

PROFESSIONAL INFORMATION
D 34.13 Other. Complementary Medicine: Health Supplement

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 SUPREME CO-ENZYME Q10 (300MG) vegetable capsules.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vegetable capsule contains:

Co-Enzyme Q10 300,00 mg

Sugar Free.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vegetable capsules

4. CLINICAL PARTICULARS
4.1 Therapeutic indications

BIOGEN SUPREME CO-ENZYME Q10, helps to maintain and support cardiovascular health and provides antioxidants.

4.2 Posology and method of administration
Adults 18 years and older:

Take 1 (one) capsule daily or as recommended by your healthcare provider.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Patients suffering from hypotension or hypertension, or patients scheduled to undergo surgical procedures, since BIOGEN SUPREME CO-ENZYME Q10 may affect blood pressure.
- Consult a health care practitioner prior to use if you are taking blood thinners.
- Consult a relevant healthcare provider for prolonged use.
- Do not exceed the recommended daily dosage.

4.5 Interaction with other medicines and other forms of interaction

- Patients must consult a healthcare practitioner if they are taking any other medicine (including complementary or traditional medicines).
- The use of BIOGEN SUPREME CO-ENZYME Q10 with antihypertensive medicines may contribute to additive blood pressure lowering effects.
- BIOGEN SUPREME CO-ENZYME Q10 might interfere with blood pressure control during and after surgery. Stop using BIOGEN SUPREME CO-ENZYME Q10 at least two weeks before a scheduled surgery.
- Caution is advised in people with diabetes or hypoglycaemia and bleeding disorders.

4.6 Fertility, pregnancy and lactation

Safety in fertility, pregnancy and lactation has not been established.

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 SUPREME CO-ENZYME Q10 does not adversely affect their performance.

4.8 Undesirable effects
4.8 a Summary of adverse reactions

Orally, BIOGEN SUPREME CO-ENZYME Q10 is generally well tolerated but it can have side effects.

Not all side effects reported for BIOGEN SUPREME CO-ENZYME Q10 are included in this leaflet.

Side effects may include:

Frequency unknown: hypersensitivity reactions; mild gastrointestinal disturbances.

Should your general health worsen or if you experience any untoward effects while BIOGEN SUPREME CO-ENZYME Q10, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop taking BIOGEN SUPREME CO-ENZYME Q10 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BIOGEN SUPREME CO-ENZYME Q10. You may need urgent medical attention or hospitalisation. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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 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>.

5. PHARMACOLOGICAL PROPERTIES

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5.1 Pharmacodynamic properties

BIOGEN SUPREME CO-ENZYME Q10 is fat soluble and acts similar to vitamins.

It acts mainly as an antioxidant, membrane stabiliser and a cofactor in many metabolic pathways.

5.2 Pharmacokinetic properties

BIOGEN SUPREME CO-ENZYME Q10 is a vitamin-like compound present in almost all cells. High concentrations are found in the heart, liver, kidney, and pancreas. BIOGEN SUPREME CO-ENZYME Q10 is a large molecule that is poorly absorbed when taken orally and metabolised in the liver. Peak levels of BIOGEN SUPREME CO-ENZYME Q10 after oral administration is reached within 5-10 hours and it has a half-life of 34 hours.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients

- Maize starch, silicon dioxide, and magnesium stearate.

6.2 Incompatibilities

Not applicable.

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 SUPREME CO-ENZYME Q10 to your pharmacist.
- Do not dispose of unused BIOGEN SUPREME CO-ENZYME Q10 in drains or sewerage systems (e.g. toilets).

6.5 Nature and contents

175 ml white PET container with a Biogen cap.

Pack size: 30 clear vegetable capsules.

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
0860 347 243

8. REGISTRATION NUMBER


Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

August 2023.

JOB: BPS_SUPREME CO-ENZYME Q10 (300MG)		SIZE: 210mm x 190mm	
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:	
 K		<input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Darning <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.			