

## PROFESSIONAL INFORMATION

### D 33.7 Combination Product. Western Herbal Medicine. Complementary medicine.

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

**SCHEDULING STATUS:** S0

#### 1. NAME OF THE MEDICINE

**BIOGEN APPETITE SUPPRESS (Vegetable capsules)**

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

##### EACH VEGETABLE CAPSULE CONTAINS:

		%NRV*
<i>Phaseolus vulgaris</i> L. (White kidney bean) [Seed, as 100,00 mg of a 4:1 extract]	400,00 mg	
<i>Coffea arabica</i> L. (Green coffee bean) [Seed extract standardised to 40 % Chlorogenic acids]	133,00 mg	
<i>Rhodiola rosea</i> L (Artic root) [Root extract standardised to 1 % salidroside]	100,00 mg	
<i>Garcinia cambogia</i> (Garcinia) [Fruit extract standardised to 60 % hydroxycitric acid (HCA)]	166,67 mg	
BioPerine® <i>Piper nigrum</i> L. (Black Pepper) [Fruit, 50:1 extract standardised to 95 % piperine]	1,67 mg	
Pantothenic Acid (Vitamin B <sub>5</sub> ) (from calcium D-pantothenate)	3,33 mg	67%
Pyridoxine (Vitamin B <sub>6</sub> )	1,33 mg	78%
Chromium (from Chromium Polynicotinate)	67,00 µg	191%

\*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010).

Sugar free

For full list of excipients, see section 6.1.

#### 3. PHARMACEUTICAL FORM

Vegetable capsules.

#### 4. CLINICAL PARTICULARS

##### 4.1 Therapeutic indications

BIOGEN APPETITE SUPPRESS, helps to suppress your appetite, and temporarily increase the feeling of fullness. Assist with weight management, improve digestion, and support glucose metabolism.

##### 4.2 Posology and method of administration

###### Adults (18 years and older):

Take 1 (one) vegetable capsule 3 (three) times daily before meals, or as recommended by your healthcare provider.

BIOGEN APPETITE SUPPRESS is not recommended for individuals below the age of 18 years.

##### 4.3 Contraindications

- If you have a hypersensitivity to any of the ingredients or the excipients listed in 6.1.
- Do not use this product if you are pregnant.
- CONTAINS CAFFEINE. Contains 13,3 mg caffeine per capsule. A cup of instant coffee contains approximately 80 mg of caffeine.

##### 4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN APPETITE SUPPRESS

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.

Please take note of the following:

- Consult a relevant healthcare provider prior to use if you are pregnant or breastfeeding.
- Consult a relevant healthcare provider prior to use if you have diabetes. Consult a relevant healthcare provider prior to use if your goal is to achieve weight loss.
- Consult a health care provider prior to use if you have a bleeding disorder.
- Consult a relevant health care provider if you are taking any other medicine or have been diagnosed with a chronic condition. Use of caffeine may result in sleep deprivation.
- Limit the use of caffeine-containing products (including tea and coffee) when taking this product. Total caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.

Nutritional supplementation should not replace a balanced diet.

Do not exceed the recommended dose without consulting a healthcare provider.

##### 4.5 Interaction with other medicines and other forms of interaction

###### Interactions with Medicines

*Anticoagulant / Antiplatelet medication:* green coffee may increase the risk of bleeding if used with anticoagulant or antiplatelet medicine.

*Antidiabetic medication:* Phaseolus vulgaris, green coffee bean and Rhodiola might increase the risk of hypoglycemia and interfere with blood glucose control when taken with antidiabetic medication.

*Diuretic medicines:* concomitant use might increase the risk of hypokalemia.

*Adenosine:* Green coffee might decrease the vasodilatory effects of adenosine and interfere with its use prior to stress testing.

*Alendronate:* Green coffee may decrease the levels and effects of alendronate.

*Antihypertensive medicine:* Green coffee bean and Rhodiola combined with antihypertensive drugs might increase the risk of hypotension.

