

Complaint to TGA: Doctor's Best Extra Strength Ginkgo

Acknowledgement:

This complaint was worked up by the Monash University BMS3052 WAM Thursday 6pm student group 16; edited and checked by Lucy Romanoff and submitted by Assoc Prof Ken Harvey.

Summary:

We allege this is a 'critical' complaint because this supplement, and many others on Australian web sites such as LeanMachine (ABN 55293601285),¹ Trusted Health Supplies (ABN 92046652410),² Rewardia (ABN 24164419354)³ and AussieWell (ABN 15036836769)⁴ appear to have been imported direct from the U.S.A. and promoted and sold without being listed on the ARTG.

Doctor's Best Extra Strength Ginkgo is a capsule form supplement that contains Ginkgo biloba leaf extract with flavone glycosides and terpene lactones.

It is claimed that Doctor's Best Extra Strength Ginkgo may help relieve symptoms of ADHD, ADD, Alzheimer's and may help prevent or treat some cancers. It is also claimed to promote mental function and memory, may improve age-related or noise-related hearing loss and is used to reduce vertigo and tinnitus (ear-ringing) through its blood-thinning effects on the vascular system. They note that some people use it for problems relating to poor blood flow in the body, including leg pain when walking (claudication), and Raynaud's syndrome (a painful response to cold, especially in the fingers and toes).

We allege that advertisements for Doctor's Best Extra Strength Ginkgo products breach the Therapeutic Goods Act 1989 42DL(1)(a),(c),(g) and 22(5) and the Therapeutic Goods Advertising Code 2015, s.4(1)(b), 4(2)(a), 4(2)(b), 4(2)(c), 4(2)(d), 5 and s.6(3),(b), (c) and (d).

We ask for an immediate investigation into the web sites (above and below) that are illegally supplying complementary medicines in Australia and making fraudulent claims.

Claims: (Doctor's Best Extra Strength Ginkgo; screen shots below):

1. May help relieve symptoms of ADHD, ADD, Alzheimer's and may help prevent or treat some cancers
2. Promotes mental function and memory
3. May improve age-related hearing loss.
4. Used to reduce vertigo and tinnitus
5. Used for problems relating to poor blood flow in the body, including leg pain when walking (claudication), and Raynaud's syndrome (a painful response to cold, especially in the fingers and toes).

Advertisement type: Internet

Where did it appear:

- https://www.leanmachine.net.au/catalog/index.php?main_page=product_info&products_id=43
- <https://trustedhealthsupplies.com.au/shop/supplements/doctors-best-extra-strength-ginkgo-120-mg-120-veggie-caps/>
- https://www.rewardia.com.au/Doctors_Best_Best_MSM_1000_mg_360_Capsules?pk=zm&pi=1310728245

¹ https://www.leanmachine.net.au/catalog/index.php?main_page=index&cPath=1

² <https://trustedhealthsupplies.com.au/product-category/herbal-supplements/>

³ https://www.rewardia.com.au/Vitamins_and_Nutrition?pk=pt&pi=209

⁴ <http://www.aussiewell.com.au/b/30158/1/doctors-best.html>

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- <http://www.aussiewell.com.au/b/30158/1/doctors-best.html>
- <https://www.megavitamins.com.au/en/supplements/212-doctor-s-best-ginkgo-extra-strength-120mg-360-vcaps-supplement.html>
- Etc

Date seen: November 28, 2018

Product:

Doctor's Best Extra Strength Ginkgo 120mg Capsules; ARTG ID: NOT LISTED

Screen shots:

LeanMachine
Health and Wellness 

Home > Supplements > Ginkgo Biloba Extra Strength 120 mg 120 vcaps: brain, cancer

Ginkgo Biloba Extra Strength 120 mg 120 vcaps: brain, cancer



larger image

Model: DRB00091
0 Units in Stock
Manufactured by: Doctor's Best

[Contact Us](#)

Description

[Buy from www.iherb.com](http://www.iherb.com)

Sharpens the Mind and Body!

- ProfileProven- Quality Assurance
- Promotes Mental Function and Memory
- Suitable for Vegetarians
- Supports circulation in the brain and other organs
- Promotes mental function and memory
- May help relieve symptoms of ADHD, ADD
- May help symptoms of Alzheimer's
- May help prevent or treat some cancers
- May improve age-related or noise-related hearing loss

https://www.leanmachine.net.au/catalog/index.php?main_page=product_info&products_id=43

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Warnings

Do not take with any other blood-thinning medication without medical advice as dosage of prescription medication may have to be reviewed and/or reduced.

Some people may be allergic to this product, although this is very rare.

May increase risk of seizures in people at risk such as epileptics.

Do not take for at least 7 days before surgery of any kind, as risk of increased bleeding may occur, although this risk is less than aspirin.

Disclaimer

Because of constraints imposed on all by the TGA (Australian Therapeutic Goods Administration), we do not claim that any supplement will diagnose, prevent, treat or cure any disease, sickness, condition or ailment. Any advice or information given here is of a general nature and everyone should discuss their individual nutritional needs with their health professional.

