

Complaint to TGA - Nature's Care Manufacture Pty Limited, Healthy Care Ginkgo Biloba 2000 Capsules

Acknowledgements:

This complaint was worked up by 2019 Monash BMS3052 students; then checked and submitted by Assoc Prof Ken Harvey.

Product and Sponsor

Product name: Healthy Care Ginkgo Biloba 2000 Capsules

Sponsor: Nature's Care Manufacture Pty Limited

Address: 5 Minna Close, BELROSE, NSW, 2085 Australia

ARTG no: 178194

Product Ingredients: Ginkgo biloba (Ginkgo) dry extract, Equiv. to dry leaf 2g (2,000mg), Equiv. to Ginkgo flavonglycosides 9.6 mg

Advertisement type:

e.g. Internet – Web site

Accessed on:

13/01/2020

URL(s) listed (screen shots appended)

- <http://healthycare.com.au/index.php/our-products/brain-mind/item/hc-ginkgo-biloba-2000-100-capsules>
- <https://www.chemistwarehouse.com.au/buy/63922/healthy-care-ginkgo-biloba-2000-100-capsules>
- <https://www.beevitamins.com.au/products/healthy-care-ginkgo-biloba-2000mg-100-softgel-capsules>
- <https://www.ebay.com.au/itm/Healthy-Care-Ginkgo-Biloba-2000-100-Capsules/153480425718>
- <https://songkhoe.com.au/products/healthy-care-ginkgo-biloba-2000-100-softgel>
- <https://oziway.com.au/services/healthy-care-ginkgo-biloba-2000mg-100-softgel-capsules.html>
- <https://koalamart.com.au/product/healthy-care-ginkgo-biloba-2000mg-%E9%93%B6%E6%9D%8F%E5%81%A5%E8%84%91%E5%81%A5%E5%BF%86%E7%89%87-100-%E7%B2%92/>
- Etc.

Complaint Summary (also for pasting into the online complaint form)

It is claimed that Healthy Care Ginkgo Biloba 2000 Capsules assists circulation, has a relaxing (vasodilating) effect on arteries and a toning effect on veins, so can increase tissue nutrition and help maintain circulation to the peripheral areas of the body such as legs, hands and feet. It is also claimed that many studies have shown positive effects of ginkgo on working memory, the speed of information processing and learning.

These are common claims by the complementary medicine industry. However, they are not in accordance with current scientific evidence. For example, the U.S. National Center for Complementary and Integrative Health (NCCIH) states that there's no conclusive evidence that ginkgo is helpful for any health condition. In particular, they say there's no good evidence that ginkgo helps with memory enhancement in healthy people or intermittent claudication.

It is alleged that these claims for Healthy Care Ginkgo Biloba 2000 Capsules breach s.9(a), 9(b), 9(d), 10(a)(ii), 10(b), and 15(2)(b) of the Therapeutic Goods Advertising Code (No.2), 2018.

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Furthermore, on a **Chinese web site** this product is claimed to, 'Prevent and cure heart and lung diseases, asthma, bronchitis, arteriosclerosis, improve heart and blood vessel tumors, delay aging, anti-allergy, anti-cancer, anti-bacterial and anti-virus'. Also, for: 'Adults (People with memory loss / People with long-term computer radiation / People with long-term diet and weight loss / People with high-intensity work)'.

These claims are a serious breach of the Therapeutic Goods Act 1899, s.42DL(7)(a) and s.42DL(5)(a); there are **restricted** and **prohibited** representations, respectively.

Some online sites such as ebay.com.au also lacked required information, a s.12(3) Code breach.

This product should be delisted from the ARTG.

Introduction

Healthy Care Ginkgo Biloba 2000 is a capsule form of supplement that contains Ginkgo biloba leaf extract containing flavone glycosides and terpene lactones. Health Care claim that taking Ginkgo Biloba supplements supports memory, attention, mental alertness, mental clarity and circulation.

Additionally, a Chinese web site claims this product can prevent and cure heart and lung diseases, asthma, bronchitis, arteriosclerosis, improve heart and blood vessel tumors, delay aging, anti-allergy, anti-cancer, anti-bacterial and anti-virus. This is not in accord with current scientific evidence.

The major active constituents of ginkgo leaf extracts are the ginkgolides and bilobalides (also known as terpenes) and the flavonoids. These vary depending on how the leaves are grown, harvested and extracted. Extracts need to be standardised and different extracts are not comparable; one of the reasons for varied clinical trial results.

This product does not appear to be standardised according to the German Commission specification; hence they can make no claims unless they do their own trials.