*Beta-adrenergic agonists:* concomitant use of large amounts of green coffee might increase cardiac inotropic effects of beta-agonists.

*Clozapine, Contraceptives, Disulfiram, Cimetidine, Estrogens, Ephedrine, Fluconazole, Fluvoxamine, Lithium, Mexiletine, Phenothiazines, Cimetidine, Quinolone antibiotics, and Terbinafine, Theophylline, Pioglitazone, Riluzole, Verapamil:* might increase the effects and adverse effects of caffeine in green coffee.

*Dipyridamole:* Green coffee might decrease the vasodilatory effects of dipyridamole and interfere with its use prior to stress testing.

*Immunosuppressants:* Rhodiola might interfere with immunosuppressive treatment.

*Monoamine oxidase inhibitors:* Concomitant use might increase the risk of a hypertensive crisis.

*Nicotine, Phenylpropanolamine:* Concomitant use might increase the risk of hypertension.

*Losartan:* Rhodiola might increase levels and adverse effects of losartan.

*Pentobarbital:* Green coffee bean might reduce the effects of pentobarbital.

*P-Glycoprotein:* Rhodiola might increase levels of P-glycoprotein substrates.

*Stimulant medicine:* Concomitant use might increase stimulant adverse effects.

###### Interactions with Diseases/Impairments

*Anxiety disorders:* Green coffee can contain caffeine. Caffeine might aggravate anxiety disorders, especially when used in amounts that provide more than 400 mg of caffeine daily. Caffeine might aggravate symptoms of mania in patients with bipolar disorder. Use with caution.

*Autoimmune disease:* Rhodiola might exacerbate certain autoimmune diseases by stimulating disease activity; avoid use or use with caution in patients with autoimmune diseases such as multiple sclerosis (MS), systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), or others. Rhodiola might have immunostimulatory effects.

*Bleeding disorders:* Green coffee can contain caffeine. Caffeine might aggravate bleeding conditions, caffeine is reported to have antiplatelet activity, caution is advised.

*Diabetes:* Green coffee might interfere with glucose control in patients with diabetes.

*Epilepsy:* Green coffee can contain caffeine. Patients with epilepsy should avoid using high doses of caffeine; low doses should be used with caution.

*Hypertension:* Green coffee might exacerbate hypertension. Use with caution. Consuming caffeinated green coffee might increase blood pressure in people with high blood pressure.

*Hyperhomocysteinemia:* Green coffee might increase plasma homocysteine levels and the risk of cardiovascular disease (cvd). Use with caution.

*Incontinence:* Green coffee can contain caffeine, which acts as a diuretic. Caffeine intake of more than 400 mg daily worsened detrusor instability (urge incontinency) in older females. Use with caution in patients with urinary incontinence.

*Irritable bowel syndrome (ibs):* Green coffee can contain caffeine, which might exacerbate diarrhea and worsen symptoms of diarrhea-predominant ibs, especially when caffeine is taken in large amounts.

*Osteoporosis:* Green coffee can contain caffeine, which might increase the risk of osteoporosis. Consuming caffeine can increase urinary excretion of calcium, although it usually remains within the normal range.

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*Clozapine, Contraceptives, Disulfiram, Cimetidine, Estrogens, Ephedrine, Fluconazole, Fluvoxamine, Lithium,*

###### Interactions with Food

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN APPETITE SUPPRESS.

##### 4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established (see section 4.3).

##### 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 BIOGEN APPETITE SUPPRESS does not adversely affect their performance.

##### 4.8 Undesirable effects

Orally, BIOGEN APPETITE SUPPRESS is well-tolerated.

###### 4.8 a Summary of adverse reactions

BIOGEN APPETITE SUPPRESS can have side effects.

###### 4.8 b Summary of adverse reactions

Constipation, diarrhea, flatulence, nausea, stomach pain, and vomiting. Dizziness, increased or decreased production of saliva, burning aftertaste, dyspepsia, and reduced taste perception.

