

PROFESSIONAL INFORMATION

TURBOVITE® FOCUS EFFERVESCENT TABLETS

SCHEDULING STATUS

[S0]

PROPRIETARY NAME AND DOSAGE FORM

TURBOVITE® FOCUS EFFERVESCENT TABLETS (effervescent tablet)

COMPOSITION

Active Ingredients	Per effervescent tablet (maximum daily dosage)	% NRV # per maximum daily dosage
<i>Panax ginseng</i> root extract	106,67 mg	-
Caffeine	100 mg	-
L-Theanine	200 mg	-
Vitamin B1 (Thiamine hydrochloride)	2,4 mg	200
Vitamin B2 (Riboflavin)	4 mg	308
Vitamin B3 (Nicotinamide)	18 mg	113
Vitamin B5 (Calcium D-Pantothenate)	6 mg	120
Vitamin B6 (Pyridoxine hydrochloride)	5 mg	294
Vitamin B9 (Folic acid)	500 µg	125
Vitamin B12 (Cyanocobalamin)	15 µg	625
Biotin (D-biotin)	100 µg	333
Vitamin C (Ascorbic acid)	500 mg	500
Magnesium (Magnesium sulfate)	84 mg	20

Nutrient Reference Values for adults and children older than 4 years.

Excipients: citric acid, maltodextrin, flavourings, polyethylene glycol 6000, polysorbate 60, simethicone, sodium bicarbonate, sodium carbonate

Contains sweeteners (mannitol 550 mg/tablet, sodium cyclamate 30 mg/tablet, and saccharin sodium 20 mg/tablet).

Contains sugar (sucrose 250 mg/tablet).

CATEGORY AND CLASS

D.34.13 Complementary Medicines: Health Supplements – Other.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

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 extract

Contain *Panax ginseng* extract which appears to improve cognitive ability in middle-aged people.

Vitamins and minerals

A sufficient intake of vitamins and minerals is necessary to maintain normal energy metabolism, and physical and physiological function. Unbalanced diet and insufficient dietary intake of vitamins and minerals can result in subnormal health.

Pharmacokinetic properties

There is insufficient information on *Panax ginseng* to rate.

Caffeine

Caffeine is metabolised by liver cytochrome P450 enzymes. It is able to cross the blood-brain barrier and placenta. Caffeine is mostly excreted through the urine.

Theanine

Theanine is able to cross the blood-brain barrier and is mostly excreted through the urine.

Vitamins and minerals

The combination of vitamins and minerals is typical of the normal diet. Therefore, the pharmacological metabolism and fate of TURBOVITE® FOCUS EFFERVESCENT TABLETS is anticipated to be similar.

INDICATIONS

TURBOVITE® FOCUS EFFERVESCENT TABLETS is a health supplement indicated for the support of cognitive performance during times of stress and for the maintenance of healthy energy levels.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients of TURBOVITE® FOCUS EFFERVESCENT TABLETS (see **COMPOSITION**). TURBOVITE® FOCUS EFFERVESCENT TABLETS contain nicotinamide, which is contraindicated in patients with liver disease or in patients with active peptic ulcer disease. Contains vitamin B12, which is contraindicated in patients with cobalamin or cobalt hypersensitivity.

WARNINGS AND SPECIAL PRECAUTIONS

Do not use if known hypersensitivity or allergy exists to any of the ingredients. If in doubt, consult your medical practitioner. The ingredients in TURBOVITE® FOCUS EFFERVESCENT TABLETS may interact with other medications (see **INTERACTIONS**). Consult a healthcare practitioner prior to use if you have diabetes, high blood pressure, glaucoma, or detrusor instability (overactive bladder syndrome). This product is not intended as a substitute for sleep.

This product is not suitable for children under the age of 18.

Porphyria: Safety has not been established.

Effects on ability to drive vehicles and use machines

TURBOVITE® FOCUS EFFERVESCENT TABLETS should not affect your ability to drive or operate machinery. However, if you think you are affected you should not drive or operate machinery until you feel better.