Claims disputed

1. **"Prevent and cure heart and lung diseases, asthma, bronchitis, arteriosclerosis, improve heart and blood vessel tumors, delay aging, anti-allergy, anti-cancer, anti-bacterial, anti-virus."**

Most of these are serious diseases and conditions for which the promotion of complementary medicines is not allowed. Also, there is no good evidence supporting such claims.^{1,2}

2. **"Ginkgo assists blood flow and so can increase tissue nutrition. It tones and helps normalise circulation as it has a relaxing (vasodilating) effect on arteries and a toning effect on veins. Improving circulation can enhance the utilization of oxygen and glucose by the body."**

NCCIH notes there's no good evidence that ginkgo helps with intermittent claudication.³

The only relevant vaguely study found was by Wu et al.⁴ which investigated the effects of IV ginkgo biloba extract on the blood flow of healthy elderly individuals. However, given the product was administered intravenously, not orally, it provided no support for the above claim.

¹ <https://www.ncbi.nlm.nih.gov/pubmed/20582906>

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2858335/>

³ <https://nccih.nih.gov/health/ginkgo/ataglance.htm>

⁴ <https://www.sciencedirect.com/science/article/abs/pii/S0944711307003157>

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3. **“Brain cells require large amount of energy to function property. Glucose and oxygen need to create energy, as the brain has very small energy reserves. Many studies have shown positive effects of ginkgo on working memory, the speed of information processing and learning.”**

According to the U.S. National Center for Complementary and Integrative Health (NCCIH) there is no conclusive evidence that Ginkgo biloba is helpful for any health condition.¹ In particular, they say there's no good evidence that ginkgo prevents or slows dementia or cognitive decline and there's no strong evidence that it helps with memory enhancement in healthy people, blood pressure, intermittent claudication or the risk of having a heart attack or stroke.

Solomon et al.⁵ (2002) examined the effectiveness of 120 mg of pure ginkgo daily compared with matching control on 230 participants. This trial was performed in healthy elderly people aged 60 to 82 years.

One day prior to taking ginkgo or placebo and again at the end of the 6-week double-blind period (while still taking ginkgo and within 3 days of the end of the study), participants underwent neuropsychological evaluation including tests of learning, memory, attention and concentration, and expressive language. They also completed a questionnaire regarding subjective impressions of their memory. Additionally, at the end of the 6 weeks of treatment, the companion was asked to complete a global questionnaire designed to provide an overall impression of change in memory for the participant. Evaluators were blinded to which randomized treatment the participants received.

The results of this 6-week study indicate that ginkgo, marketed over-the-counter as a memory enhancer, did not enhance performance on standard neuropsychological tests of learning, memory, naming and verbal fluency, or attention and concentration. Moreover, there were no differences between ginkgo participants and placebo controls on subjective self-report of memory function or on global rating by spouses, friends, and relatives. These data suggest that when taken following the manufacturer's instructions, this compound provides no measurable benefit in cognitive function to elderly adults with intact cognitive function.

In 2007, Canter and Ernst⁶ conducted a systematic review in which they analysed 15 RTCs (randomised, placebo-controlled, and double-blind) on healthy individuals aged under 60 years. They aimed to critically evaluate the data from clinical trials to determine whether standardised Ginkgo biloba improves cognitive function in healthy subjects aged under 60 years. 15 RTCs included 7 single-dose studies and 8 longer term studies (2 days to 13 weeks).

The analysis of the single dose studies revealed that these studies were either underpowered due to unrepresentative samples or did not show any effects. Similarly, the evidence from longer term studies appeared to be negative as they found no cognitive enhancement by the subjects.

Furthermore, of those studies which measured subjective effects, only one of five acute studies and one of six longer term studies reported any significant positive results.

Overall, and in line with their previous conclusions, there was no convincing evidence from randomised clinical trials for a robust positive effect of Ginkgo biloba upon any aspect of cognitive function in healthy young people, after either acute or longer-term administration.

⁵ <https://jamanetwork.com/journals/jama/fullarticle/195207>

⁶ <https://onlinelibrary.wiley.com/doi/abs/10.1002/hup.843>

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A 2009 Cochrane review concluded there was no convincing evidence that Ginkgo biloba is efficacious for cognitive impairment.⁷

Laws et al.⁸ (2012) conducted a meta-analysis to examine whether Ginkgo biloba enhances cognitive function in healthy individuals aged 18-82 years. They identified RTCs that examined the chronic administration of Ginkgo biloba (5 days to 4 months) and contained data on memory executive function and attention from which effect sizes could be derived.

