

PROFESSIONAL INFORMATION

D 34.8 Polyphenols (Health Supplement): 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 GREEN TEA EXTRACT (Vegetable capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsules contains:

Camellia sinensis (L.) Kuntze (Green tea Extract) 500,00 mg
 [Leaf; extract standardised to 95 % polyphenols]

Sugar free

CONTAINS CAFFEINE. Contains 25 mg caffeine per capsule.

A cup of instant coffee contains approximately 80 mg of caffeine

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vegetable Capsules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIOGEN GREEN TEA EXTRACT a source of antioxidants that help protect cells against the oxidative damage caused by free radicals.

4.2 Posology and method of administration

Adults (18 years and older):

Take 1 (one) vegetable capsule with or after breakfast, or as recommended by your healthcare provider.

The safety and efficacy of BIOGEN GREEN TEA EXTRACT in children younger than 18 years has not yet been established. Not suitable for children under the age of 18 years.

4.3 Contraindications

- If you have a hypersensitivity to Green tea extract or any of the excipients listed in 6.1.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN GREEN TEA EXTRACT. 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 healthcare provider if symptoms persist or worsen.
- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.
- Consult a registered healthcare professional if you are taking any other medicine (such as lithium) including chronic, complementary, or traditional medicines; or if you have high blood pressure, glaucoma, and/or detrusor instability (overactive bladder syndrome).
- Not recommended before bedtime as it may cause sleep disturbances.
- If symptoms worsen during the use of the medicinal products a doctor or a qualified healthcare provider should be consulted.
- Discontinue use and consult a healthcare provider if you develop symptoms of liver trouble such as yellowing of the skin/eyes (jaundice), stomach pain, dark urine, sweating, nausea, unusual tiredness and/or loss of appetite.
- Consult a healthcare provider prior to use if you have a liver disorder or an iron deficiency.
- Consult a health care provider for use beyond 12 weeks.
- Total caffeine intake of more than 200 mg per day is not recommended during pregnancy or breastfeeding. A cup of instant coffee contains approximately 80 mg of caffeine.
- Use of caffeine may result in sleep deprivation. Limit the use of caffeine-containing products (including tea and coffee) when taking this product.
- Only effective when taken in conjunction with a balanced diet and exercise program.

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

- Caffeine containing preparations reduce sedative action and increase side effects caused by sympathomimetic medication.
- Concomitant use of high doses of green tea extract and 5-fluorouracil might increase the effects and side effects of 5-fluorouracil.
- Adenosine might decrease vasodilatory effects of adenosine and interfere with its use prior to stress testing.
- Concomitant use of alcohol and green tea extract might increase the levels and adverse effects of caffeine.
- Concomitant use of anticoagulant or antiplatelet medication and green tea may increase the risk of bleeding.
- Consuming green tea with antidiabetic drugs might interfere with blood glucose control.
- Green tea extract contains caffeine, concomitant use of large amounts of caffeine might increase cardiac inotropic effects of beta-agonists.
- Green tea extract might interfere with the effects of bortezomib.
- Green tea extract might reduce the effects of carbamazepine and increase the risk for convulsions, reduce the levels and clinical effects of cefiprolol.
- Green tea extract might increase the levels and adverse effects of clozapine and acutely exacerbate psychotic symptoms.

Interactions with Diseases / Impairments

- Green tea extract may worsen anemia in people with iron deficiency
- Taking green tea extract might aggravate bleeding disorders. Caffeine is reported to have antiplatelet activity.
- Green tea extract contains caffeine, which might induce cardiac arrhythmias in sensitive individuals.
- Green tea extract contains caffeine, which might interfere with glucose control in patients with diabetes.
- Use with caution in patients with diarrhea. Green tea extract contains caffeine, which can exacerbate diarrhea, especially when taken in large amounts.

Interactions with Foods

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

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 GREEN TEA EXTRACT does not adversely affect their performance.

4.8 Undesirable effects

Orally, Green tea extract is well-tolerated.

Summary of adverse reactions

- Rare, unpredictable cases of liver injury associated with green tea extract-containing products have been reported. Hepatotoxicity, hypokalemia, and thrombotic thrombocytopenic purpura have rarely been reported.
- Common, bloating, constipation, diarrhea, dyspepsia, flatulence, and nausea.

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

5.1 Pharmacodynamic properties

Mechanism of action: *Green tea extract*, The antioxidant effects of green tea and its constituent catechins are thought to explain some of its clinical effects, especially related to its anti-inflammatory, anti-cancer, hepatoprotective, and cardiovascular benefits. enzymes.

5.2 Pharmacokinetic properties

Green tea extract, In human research, green tea and its catechins have been shown to protect against the oxidative damage caused by exercise. The antioxidant effects of green tea and its constituents may relate to their ability to scavenge free radicals, chelate redox active transition-metal ions, inhibit redox active transcription factors, inhibit pro-oxidant enzymes, and induce antioxidant

Green tea extract

Absorption: green tea or green tea extract has been shown to rapidly increase general levels of plasma polyphenols, as well as levels of epigallocatechin gallate (EGCG) and other individual catechins. Absorption of green tea catechins is increased when tea polyphenols were given as a green tea supplement in capsule form. Taking green tea catechins in the fasting state increases plasma levels of EGCG. However, fasting does not appear to have a significant effect on the plasma levels of total (free and conjugated) epigallocatechin, and results in lower plasma levels of total epicatechin.

Distribution: green tea ingestion resulted in the identification of 4'-O-methyl EGCG, EGCG, and epicatechin-3-gallate in prostatectomy tissue, at levels of 38.9 ± 19.5, 42.1 ± 32.4, and 17.8 ± 10.1 pmol/gram tissue, respectively. Catechins accumulated in the protein-rich fraction of plasma (60 %), in high-density lipoproteins (HDL) (23 %), and in low-density lipoproteins (LDL).

Metabolism: green tea ingestion resulted in the identification of methylated epigallocatechin and epicatechin in the urine; it was estimated that 50 % to 60 % of these catechins were methylated.

Excretion: green tea ingestion resulted in increased polyphenols in the urine.

Absorption / Distribution / Metabolism / Excretion:

No clinical data are available on the effects of BIOGEN GREEN TEA EXTRACT.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate, corn starch.

6.2 Incompatibilities

No compatibility studies has been performed, BIOGEN GREEN TEA EXTRACT must not be mixed with other medications.

6.3 Shelf Life

24 Months.

6.4 Special precautions for storage

Store in a cool, dry place at or below 25 °C.
 Do not use after expiry date.
 Keep the container tightly closed.
 Protect from light.
 KEEP OUT OF REACH OF CHILDREN.
 Store in the original package in order to protect from moisture.

6.5 Nature and contents

250 ml white PET container with a Biogen cap.
 Pack size: 60 capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen,
 23 Stag Rd,
 Glen Austin,
 South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

JOB: BPS_Green Tea Extract_60s		SIZE: 210mm x 240mm	
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
COLOURS:		FINISHING:	
<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Foil / Holographic Foil	<input type="checkbox"/> Matte <input type="checkbox"/> Gloss
<input type="checkbox"/> Available Slot	<input type="checkbox"/> Available Slot	<input type="checkbox"/> Spot UV	<input type="checkbox"/> Doming <input type="checkbox"/> Embossing
PLEASE CHECK CAREFULLY Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.			