

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE: MULTIPLE SUBSTANCE FORMULATION

Health supplements are intended only to complement health or supplement the diet.

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

BIOGEN SUPREME ANTIOXIDANT (Vegetable Capsules).

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

EACH VEGETABLE CAPSULE CONTAINS:

EACH VEGETABLE CAPSULE CONTAINS:		%NRV*
<i>Polygonum cuspidatum</i> Siebold & Zucc. (Giant Knotweed) [root, extract standardised to 50 % resveratrol providing 100 mg resveratrol]	200,00 mg	
N-Acetyl-L-Cysteine [providing L-Cysteine 50,00 mg]	67,57 mg	
Vitamin B ₃ (Nicotinamide)	50,00 mg	114 %
Vitamin C (Ascorbic Acid)	50,00 mg	50 %
<i>Vitis vinifera</i> L. (Grape) [Seed, extract standardised to 95 % proanthocyanidins]	25,00 mg	
Co-enzyme Q10	15,00 mg	
Vitamin E (d,l- α -tocopheryl acetate)	9,14 mg TE (14,38 IU)	50 %
Zinc Oxide [providing 5,50 mg elemental Zinc]	6,92 mg	50 %
Astaxanthin	2,00 mg	
Selenium Glycinate [providing 25 μ g Selenium and 48 μ g glycine]	1,25 mg	91 %

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

Sugar free

3. PHARMACEUTICAL FORM

Vegetable capsules (60's)

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIOGEN SUPREME ANTIOXIDANT, a combination of antioxidants that help fight against cell damage caused by free radicals. May assist in restoring cellular health and maintaining healthy skin.

4.2 Posology and method of administration

Adults (18 years and older):

Take 2 (two) vegetable capsules daily with meals, or as recommended by a healthcare provider.

Do not exceed the recommended dose.

Not suitable for children

Method of administration

For oral use. To be taken with food.

4.3 Contraindications

Hypersensitivity to any of the ingredients listed under section 6.1.

4.4 Special warnings and precautions for use

- BIOGEN SUPREME ANTIOXIDANT may alter the effectiveness of other medications.
- Patients should be advised to discontinue BIOGEN SUPREME ANTIOXIDANT at least 2 weeks before elective surgical procedures due to potential interference with blood glucose and bleeding control.
- Use with caution in patients with liver disorder, seizure disorder, stomach ulcers, bipolar disorder, or iron deficiency.
- BIOGEN SUPREME ANTIOXIDANT should be avoided by patients taking immunosuppressants, by patients with bleeding disorders, and by patients on 5- α -reductase inhibitors.

4.5 Interaction with other medicines and other forms of interaction

- Antihypertensive medicine: The use of co-enzyme Q10, as in BIOGEN SUPREME ANTIOXIDANT with antihypertensive medicines may contribute to additive blood pressure lowering effects.
- Anticoagulant / antiplatelet medicine: Resveratrol as in BIOGEN SUPREME ANTIOXIDANT may have antiplatelet effects and thereby increase the risk of bruising and bleeding when used with anticoagulant / antiplatelet medicine.
- Hormones: Resveratrol might have estrogenic effects.

4.6 Fertility, pregnancy and lactation

The safety and efficacy of BIOGEN SUPREME ANTIOXIDANT in pregnancy and lactation has not been established. Do not use during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

BIOGEN SUPREME ANTIOXIDANT is not likely to cause drowsiness. Patients should take caution before performing activities requiring their attention, until they are reasonably certain that BIOGEN SUPREME ANTIOXIDANT does not adversely affect their performance.

4.8 Undesirable effects

BIOGEN SUPREME ANTIOXIDANT is generally well tolerated.

Cardiovascular

Rare: hypotension.

Endocrine

Frequency unknown: insulin autoimmune syndrome (IAS)

Gastrointestinal disorders

Frequency unknown: gastrointestinal discomfort, heartburn, nausea, vomiting, diarrhoea and loose stools.

Renal and urinary disorders

Frequency unknown: change in urine odour.

Skin and subcutaneous tissue disorders

Frequency unknown: skin rash, skin irritation, itching.

Neurologic / CNS: Frequency unknown:

headache, fatigue, or dizziness. Rare: Memory loss in patients on peritoneal dialysis.

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.

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit / risk balance of the medicine. Healthcare 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>.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Class and category: D 34.12 Multiple substance formulation.

BIOGEN SUPREME ANTIOXIDANT a combination of antioxidants that help fight against cell damage caused by free radicals. May assist in restoring cellular health and maintaining healthy skin.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on BIOGEN SUPREME ANTIOXIDANT.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Magnesium stearate
- Microcrystalline cellulose

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 Years / 24 Months.

6.4 Special precautions for storage

Store in a cool, dry place at or below 25 °C.

Protect from moisture.

Keep the container tightly closed.

Store in the original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents

250 ml White PET container with a Biogen cap.

Pack size: 60 vegetable capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen.

23 Stag Road,

Glen Austin,

South Africa.

Tel: 0860 347 243.

Email: info@biogen.co.za

Website: www.biogen.co.za

8. REGISTRATION NUMBER


Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

Will be allocated by SAHPRA upon registration.

 JOB: BPS_Biogen Supreme Antioxidants_60's		 SIZE: 210mm x 220mm	
 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:  K		 FINISHING: <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Dornring <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.			