

Complaint to TGA: Blackmores CoQ10

Acknowledgement:

This complaint was worked up by the Monash University BMS3052 WAM Wednesday 11am student group 7 and WAM Thurs 6pm student group 12; then edited and submitted by Assoc Prof Ken Harvey.

Summary:

Coenzyme Q10 plays a central role in mitochondrial oxidative phosphorylation and the production of adenosine triphosphate (ATP). It also functions as an antioxidant in cell membranes and lipoproteins.

Except for rare genetic disorders, CoQ10 deficiency has not been described in the general population. It is assumed that normal biosynthesis, with or without a varied diet, provides enough CoQ10 to sustain energy production in healthy individuals.

The fundamental problem with the promotion of CoQ10 products is that advertisers extrapolate from CoQ10's important role in the body, and possible role as adjunctive therapy in heart failure and myocardial reperfusion injury, to making implied claims that taking this product as a supplement will benefit normal healthy people.

This is a common logical fallacy employed by the complementary medicine industry to mislead the public and arouse unwarranted expectations of product effectiveness.

The Therapeutic Goods Advertising Complaint Resolution Panel (CRP) determination 2012/06/006 (Pharmalife CoQ10 Capsules) has addressed this issue and is appended.

Accordingly, we allege that advertisements for Blackmores CoQ10 products breach the Therapeutic Goods Advertising Code 2015, s.4(1)(b), 4(2)(a), 4(2)(c) for claims 1-5 (below) because good evidence to support these claims is lacking. We allege an additional Code breach of s.4(4) for claim 4. Finally, we allege a breach of s.7(2) of the Code because CoQ10 is a vitamin-like co-enzyme; s.7(2) applies, but the required caveat is lacking.

Consolidated claims disputed:

1. Supports heart health

CoQ10 occurs naturally in every cell in the body with high concentrations found in the heart.

The heart is one of the most active tissues in the body, and requires an adequate supply of CoQ10

As we age, keeping your heart healthy becomes more important to ensure a healthy lifestyle.

CoQ10 assists in maintaining heart health, in particular healthy heart function.

Helps maintain healthy heart function.

2. CoQ10 levels deplete with age and it is necessary in supporting the maintenance of a healthy cardiovascular system. Helps replenish declining CoQ10 levels that may deplete with exercise and age

3. CoQ10 has essential role in the production of energy in cells.

4. Inhibits the oxidation of LDL cholesterol (bad cholesterol)

5. A powerful antioxidant to help maintain a healthy heart.

Advertisement type: Internet

Where did it appear:

- <https://www.blackmores.com.au/products/super-strength-coq10-300mg>
- <https://www.blackmores.com.au/products/coq10-150mg>
- <https://www.blackmores.com.au/products/coq10-75-mg>

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- <https://www.chemistwarehouse.com.au/buy/73360/blackmores-coq10-150mg-125-capsules-exclusive-size>
- <https://www.priceline.com.au/blackmores-coq10-150mg-30-capsules>
- <https://www.woolworths.com.au/shop/productdetails/725625/blackmores-coq10-150mg>
- <https://www.goodpricepharmacy.com.au/blackmores-coq10-150mg-90-capsules>
- <https://www.superpharmacy.com.au/products/blackmores-coq10-150mg-high-potency-30-capsules>
- <https://www.nationalpharmacies.com.au/product/blackmores-coq10-75-mg-90-caps/>
- <https://www.pharmacydirect.com.au/product/blackmores-coq10-150mg-30-capsules-020787.aspx>
- <https://www.mrvitamins.com.au/blackmores-coq10-150mg-30c>
- Etc.

N.B. Inaccurate and misleading information on the Australian Government **Health Direct** web site taken direct from company supplied ARTG Public Summary.

