

PROFESSIONAL INFORMATION
Complementary Medicine: Health Supplement

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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 CO-ENZYME Q10 capsules.
2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

		%NRV*
Co-Enzyme Q10	150,00 mg	
L-Carnitine Fumarate	100,00 mg	
Vitamin C (Ascorbic acid)	75,00 mg	75

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

Sugar Free.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Bovine Gelatine Capsules.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications

BIOGEN CO-ENZYME Q10, with L-Carnitine and Vitamin C, an antioxidant rich product that contributes to the protection of cells from oxidative stress. Co-Enzyme Q10 is essential for energy production at cellular level and supports cardiovascular health.

4.2 Posology and method of administration
Adults: Take 1 capsule twice 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 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 co-enzyme Q10 with antihypertensive medicines may contribute to additive blood pressure lowering effects.
- Co-Enzyme Q10 might interfere with blood pressure control during and after surgery. Stop using 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 CO-ENZYME Q10 does not adversely affect their performance.

4.8 Undesirable effects
Gastrointestinal disorders
Less frequent: gastrointestinal disturbances including nausea and vomiting, diarrhoea, appetite suppression, heartburn and epigastric discomfort.

Nervous system disorders
Less frequent: headache.

Skin and subcutaneous tissue disorders
Less frequent: allergic rash.

Reporting of side effects

 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
Category and class: D 34.12 Multiple Substance Formulation. Complementary Medicine: Health Supplement.

5.1 Pharmacodynamic properties

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.

Vitamin C contributes to the absorption of iron.

5.2 Pharmacokinetic properties

Co-enzyme Q10 is a vitamin-like compound present in almost all cells. High concentrations are found in the heart, liver, kidney, and pancreas. Co-enzyme Q10 is a large molecule that is poorly absorbed when taken orally and metabolised in the liver. Peak levels of 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

- Magnesium stearate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 Months.

6.4 Special precautions for storage

Store at or below 25 °C.

Store in the original package in order to protect from moisture.

6.5 Nature and contents

250 ml and 175 ml white PET container with a Biogen cap.

Pack size: 30, 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
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 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

November 2022.