Effect sizes were non-significant and close to zero for memory ($d = -0.04$: 95%CI -0.17 to 0.07), executive function ($d = -0.05$: 95%CI -0.17 to 0.05) and attention ($d = -0.08$: 95%CI -0.21 to 0.02). Meta-regressions showed that effect sizes were not related to participant age, duration of the trial, daily dose, total dose or sample size.

Meta-regression analysis found that the outcomes were not influenced by age, daily dose, total dose over the course of the trial, formulation of Ginkgo biloba, or the duration of the trial.

It was concluded that Ginkgo biloba had no ascertainable positive effects on a range of targeted cognitive functions in healthy individuals.

In summary, it is alleged that the claims for Healthy Care Ginkgo Biloba 2000 Capsules breach s.9(a), 9(b), 9(d), 10(a)(ii), 10(b), and 15(2)(b) of the Therapeutic Goods Advertising Code (No.2), 2018.

Furthermore, on a **Chinese web site** this product is claimed to, 'Prevent and cure heart and lung diseases, asthma, bronchitis, arteriosclerosis, improve heart and blood vessel tumors, delay aging, anti-allergy, anti-cancer, anti-bacterial and anti-virus'. Also, for: 'Adults (People with memory loss / People with long-term computer radiation / People with long-term diet and weight loss / People with high-intensity work)'

These claims are a serious breach of the Therapeutic Goods Act 1899, s.42DL(7)(a) and s.42DL(5)(a); restricted and prohibited representations, respectively.

Other online sites such as ebay.com.au lacked required information, a s.12(3) Code breach.

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Signed and dated

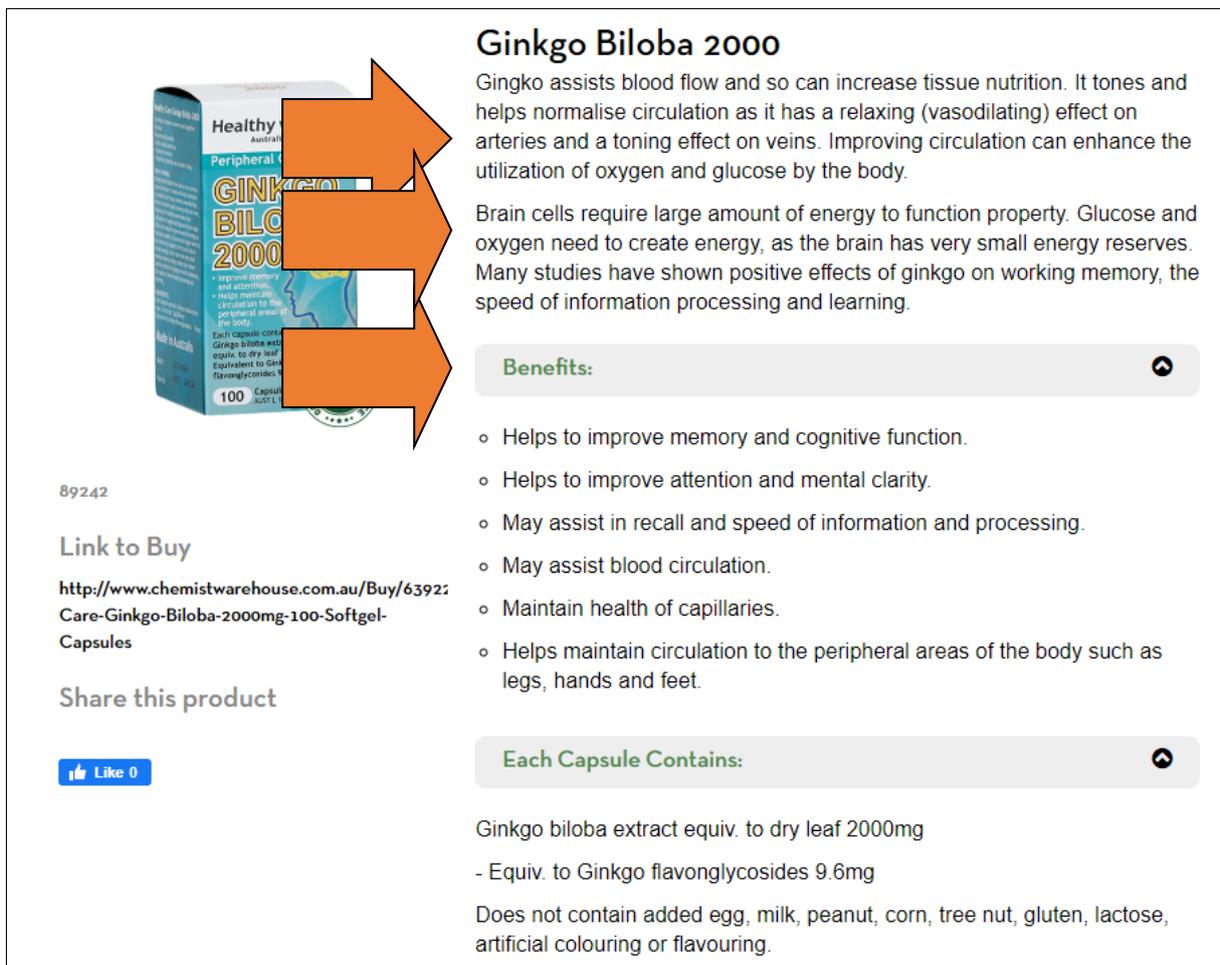
Dr Ken Harvey MB BS, FRCPA, AM
Associate Professor
Public Health and Preventive Medicine
Monash University
15 January 2020