- <https://www.healthdirect.gov.au/medicines/brand/amt,920941011000036100/coq10-blackmores>

Date seen: November 16, 2018

Products:

1. BLACKMORES COQ10 150mg; ARTG ID: 299595

Active ingredients: ubidecarenone

Sponsor: Blackmores Ltd

Specific Indications:

CoQ10 is an antioxidant and free radical scavenger which may help/aid/assist in supporting the maintenance of healthy cardiovascular function/healthy cardiovascular system/healthy heart. Helps maintain healthy arteries by inhibiting the oxidation of LDL cholesterol. Helps maintain healthy heart function/Helps maintain heart health. Coenzyme Q10 inhibits oxidation of LDL cholesterol. Replenishes/Increases/Raises blood CoQ10 levels Helps replenish declining CoQ10 levels CoQ10 is essential for energy production by mitochondria / CoQ10 is involved with the production of energy in cells Supports cellular energy production Supplementation with Co Q10 replenishes plasma/serum Co Q10 levels reduced by statin therapies (HCP Only) Supplementation with Co Q10 replenishes plasma/serum Co Q10 levels that may/can be reduced by certain medications

2. BLACKMORES SUPER STRENGTH COQ10 300mg; ARTG ID: 298346

Active ingredients: ubidecarenone

Sponsor: Blackmores Ltd

Specific Indications: as above.

3. BLACKMORES SUPER STRENGTH COQ10 300mg; ARTG ID: 281319

Active ingredients: ubidecarenone

Sponsor: Blackmores Ltd

Specific Indications: as above.

4. BLACKMORES COQ10 75mg; ARTG ID: 211921

Active ingredients: ubidecarenone

Sponsor: Blackmores Ltd

Specific Indications: as above.

5. BLACKMORES COQ10 150mg; ARTG ID: 211661

Active ingredients: ubidecarenone

Sponsor: Blackmores Ltd

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Specific Indications: as above.

Screen shots:



Super Strength CoQ10 300mg

A high potency, one-a-day dose of CoQ10 that helps replenish levels of CoQ10 that may deplete with age.

\$33.99 30 capsule \$1.13 per capsules

<https://www.blackmores.com.au/products/super-strength-coq10-300mg>

Overview

As we age, keeping your heart healthy becomes more important to ensure a healthy lifestyle. CoQ10 levels deplete with age and it is necessary in supporting the maintenance of a healthy cardiovascular system.

Why use

- Super strength one-a-day 300mg dose
- Helps support healthy cardiovascular function
- Helps support healthy arteries
- Inhibits the oxidation of LDL (bad) cholesterol
- Blackmores is a proud supporter of the Heart Research Institute, a centre for scientific excellence in cardiovascular research

The Blackmores difference

Blackmores, the No.1 brand in heart health* has a range of CoQ10 products specifically formulated to support your heart health.

Blackmores Super Strength, one-a-day dose is a convenient way to help replenish CoQ10 levels that may deplete with age.

CoQ10 occurs naturally in every cell in the body with high concentrations found in the heart. CoQ10 is a powerful antioxidant which helps to maintain the health of arteries and also inhibits the oxidation of LDL cholesterol.

<https://www.blackmores.com.au/products/super-strength-coq10-300mg>

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CoQ10 150mg

A natural source of coenzyme Q  a powerful antioxidant to help maintain a healthy heart.

\$26.99 30 capsules \$0.90 per capsule

<https://www.blackmores.com.au/products/coq10-150mg>

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Overview

CoQ10 occurs naturally in every cell in the body with high concentrations found in the heart. CoQ10 assists in maintaining heart health, in particular healthy heart function.

Why use

- Helps replenish declining CoQ10 levels that may deplete with exercise and age
- Helps maintain healthy heart function
- Inhibits the oxidation of LDL cholesterol (bad cholesterol)
- CoQ10 has essential role in the production of energy in cells
- Blackmores is a proud supporter of the [Heart Research Institute](#), a centre for scientific excellence in cardiovascular research


The Blackmores difference

The heart is one of the most active tissues in the body, and requires an adequate supply of CoQ10.

