

PROFESSIONAL INFORMATION

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

Vitatech Focus Support Tablets 30

2. COMPOSITION

Each tablet contains:

Ingredients	Per tablet
L-Theanine	200,0 mg
Caffeine Anhydrous	200,0 mg

For full list of excipients, see section 6.a

3. PHARMACEUTICAL FORM

White, round or oval tablet.

4. CLINICAL PARTICULARS

(a) Therapeutic indication

Caffeine works by stimulating the central nervous system (CNS), heart, muscles, and the centres that control blood pressure. It is mainly used to stimulate mental alertness. Caffeine can raise blood pressure, but might not have this effect in people who use it all the time. **Vitatech Focus Support may** assist to maintain optimal alertness through a biochemical process at cellular level.

L-theanine has been used for a variety of conditions including anxiety, cognitive impairment, to improve mental alertness, and boost immune function; however, limited clinical information is available to support these claims.

(b) Dosage and method of administration

Adults: Take 1 tablet per day with a glass of water after a meal.

Do not exceed the recommended dose.

Always consult your healthcare professional if you are taking any other medicine.

Only take the medication as indicated on the packet or container.

If you skip a dose, do not take a double dose.

Take at least two hours before or after taking other medication.

(c) Contraindications

Hypersensitivity to any of the ingredients or the excipients. Not for use in children under the age of 18 years.

(d) Special warnings and precautions for use

CONTAINS CAFFEINE. Do not consume if you have allergies to sulphur.

Vitatech Focus Support should be used with care if patients have any of these health problems:

- Anxiety disorders,
- Bipolar disorder. Too much caffeine might make this condition worse,
- Bleeding disorders: it might aggravate bleeding disorders.
- Heart conditions: Caffeine can cause irregular heartbeat in sensitive people.
- Diabetes: Some research suggests that caffeine may affect the way the body uses sugar and might worsen diabetes. If you have diabetes, use caffeine with caution,
- Diarrhea, when taken in large amounts, might worsen diarrhea,
- Epilepsy, avoid using caffeine in high doses.
- Glaucoma, increases the pressure inside the eye. The increase occurs within 30 minutes and lasts for at least 90 minutes after drinking caffeinated beverages,
- High blood pressure, might increase blood pressure in people with high blood pressure,
- Loss of bladder control, can make bladder control worse by increasing frequency of urination and the urge to urinate,
- Irritable bowel syndrome (IBS), large amounts, might worsen diarrhea in people with IBS,
- Weak bones (osteoporosis): Caffeine can increase the amount of calcium that is flushed out in the urine. If you have osteoporosis or low bone density, caffeine should be limited to less than 300 mg per day (approximately 2-3 cups of coffee). It is also a good idea to get extra calcium to make up for the amount that may be lost in the urine. If you are generally healthy and getting enough calcium from your food or supplements, taking up to 400 mg of caffeine per day (3-5 cups of coffee) doesn't seem to increase the risk of getting osteoporosis,
- older women with an inherited disorder that affects the way vitamin D is used should use caffeine with caution. Vitamin D works with calcium to build bones,
- Parkinson disease, with creatine might make Parkinson disease get worse faster. If you have Parkinson disease and take creatine, use caffeine with caution and
- Schizophrenia, might worsen symptoms of schizophrenia.

Any other supplementation should be taken into account when prescribing / suggesting **VITATECH FOCUS SUPPORT**.

(e) Interaction with other medicines and other forms of interaction

Major Interaction

Do not take this combination with

- Stimulant medicines, like Ephedrine interacts with CAFFEINE

Moderate Interaction

Be cautious with this combination:

- Cardiac stress test medicines, like Adenosine (Adenocard). Stop consuming caffeine-containing products at least 24 hours before a cardiac stress test.
- Antibiotics (Quinolone antibiotics),
- Cimetidine (Tagamet),
- Clozapine (Clozaril),
- Dipyridamole (Persantine) before a cardiac stress test,
- Disulfiram (Antabuse),
- Estrogens, some estrogen pills include conjugated equine estrogens (Premarin), ethinyl estradiol, estradiol, and others,
- Fluvoxamine (Luvox), Lithium, your body naturally gets rid of lithium. Caffeine

can increase how quickly your body gets rid of lithium. If you take products that contain caffeine and you take lithium, stop taking caffeine products slowly. Stopping caffeine too quickly can increase the side effects of lithium.

- (Anticoagulant / Antiplatelet drugs), (Lovenox), heparin, warfarin (Coumadin), and others,
- Medications for depression (MAOIs),
- Phenylpropanolamine
- Pentobarbital (Nembutal) can block the sleep-producing effects of pentobarbital.