⁷ <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003120.pub3/full>

⁸ <https://onlinelibrary.wiley.com/doi/abs/10.1002/hup.2259>

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15 January 2020 Appendix (Screen shots with offending claims arrowed)



Healthy Care Australia
Peripheral Circulation
GINKGO BILOBA 2000
100 Capsules

89242

Link to Buy
<http://www.chemistwarehouse.com.au/Buy/6392-Care-Ginkgo-Biloba-2000mg-100-Softgel-Capsules>

Share this product
Like 0

Ginkgo Biloba 2000

Ginkgo assists blood flow and so can increase tissue nutrition. It tones and helps normalise circulation as it has a relaxing (vasodilating) effect on arteries and a toning effect on veins. Improving circulation can enhance the utilization of oxygen and glucose by the body.

Brain cells require large amount of energy to function property. Glucose and oxygen need to create energy, as the brain has very small energy reserves. Many studies have shown positive effects of ginkgo on working memory, the speed of information processing and learning.

Benefits:

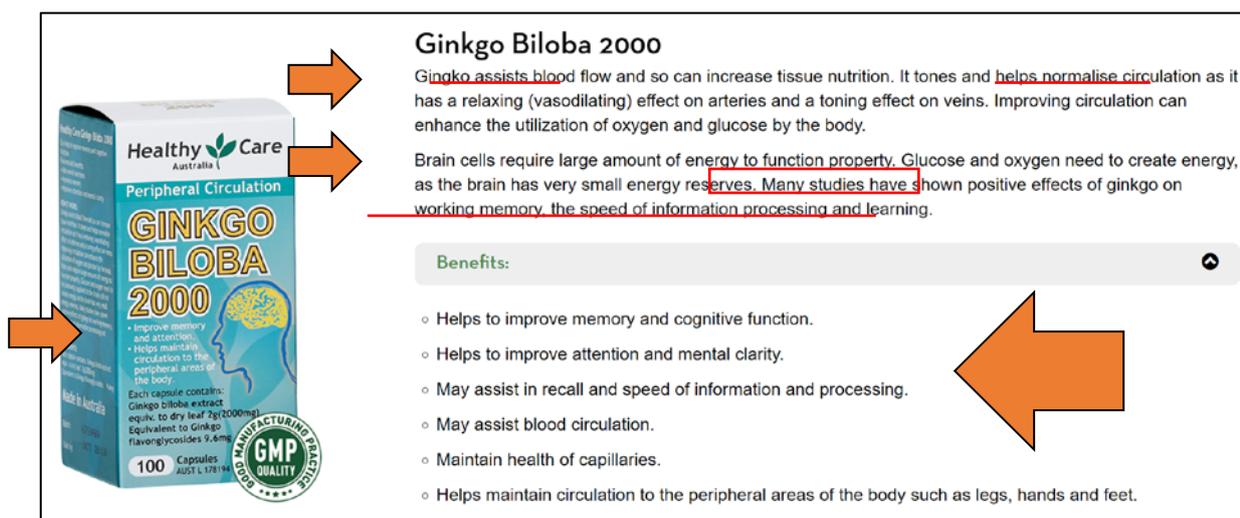
- Helps to improve memory and cognitive function.
- Helps to improve attention and mental clarity.
- May assist in recall and speed of information and processing.
- May assist blood circulation.
- Maintain health of capillaries.
- Helps maintain circulation to the peripheral areas of the body such as legs, hands and feet.