<https://www.blackmores.com.au/products/coq10-150mg>

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[Home](#) / [Health](#) / [Vitamins](#) / [Blackmores](#) / [Blackmores Heart & Circulation](#)





**Blackmores CoQ10 150mg
125 Capsules Exclusive
Size**

Product ID: 73360
★★★★★ 4.7 (6) [Write a review](#)

\$39.99



QTY
1 ▼



General Information

A natural source of coenzyme Q10 and a powerful antioxidant to help maintain a healthy heart.

CoQ10 occurs naturally in every cell in the body with high concentrations found in the heart. CoQ10 assists in maintaining heart health, in particular healthy heart function.

Size: 125 capsules

Warnings

Always read the label. Follow the directions for use. Supplements may only be of assistance if dietary intake is inadequate.

CAUTION

Do not take while on warfarin therapy without medical advice. If you are already taking heart medication see your doctor before making any changes.


Ingredients


Active Ingredients: Ubidecarenone (coenzyme Q10) 150mg

<https://www.chemistwarehouse.com.au/buy/73360/blackmores-coq10-150mg-125-capsules-exclusive-size>

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Home > Blackmores CoQ10 150mg 30 Capsules Like 0





CLICK ON IMAGE TO ZOOM 

BLACKMORES CoQ10 150mg 30 Capsules

Be the first to [review](#) this product

SKU: 304573
\$20.99

ADD TO BASKET 

ADD TO WISHLIST 

Blackmores CoQ10 150mg is a natural source of coenzyme Q10 and a powerful antioxidant. It provides support for cellular energy production and helps maintain normal healthy functioning of the heart.

▼ More Product Information

Antioxidant. Helps maintain healthy arteries and a healthy cardiovascular system. Reduces the oxidation of LDL cholesterol. Natural source. Convenient 1-a-day dose.

Coenzyme Q10 is found naturally in the body and plays an essential role in the production of energy in all cells. As such it is important for the health of virtually all human tissues and organs. The heart is one of the most active tissues in the body, and requires an adequate supply of CoQ10. CoQ10 assists in maintaining heart health, in particular heart muscle function. The body's ability to synthesise CoQ10 declines with age and with exercise. CoQ10 inhibits the oxidation of LDL-cholesterol. Cholesterol is very susceptible to free radical damage, which leads to the formation of a toxic derivative called oxidised LDL-cholesterol. It is currently understood that LDL-cholesterol may be harmful to the body after it has become oxidised.

Product	Blackmores CoQ10 150mg 30 Capsules
Brand	Blackmores
Category	Heart & Cholesterol Health

<https://www.priceline.com.au/blackmores-coq10-150mg-30-capsules>

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Claims disputed and the rationale:

1. **Supports heart health** - *CoQ10 occurs naturally in every cell in the body with high concentrations found in the heart. The heart is one of the most active tissues in the body and requires an adequate supply of CoQ10. As we age, keeping your heart healthy becomes more important to ensure a healthy lifestyle.*

These are merely motherhood statements that provide no support for CoQ10 supplementation.

CoQ10 assists in maintaining heart health, in particular healthy heart function. Helps maintain healthy heart function.

Zhou et al. (2005) conducted an RCT using **six healthy males** (mean age of 29.7 years) who were treated with 150mg CoQ10 for two weeks to **assess its potential effects on cardiovascular function**, as measured by participants VO2 max.¹ This parameter determines the maximum amount of oxygen required during exercise and is a good indicator of heart health. Participants had blood samples taken prior to and post high endurance exercise. These results were then statistically analyzed. No significant improvement in VO2 max was found after two weeks supplementation.

A Cochrane review, (Flowers et al., 2014), evaluated the effect of CoQ10 supplementation for the **primary prevention of cardiovascular disease (CVD)**.² The review included trials administering CoQ10 as a single supplement in healthy adults, or those at high risk of CVD (but without a diagnosis of CVD), and assessed cardiovascular events or major CVD risk factors, such as blood pressure and lipid levels.