Cardiovascular - *Rare:*

Although acute administration of caffeine, a constituent of green coffee, can cause increased blood pressure, regular consumption does not seem to increase either blood pressure or pulse, even in mildly hypertensive patients.

Dermatologic - *Rare:*

Hypersensitivity reactions, including anaphylaxis, in sensitive individuals.

Gastrointestinal - *Rare:*

Unknown frequency: Nausea, vomiting, diarrhea, flatulence, constipation, satiety, and stomach pains and stomach irritation. Dry mouth or excessive saliva production, a burning aftertaste.

Hepatic - *Rare:*

Orally, garcinia and its constituent hydroxycitric acid (HCA) might cause liver toxicity.

*Immunologic - Rare:*

Hypersensitivity reactions, including anaphylaxis, in sensitive individuals.

Neurologic/CNS - *Rare:*

Dizziness and headache.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

###### 4.8 c Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine 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

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

D 33.7 Combination Product.

##### 5.1 Pharmacodynamic properties

*Green coffee bean:*

In addition to caffeine, chlorogenic acid and quinides found in green coffee are thought to promote weight loss. In mice, a green coffee bean extract had an inhibitory effect on body fat accumulation and weight gain. Caffeine suppressed fat absorption, and chlorogenic acid was found to reduce hepatic triglyceride levels. The phenolic compounds, neochlorogenic acid and feruloylquinic acid were found to enhance hepatic carnitine palmitoyl-transferase activity. Green coffee extract may reduce appetite.

*Rhodiola rosea:*

The phenylpropanoid glycoside called salidroside, rhodioloside, or rhodosine is thought to be responsible for many of the stimulant or "adaptogenic" effects of rhodiola. Rhodiola may improve mood by regulating the activity of serotonin, dopamine, and norepinephrine.

*Garcinia cambogia:*

Hydroxycitric acid (HCA) is the principal acid in garcinia fruit rind. HCA competitively inhibits the extramitochondrial enzyme adenosine triphosphate (ATP) citrate lyase, which is involved in the conversion of carbohydrate to fat (lipogenesis). Inhibition of this enzyme prevents cleavage of citrate to oxaloacetate and acetyl-CoA, limiting the availability of acetyl-CoA for lipogenesis.

*Panthothenic acide (Vitamin B<sub>5</sub>):*

Precursor of coenzyme A (CoA) and acyl carrier protein, is involved in gluconeogenesis; energy release from carbohydrates; fatty acid synthesis/degradation; and the synthesis of sterols, acetylcholine, steroid hormones, porphyrins, and other compounds. Vitamin B<sub>5</sub> also seems to be essential for normal epithelial function.

*Pyridoxine (Vitamin B<sub>6</sub>):*

For kidney stones, vitamin B<sub>6</sub> is thought to be beneficial by decreasing urinary excretion of oxalate in some patients. Most kidney stones are composed of calcium oxalate, and high urinary oxalate has been associated with development and recurrence of kidney stones.

*Black Pepper (Biperine):*

Piperine, a constituent of black pepper, seems to increase oral absorption of medicine and other substances by forming a complex with them. Black pepper is said to influence metabolic function. It might also have lipolytic activity related to the outer layer of the fruit.

*Chromium:*

Chromium may induce these effects by affecting the brain's hunger receptors. Chromium might sensitize insulin-sensitive glucoreceptors in the brain, resulting in appetite suppression, activation of the sympathetic nervous system, stimulation of thermogenesis, and down-regulation of insulin secretion.

##### 5.2 Pharmacokinetic properties

*White kidney bean (Phaseolus vulgaris):*

There is insufficient reliable information available about the pharmacokinetics.

*Green coffee bean:*

*Absorption:* The chlorogenic acids (CGAs) are a complex mixture of compounds. In one study, concentrations of CGAs peaked 30-60 minutes after ingestion, and again 90-240 minutes after ingestion, with values varying widely between individuals.

