

# Complaint to TGA - RF Six Pty Ltd, Microgenics Ginkgo 7000

## 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: Microgenics Ginkgo 7000

Sponsor: RF Six Pty Ltd

Address: 44 Raglan Street, Preston, VIC, 3072 Australia

ARTG no: 307457

Product Ingredients: Ginkgo biloba (Ginkgo) dry extract, Equiv. to dry leaf 7g (7,000mg), Equiv. to Ginkgo flavonglycosides 33.6mg)

## Advertisement type:

e.g. Internet – Web site

## Accessed on:

09/01/2020

## URL(s) listed (screen shots appended)

- <https://www.micro-genics.com.au/products/microgenics-ginkgo-7000-100-capsules/>
- <https://www.ebay.com.au/itm/Microgenics-Ginkgo-7000-100-Capsules-/323820104940>
- Etc.

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

It is claimed that Microgenics Ginkgo 7000 is “a powerful aid to circulatory problems and has strong antioxidant properties to protect both the central nervous system and the cardiovascular system from damage and the effects of ageing”. It is also claimed to improve memory, focus and cognition, improve circulation to the peripheral areas of the body, such as hands and feet and improve tinnitus (ringing of the ear).

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, intermittent claudication or tinnitus.

The citations listed to support the claims for the Microgenics product were unable to be accessed.

It is alleged that the claims for Microgenics Ginkgo 7000 breach s.9(a), 9(b), 9(d), 10(a)(ii), 10(b), 15(2)(b) and 15(3)(b) of the Therapeutic Goods Advertising Code (No.2), 2018. Some online sites such as ebay.com.au lacked required information, a s.12(3) Code breach. This product should be delisted from the ARTG.

## Introduction

Microgenics Ginkgo 7000 is a tablet form of supplement that contains Ginkgo biloba leaf extract containing flavone glycosides and terpene lactones. There is a common belief (extensively promoted by the complementary medicine industry) that taking Ginkgo Biloba supplements supports memory and concentration, cognition, circulation, and tinnitus (ringing in ears). This is not in accord with current scientific evidence.

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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.

### Claims disputed

1. **“Support memory, concentration and cognition. A powerful aid to circulatory problems and has strong antioxidant properties to protect both the central nervous system and the cardiovascular system from damage and the effects of ageing. Scientific research has shown that supplementing with ginkgo can help improve blood flow to the brain, and as a result improve memory and concentration.”**

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.<sup>1</sup> 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.<sup>2</sup> (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 Ernst<sup>3</sup> 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.

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<sup>1</sup> <https://nccih.nih.gov/health/ginkgo/ataglance.htm>

<sup>2</sup> <https://jamanetwork.com/journals/jama/fullarticle/195207>

<sup>3</sup> <https://onlinelibrary.wiley.com/doi/abs/10.1002/hup.843>

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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.

A 2009 Cochrane review concluded there was no convincing evidence that Ginkgo biloba is efficacious for cognitive impairment.<sup>4</sup>

Laws et al.<sup>5</sup> (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.

### 2. **“Support circulation. Ginkgo is not only beneficial to improve the circulation to the brain, but also to the peripheral areas of the body, such as hands and feet”.**

NCCIH notes there’s no good evidence that ginkgo helps with intermittent claudication.<sup>1</sup>

The only relevant vaguely study found was by Wu et al.<sup>6</sup> 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.

### 3. **“Support with tinnitus. Ginkgo can help reduce or prevent the phantom noises that irritate the ear, called tinnitus”**

NCCIH notes there’s no good evidence that ginkgo helps with intermittent claudication.<sup>1</sup>

An updated Cochrane review (2013) assessed the effect of Ginkgo biloba in patients who are troubled by tinnitus.<sup>7</sup> Four trials with a total of 1543 participants were included in the review. Three trials (1143 participants) included patients with a primary complaint of tinnitus and one (400 participants) included patients with mild to moderate dementia, some of whom had tinnitus. There was no evidence that Ginkgo biloba was effective in patients with a primary complaint of tinnitus.

Several indications / claims made are not found in the ARTG entry, a s.9(d) Code breach. For example, 'powerful aid to circulatory problems', 'protect both the central nervous system and the cardiovascular system from damage and the effects of ageing', 'improve blood flow / circulation to the brain', 'tinnitus'.

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<sup>4</sup> <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003120.pub3/full>

<sup>5</sup> <https://onlinelibrary.wiley.com/doi/abs/10.1002/hup.2259>

<sup>6</sup> <https://www.sciencedirect.com/science/article/abs/pii/S0944711307003157>

<sup>7</sup> <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003852.pub3/full>

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Finally, the citations listed to support the claims for the Microgenics product were unable to be accessed. Attempting to copy and paste their Ginkgo references 1-6 into a web browser produced:

O[[WZ!SPURZWYPUNLYJVTHY[PJSL--)- --  
O[[WZ!^^^PTNH[L^H`UL[WHNLQZW&WYVM9LM\$7YVM/LYIZF.PURNV)PSVIHWO  
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QV\YUHS7HWLY0UMVYTH[PVUHZW\_&7HWLY0+\$-  
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O[[WZ!^^^UJIPUSTUPONV]W\ITLK-  
O[[WZ!^^^UJIPUSTUPONV]WTJHY[PJSLZ74\*--