Each Capsule Contains:

Ginkgo biloba extract equiv. to dry leaf 2000mg
- Equiv. to Ginkgo flavonglycosides 9.6mg

Does not contain added egg, milk, peanut, corn, tree nut, gluten, lactose, artificial colouring or flavouring.

http://healthycare.com.au/index.php/our-products/brain-mind/item/hc-ginkgo-biloba-2000-100-capsules?category_id=72



Healthy Care Australia
Peripheral Circulation
GINKGO BILOBA 2000
100 Capsules

Ginkgo Biloba 2000

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<http://healthycare.com.au/index.php/our-products/brain-mind/item/hc-ginkgo-biloba-2000-100-capsules>

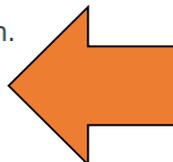
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Common Uses

Can help to improve memory and cognitive function.

Features and benefits

- Aids mental alertness
- Improves memory
- Improves attention and mental clarity



<https://www.chemistwarehouse.com.au/buy/63922/healthy-care-ginkgo-biloba-2000-100-capsules>

Healthy Care Ginkgo Biloba 2000 (100 Capsules)
★★★★★ 1 product rating | Write a review

Condition: **New**

Bulk savings:

Buy 1 AU \$21.20 each	Buy 2 AU \$20.78 each	Buy 3 AU \$20.14 each
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Quantity: 4 or more for AU \$19.50 each
10 available

Unit price: **AU \$21.20 each**

Lacks required information

[Buy It Now](#) [Add to cart](#) [Add to Watchlist](#)

[30-day returns](#) Sent from Australia

Postage: **AU \$8.95** Standard Postage | [See details](#)
Item location: Northfield, Australia
Posts to: Worldwide

Delivery: Estimated between **Thu. 16 Jan. and Fri. 17 Jan.**

Payments: [PayPal](#) | [See payment information](#)

<https://www.ebay.com.au/itm/Healthy-Care-Ginkgo-Biloba-2000-100-Capsules/153480425718>

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Koala Mart
树懒澳洲直销

我的账号 诚招代理

搜索产品...

全部商品 限时特价 超值套装 品牌专区 英文服务 关于我们

¥0.00 0件商品

首页 > 保健品 > 成人保健品 > Healthy Care Ginkgo Biloba 2000mg 银杏健脑健忆片 100粒



Healthy Care Ginkgo Biloba 2000mg 银杏健脑健忆片 100粒

¥81.00

1 加入购物车

分类: [成人保健品](#)
标签: [Healthy Care](#)

描述

Healthy Care 银杏果健脑由植物银杏叶汁浓缩提取,以增强脑部血液循环的卓越功效,可以增加人体的血液循环,提高水平的氧气送到大脑帮助改善大脑功能和心理警觉。改善血液循环也有助于缓解冷手和脚。

产品功效:

防治心肺疾病、哮喘、气管炎、动脉硬化改善心脏、血管肿瘤,延缓衰老、抗过敏、抗癌、抗菌、抗病毒。

适用方法:

成人每日三次,每次一片或遵照专业营养师指示食用

适用人群:

成年人(记忆力减退人群/长期受到电脑辐射人群/长期节食减肥人群/高强度工作人群)

koalamart.com.au/product/healthy-care-ginkgo-biloba-2000mg-银杏健脑健忆片-100-粒/

Google translation follows.

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Home > Health Supplements > Health Supplements for Adults > Healthy Care Ginkgo Biloba 2000mg



Healthy Care
Australia
Super Forte
GINKGO BILOBA 2000
100 capsules

Healthy Care Ginkgo Biloba 2000mg

¥ 81.00

1

Category: [Adult Health Products](#)
Tags: [Healthy Care](#)

description

Healthy Care Ginkgo Biloba is extracted from the concentrated ginkgo biloba juice to enhance the excellent blood circulation in the brain. It can increase blood circulation in the human body and increase the level of oxygen to the brain to help improve brain function and mental alertness. Improved blood circulation also helps to relieve cold hands and feet.

Benefits:

Prevent and cure heart and lung diseases, asthma, bronchitis, arteriosclerosis, improve heart and blood vessel tumors, delay aging, anti-allergy, anti-cancer, antibacterial, anti-virus

Applicable method:

Adults take one tablet three times daily or as directed by a professional dietitian

For people:

Adults (People with memory loss / People with long-term computer radiation / People with long-term diet and weight loss / People with high-intensity work)

Google translated page above

<https://koalamart.com.au/product/healthy-care-ginkgo-biloba-2000mg-%E9%93%B6%E6%9D%8F%E5%81%A5%E8%84%91%E5%81%A5%E5%BF%86%E7%89%87-100-%E7%B2%92/>