They found six completed randomised controlled trials with a total of 218 participants randomised. All were conducted in participants at high risk of CVD. Two examined CoQ10 supplementation alone and four examined CoQ10 supplementation in patients on statin therapy.

The trials were small and short-term, none measured cardiovascular events or adverse events, and two of the six trials were regarded as being at high risk of bias. Only a few small trials contributed to the analyses and **no conclusions could be drawn**.

Another Cochrane review (Ho et al, 2016) reviewed the **blood pressure lowering efficacy of coenzyme Q10 for primary hypertension**.³ This review provided moderate-quality evidence that coenzyme Q10 **does not have a clinically significant effect on blood pressure**. In one of three trials reporting adverse effects, coenzyme Q10 was well tolerated. Due to the small number of individuals and studies available for analysis, more well-conducted trials are needed.

References cited by other sponsors to support similar claims included:

- Alehagen et al. (2015) who studied the **combination of selenium and CoQ10 on cardiovascular mortality** (KiSel-10 intervention study) over 4-years in an elderly selenium-deficient Swedish population.⁴ This study was judged irrelevant due to combination therapy.
- **A Health Canada Monograph on CoQ10** that cited studies in **heart failure and protection of myocardial reperfusion injury** (Rosenfeldt et al. 2007; Baggio et al. 1994; Langstone et al. 1988).⁵ Also judged irrelevant to primary prevention in healthy people.
- Shah et al. (2007) who found that one 50 mg dose of CoQ10 **had no effect on ECG variables**

¹ <https://www.ncbi.nlm.nih.gov/pubmed/16230985>

² <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010405.pub2/full>

³ <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD007435.pub3/full>

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4666408/>

⁵ <http://webprod.hc-sc.gc.ca/nhp/nd-bdipsn/atReq.do?atid=ubiquinol&lang=eng>

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in 26 young health volunteers and exhibited only mild and transient effect on systolic blood pressure.⁶

Another Cochrane review (Madmani ME, et al., 2014) looked at trials that assessed the beneficial and harmful effects of **coenzyme Q10 in patients with heart failure**.⁷ **No conclusions could be drawn** on the benefits or harms of coenzyme Q10 in heart failure as trials published to date lacked information on clinically relevant endpoints. Until further evidence emerged to support the use of coenzyme Q10 in heart failure, the authors concluded there might be a need to re-evaluate whether additional trials testing coenzyme Q10 in heart failure are desirable.

A more recent meta-analysis of the efficacy of **coenzyme Q10 in patients with cardiac failure** was performed by Lei and Liu (2017).⁸ Compared with the meta-analysis published by Madmani in 2014 (above), the authors included 14 additional clinical investigations and 2149 more participants than in the previous meta-analysis. They also assessed the efficacy of coenzyme Q10 in the endpoints of mortality and NYHA classification.

They found that in patients with heart failure, the administration of coenzyme Q10 resulted in lower mortality and improved exercise capacity compared with the effects of placebo treatment. However, no significant difference was found between coenzyme Q10 and placebo in the endpoints of left heart ejection fraction and New York Heart Association (NYHA) cardiac function classification. They noted several limitations in their meta-analysis and concluded that more rigorous, large-sample, international trials were needed to confirm their results.

See also: U.S. National Center for Complementary and Integrative Health (NCCIH) Coenzyme Q10.⁹

Taking all the above into account, we dispute the implied claim that taking supplementary CoQ10 in people without cardiovascular disease supports heart health, maintains healthy heart tissue and assists in the maintenance of a healthy cardiovascular system.

We allege these claim breaches the Therapeutic Goods Advertising Code 2015, s.4(1)(b), 4(2)(a) & 4(2)(c).