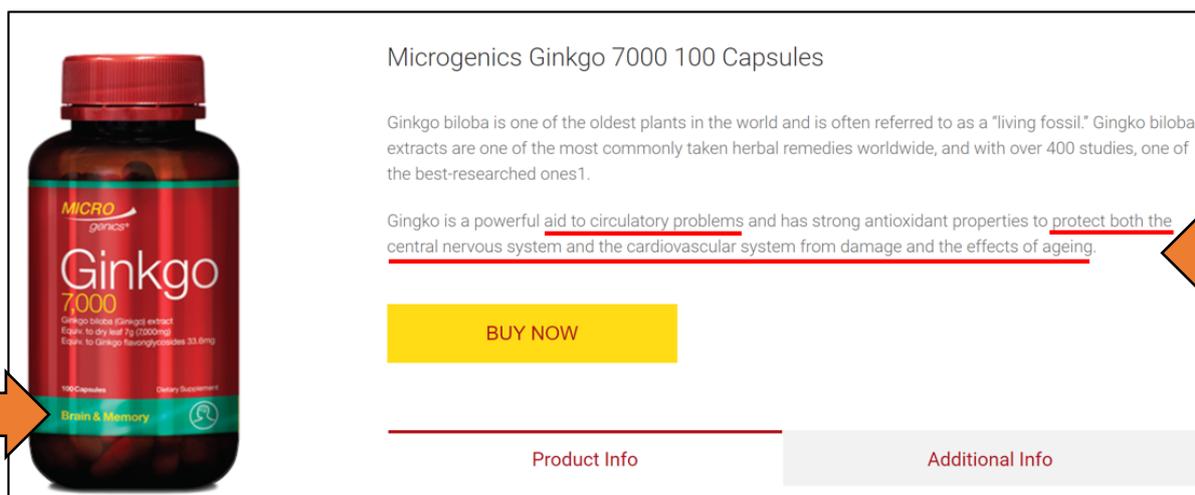
In summary, it is alleged that the claims for Microgenics Ginkgo 7000 breach s.9(a), 9(b), 9(d), 10(a)(ii), 10(b), 15(2)(b) and 15(3)(b) the Therapeutic Goods Advertising Code (No.2), 2018. Some online sites such as ebay.com.au lacked required information, a s.12(3) Code breach. This product should be delisted from the ARTG.

Signed and dated

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

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## Appendix (Screen shots with offending claims arrowed)



Microgenics Ginkgo 7000 100 Capsules

Ginkgo biloba is one of the oldest plants in the world and is often referred to as a "living fossil." Ginkgo biloba extracts are one of the most commonly taken herbal remedies worldwide, and with over 400 studies, one of the best-researched ones<sup>1</sup>.

Ginkgo is a powerful aid to circulatory problems and has strong antioxidant properties to protect both the central nervous system and the cardiovascular system from damage and the effects of ageing.

**BUY NOW**

Product Info Additional Info

### INGREDIENT INFORMATION

#### Support memory and concentration

Ginkgo has traditionally been used to support memory and concentration. It does this by increasing the blood flow to the brain. Reduced blood flow to the brain has been linked to memory loss, confusion and dizziness. Scientific research has shown that supplementing with ginkgo can help improve blood flow to the brain, and as a result improve memory and concentration<sup>2</sup>. Interestingly, the leaves of the Ginkgo biloba tree have the same shape as the two halves of our brain. This is a nice visual to help you remember what Ginkgo is used for.

#### Support cognition

Ginkgo can also be used to help improve cognition. Studies have shown that it can help improve cognition in those with mild to moderate cognitive impairment when used long-term (approximately 6 months)<sup>(3,4)</sup>

#### Support circulation

Ginkgo is not only beneficial to improve the circulation to the brain, but also to the peripheral areas of the body, such as hands and feet. Research found that the blood flow to the small blood vessels in nailbeds increased by 57% 1 hour after taking a ginkgo supplement<sup>5</sup>. For this reason, it may be a useful herb for those who suffer from cold hands and feet due to poor circulation.

#### Support with tinnitus

Ringing in the ears is a symptom that can have many underlying causes, including problems with the circulation. Ginkgo leaf contains antioxidants that help promote circulation, and flavonoids and terpenoids that protect the nerves and blood vessels from free radicals. This combination can help reduce or prevent the phantom noises that irritate the ear, called 'tinnitus'<sup>6</sup>.

#### SUMMARISED

- Ginkgo can help improve memory, focus and cognition
- Ginkgo can help improve circulation to the peripheral areas of the body, such as hands and feet
- Ginkgo can help improve tinnitus (ringing of the ear)

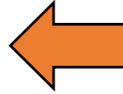
<https://www.micro-genics.com.au/products/microgenics-ginkgo-7000-100-capsules/>

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## APPROVED LABEL CLAIM

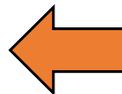
Microgenics Ginkgo 7,000 contains Ginkgo biloba leaf extract, a source of antioxidants which reduce free radicals formed in the body. Ginkgo also supports cognitive function, focus and mental clarity as well as memory and mental recall. Ginkgo supports blood flow to the peripheral areas of the body such as legs, hands and feet.

- üüGinkgo supports cognitive function
- üüMaintains mental concentration, focus and clarity
- üüMaintains memory and mental recall



## CUSTOMER PROFILE

- Poor memory and concentration
- Ageing population
- Tinnitus (ringing of the ears)
- Cold hands and feet due to poor circulation



<https://www.micro-genics.com.au/products/microgenics-ginkgo-7000-100-capsules/>



Mouse over image to zoom



### Microgenics Ginkgo 7000 100 Capsules

Condition: **New**

Quantity:  Limited quantity available / [7 sold](#)

Price: **AU \$12.99**

[Buy It Now](#)

[Add to cart](#)

[Add to Watchlist](#)

Longtime member    More than 53% sold    No returns

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

Delivery: Estimated by **Tue. 14 Jan.**

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

Got A Senior's Card? [Health Insurance Compare](#)

Returns: No returns accepted | [See details](#)

[Have one to sell?](#) [Sell it yourself](#)

<https://www.ebay.com.au/itm/Microgenics-Ginkgo-7000-100-Capsules-/323820104940>