Minor Interaction

Be watchful with this combination

- Alcohol,
- Birth control pills (Contraceptive drugs), birth control pills include ethinyl estradiol and levonorgestrel (Triphasil), ethinyl estradiol and norethindrone (Ortho-Novum 1/35, Ortho-Novum 7/7/7), and others,
- Fluconazole (Diflucan),
- Medications for diabetes (Antidiabetes drugs),
- Mexiletine (Mexitil),
- Terbinafine (Lamisil) and
- Anti-acids, such as altretamine, cisplatin, should be taken at least 2 hours before or after **VITATECH FOCUS SUPPORT**,

(f) Pregnant or Breastfeeding

Pregnancy and breast-feeding: Caffeine is **POSSIBLY SAFE** in pregnant or breast-feeding women when used daily amounts of less than 300 mg. This is about the amount in about 3 cups of coffee. Consuming larger amounts during pregnancy or when breast-feeding is **POSSIBLY UNSAFE**. When consumed in larger amounts during pregnancy, caffeine might increase the chance of miscarriage and other problems. Also, caffeine can pass into breast milk, so nursing mothers should closely monitor caffeine intake to make sure it is on the low side. High intake of caffeine by nursing mothers can cause sleep disturbances, irritability, and increased bowel activity in breast-fed infants. Before using **VITATECH FOCUS SUPPORT**, please consult your health care provider

(g) Ability to drive and use machines

VITATECH FOCUS SUPPORT should not affect the ability of individuals to drive or operate machinery.

(h) Side Effects

When taken by mouth: Caffeine is **LIKELY SAFE** for most healthy adults when used in doses up to 400 mg per day. This amount of caffeine is similar to what is found in about 4 cups of coffee.

Caffeine is **POSSIBLY UNSAFE** when taken by mouth for a long time or in high doses (>400 mg per day). Caffeine can cause insomnia, nervousness and restlessness, stomach irritation, nausea, increased heart rate and respiration, and other side effects. Larger doses might cause headache, anxiety, agitation, and chest pain.

Caffeine is **LIKELY UNSAFE** when taken by mouth in very high doses as it can cause irregular heartbeats and even death. Products with very concentrated or pure caffeine have a high risk of being used in doses that are too high. Avoid using these products.

(i) Overdose

In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

(j) Effects when no further used

There should be no side effects or any withdrawal symptoms after you stop using
VITATECH FOCUS SUPPORT

(5) PHARMACOLOGICAL PROPERTIES

(a) PHARMACOLOGICAL CLASSIFICATION

34.3 Category D (Health Supplement) [S0]

(b) PHARMACOLOGICAL ACTION

Caffeine is a natural stimulant found in coffee, tea, chocolate, other food, drinks and synthetic. Caffeine stimulates the central nervous system. Caffeine is the most widely used central nervous system (CNS) stimulant in the world. It has numerous pharmacological and physiological effects, including cardiovascular, respiratory, renal, and smooth muscle effects, as well as effects on mood, memory, alertness, and physical and cognitive performance. This chapter provides a brief summary of the metabolism and physiological effects of caffeine.

Theanine improves cognitive function, including learning and memory, in human and animal studies, possibly via a decrease in NMDA-dependent CA1 long-term potentiation (LTP) and an increase in NMDA-independent CA1-LTP and also its potential role as an apparent anxiolytic and the calming effect due to its upregulation of inhibitory neurotransmitters and possible modulation of serotonin and dopamine in selected areas of the brain.

(6) PHARMACEUTICAL PARTICULARS

(a) Other ingredients

Microcrystalline cellulose, di-calcium phosphate & magnesium stearate.

(b) Shelf life

2 years

(c) Storage conditions

Store at or below 25 °C.

Protect from sunlight and moisture.

Keep out of reach of children

Store in original packaging

Do not store in a fridge

Always seal the container properly before storage

(d) Presentation and packaging

White with green lid packaged container with tamperproof induction seal

Clearly labelled with detailed information printed on the label.

Containing 30 tablets.



(e) Disposal and handling

Wrap the contents and the container properly in put in a plastic bag.

Dispose the wrapped package in the normal household waste bag after soaking in water till dissolved.

(7) NAME AND ADDRESS OF REGISTRATION HOLDER

Serfie Imports & Exports (PTY) Ltd

Cnr Parkin & Delson Street, North End, Gqeberha 6001

Tel no: +27 (0) 41 816 3100

Email: info@vitatechhealth.com

Website: www.vitatechhealth.com

(8) REGISTRATION NUMBER

To be allocated

(9) DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

August 2021

(10) COMPLEMENTARY MEDICINE

This medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. This medicine is not intended to diagnose, treat, cure or prevent any disease.