2. CoQ10 levels deplete with age and it is necessary in supporting the maintenance of a healthy cardiovascular system. Helps replenish declining CoQ10 levels that may deplete with exercise and age

There are inconsistencies with measurements of plasma levels of CoQ10 in individuals of different ages with varying levels of physical activity. Among young people, more physical activity may correlate with lower CoQ10 levels in plasma, but in older people, higher levels of physical activity are related to higher plasma levels of CoQ10. More physical activity in older people may thus negate any need for supplements of CoQ10.¹⁰

Only rare cases of documented coenzyme Q10 deficiency with symptoms of weakness, fatigue, and seizures have been reported.¹¹ Thus it can be assumed that a varied diet and a normal in-vivo synthesis will supply enough CoQ10 to healthy individuals.¹²

In conclusion, the finding that CoQ10 levels decrease in the elderly does not appear to hold if they exercise (which is recommended because it produces a variety of health benefits).

⁶ <https://www.ncbi.nlm.nih.gov/pubmed/17341532>

⁷ <https://www.ncbi.nlm.nih.gov/pubmed/24049047>

⁸ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5525208/>

⁹ <https://nccih.nih.gov/health/coq10>

¹⁰ <https://www.ncbi.nlm.nih.gov/pubmed/24384733>

¹¹ <https://naturalmedicines.therapeuticresearch.com/databases/food,-herbs-supplements/professional.aspx?productid=938>

¹² <https://www.nature.com/articles/1600880>

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We allege these claim breaches the Therapeutic Goods Advertising Code 2015, s.4(1)(b), 4(2)(a) & 4(2)(c).

3. CoQ10 has essential role in the production of energy in cells

This is an established fact but provides no justification for taking CoQ10 as a supplement.

4. Inhibits the oxidation of LDL cholesterol (bad cholesterol).

We found one old paper that supports this claim.¹³ However, we are unaware that this in-vitro observation has any relevance to the implied claim that CoQ10 supplementation will be useful for healthy people. It is also inappropriate use of scientific language.

Sunesen et al. (2001) noted that while the amount of CoQ10 in body plasma increased by 126% after 10 days of supplementation in 18 young, healthy volunteers (nine women, nine men), very-low-density-lipoprotein (VLDL), low-density-lipoprotein (LDL) and high-density-lipoprotein (HDL) levels did not statistically differ from baseline levels.¹⁴

Similarly, Zhou et al., (2005) found no significant changes in lipid profile after CoQ10 supplementation for 2 weeks in six healthy young males.¹

Fallah et al (2018) investigated the effects of coenzyme Q10 supplementation on glycaemic control and markers of lipid profiles in diabetic haemodialysis patients (HD) in a randomized, double blind, placebo-controlled clinical trial of 60 patients.¹⁵ They found that CoQ10 supplementation in diabetic HD patients for 12 weeks had beneficial effects on markers of insulin metabolism, but it did not affect fasting glucose, HbA1c and lipid profiles.

Jorat et al., (2018) performed as systematic review and meta-analysis of randomized controlled trials on the effects of coenzyme Q10 supplementation on lipid profiles among patients with coronary artery disease.¹⁶ They found that that CoQ10 supplementation significantly decreased total cholesterol and increased high-density lipoprotein ("good" cholesterol) but did not affect triglycerides or low-density lipoprotein ("bad" cholesterol) in patients with coronary artery disease.

Zhang et al., 2018 investigated the effect of 24 weeks of 120 mg CoQ10 or placebo on CVD risk factors in 101 Chinese patients with dyslipidaemia.¹⁷ On the 24th week, compared to placebo, CoQ10 supplementation modestly lowered blood pressure and reduced triglyceride and low-density lipoprotein cholesterol.

In conclusion, CoQ10 could be considered as adjunct therapy in some patients with CVD poorly uncontrolled by conventional treatment. However, we dispute the implied claim that taking CoQ10 as a supplement in healthy individuals assists with cholesterol levels (or the prevention of CVD).

We allege this claim breaches the Therapeutic Goods Advertising Code 2015, s.4(1)(b), 4(2)(a), 4(2)(c) and 4(4).

5. A powerful antioxidant to help maintain a healthy heart. CoQ10 is an antioxidant. However, this fact provides no justification for the claim that CoQ10 supplementation is required to maintain a healthy heart.

