema, itchy throat, urticaria, itching
Nervous system disorders	frequency unknown	Anxiety, headache, insomnia
Gastrointestinal Disorders	frequency unknown	Abdominal discomfort, diarrhoea, dysphagia, heartburn, nausea, vomiting
Skin and subcutaneous tissue disorders	frequency unknown	Hypersensitivity reaction (dermatitis, erythema and urticaria)

If symptoms persist, or if any adverse reactions occur, advise the patient to consult a healthcare provider.
Reporting of suspected adverse reactions
Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care 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

4.9 Overdose
Symptoms
See **4.8 Undesirable effects**
In overdose, side effects can be precipitated and/or be of increased severity.
At doses of more than 600 mg per day, caffeine may cause anxiety, tachycardia, palpitations, insomnia, restlessness, nervousness, tremor and headache.
Treatment
There is no evidence that this product can lead to an overdose when used as recommended.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Category and class: D.34.13 Complementary Medicines: Health Supplements – Other
Pharmacotherapeutic classification: Vitamin B-Complex, other combinations
ATC code: A11EX
Theanine and caffeine
Theanine appears to support relaxation and reduce tension-anxiety. Theanine and caffeine in combination appear to influence cognitive performance by improving accuracy and alertness during cognitive tasks.
Panax ginseng
Contains *Panax ginseng* extract which appears to improve cognitive ability in middle-aged people.
Vitamin B1
Thiamine is a water-soluble B vitamin that is essential for carbohydrate metabolism in its diphosphate form.
Vitamin B2
Riboflavin is an essential for the utilisation of energy from food. Additionally, the active phosphorylated forms (flavine mononucleotide and flavine adenine dinucleotide) are involved as coenzymes in oxidation-reduction metabolic reactions.
Vitamin B3
Nicotinamide is a water-soluble B vitamin which is converted in the body to nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP). Both NAD and NADP are essential components of oxidation-reduction reactions, ATP synthesis and ADP-ribose transfer reactions.
Vitamin B5
It is a component of coenzyme A which is essential in the metabolism of carbohydrate, fat, and protein.
Vitamin B6
Pyridoxine is essential for amino acid metabolism and to a lesser extent involved in carbohydrate and fat metabolism.
Vitamin B9
Folic acid is reduced in the body to tetrahydrofolate, which is a coenzyme for various metabolic processes including the synthesis of purine and pyrimidine nucleotides, and hence in the synthesis of DNA; it is also involved in some amino acid conversions, and in the formation and utilisation of formate.
Vitamin B12
Vitamin B12, in the form cyanocobalamin, can be converted to coenzyme B12, which is an essential component for the conversion of methylmalonate to succinate and for the synthesis of methionine from homocysteine. Additionally, vitamin B12 is a requirement for nucleoprotein and myelin synthesis, cell reproduction, normal growth, normal erythropoiesis and is also involved in maintaining sulfhydryl groups in the reduced form that is required by enzymes involved in both fat and carbohydrate metabolism as well as protein synthesis.
Biotin
It is an essential coenzyme in fat metabolism and in other carboxylation reactions.
Vitamin C
The beneficial effects of vitamin C are primarily associated with its use as an antioxidant and ability to scavenge free radicals.
Magnesium
Extracellular magnesium is essential for maintaining nerve and muscle electrical potentials as well as for transmitting nerve impulses across neuromuscular junctions. Additionally, magnesium appears to have neuroprotective effects.

5.2 Pharmacokinetic properties
Panax ginseng
Absorption: Oral doses of P. ginseng are typically absorbed in the intestines. However, this absorption is limited by factors like extensive metabolism in the gastrointestinal tract, poor membrane permeability and low solubility of deglycosylated products.
Distribution: After oral ingestion protopanaxadiol and protopanaxatriol ginsenosides can be detected in the blood plasma.
Metabolism: It has been proven that metabolism of ginsenosides occurs via degradation processes that are already taking place in the gastrointestinal tract as a result of gut microorganisms, intestinal enzymes or gastric fluid. Additionally, protopanaxadiol saponins are known to degrade at a faster rate than protopanaxatriol saponins, thus resulting in them having a lower bioavailability .
Excretion: While the excretion of P. ginseng has not been extensively studied, it is believed that trace amounts of the ginsenosides are excreted in the urine.
Caffeine
Absorption: Caffeine is absorbed readily after oral administration and is widely distributed throughout the body
Distribution: Caffeine passes readily into the central nervous system and the saliva; low concentrations are also present in breast milk. Caffeine crosses the placenta.
Metabolism: Caffeine is metabolised almost completely in the liver via oxidation, demethylation and acetylation. The metabolism of caffeine is dose-dependent with clearance decreasing as the dose is increased.
Excretion: Caffeine is excreted in the urine as 1-methyluric acid, 1-methylxanthine, 7-methylxanthine, 1,7-dimethylxanthine (paraxanthine), 5-acetylamino-6-formylamino-3-methyluracil (AFMU), and other metabolites with only about 1 % unchanged. The plasma half-life of caffeine is decreased by smoking and by exercise and is increased by liver disease such as cirrhosis and viral hepatitis, and in pregnancy.
Theanine
Absorption: Oral administration of theanine is absorbed through the intestines tract. Theanine levels typically peak approximately 50 minutes after consumption.
Distribution: After absorption, theanine is distributed to the plasma and erythrocytes. Additionally, theanine has the capacity to cross the blood-brain barrier in a dose-dependent manner.
Metabolism: In the intestines theanine is hydrolysed into ethylamine and glutamic acid.
Excretion: Theanine and its metabolites are excreted in the urine, with only a small fraction remaining stored in the erythrocytes. Elimination typically occurs between 3 and 24 hours after consumption. Majority of the theanine is excreted as ethylamine and glutamic acid, while only 2,4 % to 3,1 % of theanine is excreted unchanged.
Vitamins and minerals
The combination of vitamins and minerals is typical of the normal diet. Therefore, the pharmacological metabolism and fate of Turbovite® Focus capsules is anticipated to be similar.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Gelatine capsule (Capsule constituents: bovine gelatine, colourants, titanium dioxide)
Magnesium stearate

6.2 Incompatibilities
None known

6.3 Shelf life
24 months

6.4 Special precautions for storage
- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- Keep in original packaging until required for use.

6.5 Nature and contents of container
Turbovite® Focus capsules are purple capsules.
Turbovite® Focus capsules are available in a PVC/aluminium foil blister pack with 3 strips. One strip contains 10 capsules each and includes a patient information leaflet in a printed unit carton.

6.6 Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
Nativa (Pty) Ltd
260 Cradock Avenue, Lyttelton, Centurion, 0157, Gauteng, South Africa
Tel: +27 (0) 12 664 7110
Customer care line: 0860 628 482
Email: health@nativa.co.za

8. REGISTRATION NUMBER(S)
To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
To be allocated

10. DATE OF REVISION OF THE TEXT