*Metabolism:* After ingestion of CGAs, hydrolysis by the gut microflora produces free hydroxycinnamates, including caffeic, ferulic, and p-coumaric acids.

*Excretion:* About 6% of ingested chlorogenic acid and 11% of ingested caffeic acid were excreted in the urine.

*Rhodiola rosea:*

*Absorption:* The bioavailability of salidroside, a constituent of rhodiola, was 32.1% in animal research. When administered at a dose of 12 mg/kg, the peak serum concentration of salidroside was 4.3 mcg/mL.

*Excretion:* When administered at a dose of 12 mg/kg, the mean residence time of salidroside was 41.7 minutes when given orally.

*Garcinia cambogia:*

*Absorption:* After oral administration of hydroxycitric acid (HCA) 2 grams in humans, plasma concentrations of HCA were 0.8 mcg/mL after 30 minutes and 8.4 mcg/mL after 2 hours.

*Panthothenic acide (Vitamin B<sub>5</sub>):*

*Absorption:* Vitamin B<sub>5</sub> is absorbed in the intestine and delivered directly into the bloodstream by active transport. At higher dosages, passive diffusion may occur.

*Distribution:* Red blood cells carry Vitamin B<sub>5</sub> throughout the body. Vitamin B<sub>5</sub> is predominantly present in the form of coenzyme A (CoA) in the body.

*Metabolism:* Acts as a precursor for the synthesis of CoA and acyl carrier protein.

*Excretion:* Vitamin B<sub>5</sub> is excreted in the urine.

*Pyridoxine (Vitamin B<sub>6</sub>):*

*Absorption:* Vitamin B<sub>6</sub> is absorbed passively in the upper gastrointestinal tract.

*Metabolism:* In the liver, Vitamin B<sub>6</sub> is converted to the coenzyme pyridoxal phosphate.

*Excretion:* Vitamin B<sub>6</sub> metabolites are excreted in the urine.

*Black Pepper (Biperine):*

There is insufficient reliable information available about the pharmacokinetics of black pepper

*Chromium:*

*Absorption:* When ingested and after absorption, chromium is bound to transferrin.

*Distribution:* The distribution may occur across fast, medium, and slow compartments, with serum chromium not in equilibrium with tissue-organ stores. Once absorbed, chromium concentrates in the kidney, heart, liver, brain, muscle, spleen, testes, epididymis, and lung.

*Excretion:* The small percentage of chromium that is absorbed is rapidly excreted in the urine.

#### 6. PHARMACEUTICAL PARTICULARS

##### 6.1 List of excipients

- Microcrystalline cellulose, Maize starch, Silicon dioxide and Magnesium stearate.

##### 6.2 Incompatibilities

No compatibility studies have been performed; BIOGEN APPETITE SUPPRESS must not be mixed with other medications.

##### 6.3 Shelf Life

24 Months.

##### 6.4 Special precautions for storage

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Store in the original container and keep the container tightly sealed.
- Do not use after the expiry date stated on the label.
- Return all unused BIOGEN APPETITE SUPPRESS to your pharmacist.
- Do not dispose of unused BIOGEN APPETITE SUPPRESS in drains or sewerage systems (e.g. toilets).

##### 6.5 Nature and contents

90 White to off-white vegetable capsules are available in a white 250 ml PET container sealed with a white plastic screw cap. The container contains a non-edible silica gel sachet and a foam insert.

##### 6.6 Special precautions for disposal

No special requirements.

#### 7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen.

23 Stag Rd,

Glen Austin,

South Africa.

info@biogen.co.za

www.biogen.co.za


Tel: 011 589 2322.

#### 8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

#### 9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

<b>JOB:</b> 41662_BPS_Appetite Suppres_90s	<b>SIZE:</b> 250mm x 340mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input type="checkbox"/> Other: <input checked="" type="checkbox"/>	
<b>COLOURS:</b>  K	<b>FINISHING:</b> <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing
<b>PLEASE CHECK CAREFULLY</b>	Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.