Current recommendations are that a healthy diet can provide all the antioxidants you need to

¹³ <https://www.ncbi.nlm.nih.gov/pubmed/9266510>

¹⁴ <https://www.ncbi.nlm.nih.gov/pubmed/11305624>

¹⁵ <https://www.ncbi.nlm.nih.gov/pubmed/30251010>

¹⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6176512/>

¹⁷ <https://www.ncbi.nlm.nih.gov/pubmed/29454678>

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fight free radical damage.^{18,19}

We allege this claim breaches the Therapeutic Goods Advertising Code 2015, s.4(1)(b), 4(2)(a) & 4(2)(c).

In addition, we allege that as CoQ10 is a vitamin-like co-enzyme that s7(2) of the Code applies and that the absence of a statement to this effect is a breach of the Code.

Finally, we point out that the ARTG Public Summary of these products also contain many indications &/or claims that lack evidence and need correction.

Previous complaints:

Eight upheld complaints about CoQ10 products were found on the CRP web site, including one referred to the Secretary.²⁰ Typically, no outcome of the latter referral is available on the TGA web site.

CRP determination 2012/06/006 (Pharmalife CoQ10 Capsules) is especially relevant, para 29-33.²¹

29. The Panel was generally satisfied that the active ingredient of the advertised product, co-enzyme Q10, was the subject of a range of research that supported a view that it could play a role in relation to heart health or cardiovascular health, heart function, ATP production, antioxidant effects, and some other aspects of human physiology. However, the Panel noted that for co-enzyme Q10 in the form of a supplement to offer clinically significant benefits in these respects, the consumer taking the supplement would need to have inadequate levels of co-enzyme Q10 in their diet and/or as a result of the natural production of co-enzyme Q10 in their bodies.
30. It appeared to the Panel that while some consumers do fall within this category, the ordinary and typical consumer viewing the advertisement would not necessarily derive any such benefits from co-enzyme Q10 supplementation at all, since an ordinary and typical consumer would most likely already obtain sufficient levels of co-enzyme Q10 through their diet or through the natural production of co-enzyme Q10 in the body.
31. The Panel was therefore satisfied that a primary question was whether the advertisement conveyed accurately and clearly that co-enzyme Q10 supplementation was only likely to offer the advertised benefits to that category of consumers with inadequate current levels of co-enzyme Q10, or whether it instead conveyed that any and all consumers would derive the advertised benefits through consumption of the advertised product.
32. The advertisement stated that “as you age, the naturally occurring levels of Coenzyme Q10 in your body declines, meaning energy is not as easily transported between the body’s cells, resulting in a drop in your energy levels and endurance.” In one sense, these words appeared to convey that some consumers would have a greater need for supplemental co-enzyme Q10 than others. However, it also implied that declining co-enzyme Q10 levels are always a result of ageing and will always have an appreciable effect on energy transfer between cells, energy levels, and endurance. The Panel was therefore satisfied that an ordinary and reasonable consumer would conclude that the claims about increased oxygen uptake, improved heart function, increased energy levels, muscle activity, reduced risk of cell damage, and other claims about the product’s effects were true for any consumer, regardless of their current co-enzyme Q10 status.

¹⁸ <https://theconversation.com/health-check-the-untrue-story-of-antioxidants-vs-free-radicals-15920>

¹⁹ <https://theconversation.com/what-are-antioxidants-and-are-they-truly-good-for-us-86062>

²⁰ <http://www.tgacrp.com.au/complaint-register/?search=Q10>

²¹ <http://www.tgacrp.com.au/complaint-register/?search=Pharmalife%20CoQ10%20Capsules>

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33. The Panel was therefore satisfied that the representations had not been verified, were not correct and balanced, were likely to arouse unwarranted expectations, and were misleading, in breach of sections 4(1)(b), 4(2)(a), and 4(2)(c) of the Code. These aspects of the complaint were therefore justified.

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