INTERACTIONS

Take TURBOVITE® FOCUS EFFERVESCENT TABLETS a few hours before or after taking other medications (see **DOSAGE AND DIRECTIONS FOR USE**). If you are taking antidepressant medication, blood thinners or digoxin, consult your doctor, pharmacist or other healthcare professional before use. You should consult a healthcare practitioner prior to use if you are taking lithium. Avoid taking TURBOVITE® FOCUS EFFERVESCENT TABLETS with health supplements or foods that contain caffeine or increase blood pressure (e.g. medications, coffee, tea, colas, cocoa, guarana, maté, bitter orange extract, synephrine, octopamine, ephedra, ephedrine).

TURBOVITE® FOCUS EFFERVESCENT TABLETS contain magnesium which may interact with tetracycline antibiotics and reduce their absorption. It is recommended that all oral antibiotics are taken at least two (2) hours before, or four (4) to six (6) hours after TURBOVITE® FOCUS EFFERVESCENT TABLETS or similar supplements. Folic acid can mask a vitamin B12 deficiency. If in doubt, consult your medical practitioner.

HUMAN REPRODUCTION

Pregnancy

It is not advisable to take TURBOVITE® FOCUS EFFERVESCENT TABLETS while you are pregnant as it contains caffeine and *Panax ginseng*.

Women of Childbearing Potential

There are no known restrictions for use of TURBOVITE® FOCUS EFFERVESCENT TABLETS in women of childbearing age.

Lactation

It is not advisable to take TURBOVITE® FOCUS EFFERVESCENT TABLETS while you are breastfeeding as it contains caffeine.

Fertility

There are no known effects of TURBOVITE® FOCUS EFFERVESCENT TABLETS on fertility.

DOSAGE AND DIRECTIONS FOR USE

Dosage

Do not exceed the recommended daily dosage.

Adults 18 years and older:

Take one (1) effervescent tablet daily.

Directions for use

Dissolve one (1) effervescent tablet in a glass of water daily, after a meal. Take a few hours before or after taking other medications (see **INTERACTIONS**).

SIDE EFFECTS

If you experience any side effects or sensitivity towards any of the ingredients, discontinue use.

If symptoms persist, or if any adverse reactions occur, consult a medical practitioner.

Side effects may include, but are not limited to:

Nervous system disorders:

Frequency unknown: anxiety, headaches and insomnia

Gastrointestinal disorders:

Frequency unknown: dyspepsia (including upper abdominal (epigastric) discomfort and nausea), vomiting, dysphagia, heartburn and diarrhoea

Skin and subcutaneous tissue disorders:

Frequency unknown: hypersensitivity reaction (dermatitis, erythema and urticaria)

For other side effects related to overdosage, see **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**

Product issues

No product issues are available on TURBOVITE® FOCUS EFFERVESCENT TABLETS.

Post-marketing data

No side effects of TURBOVITE® FOCUS EFFERVESCENT TABLETS have been reported post-marketing.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Symptoms of Overdosage

See **SIDE EFFECTS**.

Do not exceed the recommended daily dosage.

Possible symptoms of TURBOVITE® FOCUS EFFERVESCENT TABLETS overdose may include but are not limited to, headache, insomnia, flushing of the skin, polyuria, and chromaturia, dizziness and drowsiness. Patients with a history of oxalate kidney stones should avoid high doses of vitamin C due to increased risk of kidney stone formation.

Treatment of Overdosage

If an accidental overdose occurs, consult a medical practitioner.

Treatment is symptomatic and supportive.

IDENTIFICATION

Light yellow, round, orange flavoured effervescent tablets.

PRESENTATION

One (1) white, polypropylene tube with white spiral cap, containing 10 effervescent tablets, with a leaflet, in a unit carton.

Two (2) white, polypropylene tubes with above description, containing 10 effervescent tablets each (20 effervescent tablets in total), with a leaflet, in a unit carton.

Three (3) white, polypropylene tubes with above description, containing 10 effervescent tablets each (30 effervescent tablets in total), with a leaflet, in a unit carton.

STORAGE INSTRUCTIONS

Store at or below 25 °C.

Replace cap firmly after use.

Protect from light and moisture.

Keep in original packaging until required for use.

Do not use after the expiry date printed on the carton and tube.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

To be allocated

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Nativa (Pty) Ltd

260 Cradock Avenue, Lyttelton, Centurion, 0157, Gauteng, South Africa

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Customer care line: 0860 628 482

Email: health@nativa.co.za

Website: www.nativa.co.za

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

To be allocated

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To be allocated

COMPLEMENTARY MEDICINE

Health Supplement

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.

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