LeanMachine cannot take responsibility for any undesirable outcome from using any product, as we have no control over individual health, use, mis-use, sensitivity, suitability or interactions with prescription medication.

https://www.leanmachine.net.au/catalog/index.php?main_page=product_info&products_id=43



Doctor's Best, Extra Strength Ginkgo, 120 mg, 120 Veggie Caps

Ginkgo is often used for memory disorders including Alzheimer's disease. It is also used for conditions that seem to be due to reduced blood flow in the brain, especially in older people. These conditions include memory loss, headache, ringing in the ears, vertigo, difficulty concentrating, mood disturbances, and hearing disorders. Some people use it for other problems related to poor blood flow in the body, including leg pain when walking (claudication), and Raynaud's syndrome (a painful response to cold, especially in the fingers and toes).

Price: \$19.99

PRICE: **\$17.99 inc. GST**

2 in stock (can be backordered)

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- ★ Science-Based Nutrition
- ★ Dietary Supplement
- ★ ProfileProven- Quality Assurance
- ★ Promotes Mental Function and Memory
- ★ Suitable for Vegetarians

Suggested Use

Take one capsule once or twice a day with or without food. When taking two capsules daily, take one in the morning and one in the afternoon.

<https://trustedhealthsupplies.com.au/shop/supplements/doctors-best-extra-strength-ginkgo-120-mg-120-veggie-caps/>

Home » MORE..... » Doctors Best, Extra Strength Ginkgo, 120 mg, 120 Veggie Caps



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Doctors Best, Extra Strength Ginkgo, 120 mg, 120 Veggie Caps

Our Price: **\$22.84**

2+ : \$21.70
3+ : \$21.01
4+ : \$19.41

Add to Cart

Qty 

Description

- Science-Based Nutrition
- Dietary Supplement
- ProfileProven - Quality Assurance
- Promotes Mental Function and Memory
- Vegan
- Non-GMO and Gluten Free

Extra Strength Ginkgo supplies premium quality Ginkgo biloba standardized extract, guaranteed to contain a minimum 24% flavone glycosides and 6% terpene lactones, as verified by independent laboratory analysis.

Supports circulation in the brain, promotes mental function and memory.

This Ginkgo Extract is guaranteed by the ProfileProven Quality Assurance system developed by Ethical Naturals, Inc. This process includes the most extensive testing and screening at every stage of manufacturing to assure purity and potency.

Suggested Use

Adult Use: Take 1 capsule once or twice daily, with or without food, or as recommended by a nutritionally-informed physician. When taking two capsules daily, take one in the morning and one in the afternoon.

<http://www.aussiewell.com.au/p/8563745/doctors-best-extra-strength-ginkgo-120-mg-120-veggie-caps.html>

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Claims disputed and rationale:

First, the U.S. National Center for Complementary and Integrative Health (NCCIH) states that there is no conclusive evidence that ginkgo is helpful for any health condition.⁵ They say ginkgo doesn't help prevent or slow dementia or cognitive decline, there's no strong evidence that ginkgo helps with memory enhancement in healthy people, blood pressure, intermittent claudication, tinnitus, age-related macular degeneration, the risk of having a heart attack or stroke, or with other conditions.

Second, herbal products are chemical soups; depending on how grown, how extracted, etc., not all herbal preparations are the same. For example, EGb 761 is the classic standardised, specified and reproducible extract of Ginkgo on which many trials have been done. It contains approximately 24% flavone glycosides (primarily quercetin, kaempferol and isorhamnetin) and 6% terpene lactones (2.8-3.4% ginkgolides A, B and C, and 2.6-3.2% bilobalide). Ginkgolide B and bilobalide account for about 0.8% and 3% of the total extract, respectively. Other constituents include proanthocyanadins, glucose, rhamnose, organic acids, D-glucaric and ginkgolic acids.

While Doctor's Best Extra Strength Ginkgo states it contains a minimum of 24% flavone glycosides and 6% terpene lactones there is no guarantee that this extract is therapeutically identical to those used in clinical trials. Extrapolating results from clinical trials using a well characterised and reproducible extract to another similar, but not identical, extract is inappropriate. Evidence for claims should come from clinical trials conducted on the exact product promoted.

Individual claims are now assessed:

1. May help relieve symptoms of ADHD, ADD, Alzheimer's and may help prevent or treat some cancers

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.^{6,7,8,9}

We allege this claim breaches the Therapeutic Good Advertising Code 2015, s.4(1)(b), 4(2)(a), 4(2)(c) & 5.

2. Promotes mental function and memory

A 2009 Cochrane review concluded there was no convincing evidence that Ginkgo biloba is efficacious for dementia and cognitive impairment.¹⁰

Solomon et al. (2002) examined the effectiveness of 120 mg of pure ginkgo daily compared with matching control on 230 participants.¹¹ 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

⁵ <https://nccih.nih.gov/health/ginkgo/ata glance.htm>

⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3679686/>

⁷ <https://www.ncbi.nlm.nih.gov/pubmed/21827936>

⁸ <https://www.ncbi.nlm.nih.gov/pubmed/26268332>

⁹ <https://www.ncbi.nlm.nih.gov/pubmed/20582906>

¹⁰ <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003120.pub3/full?>

¹¹ <https://jamanetwork.com/journals/jama/fullarticle/195207>

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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.

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

3. May improve age-related hearing loss.

Polanski et al (2013) investigated the effect of four agents, including ginkgo, on age-related hearing loss (presbycusis) in a randomized, double-blind, placebo-controlled trial of 120 participants.¹² All participants were evaluated at recruitment and after six months, using pure tone audiometry (at isolated and average frequencies), speech recognition threshold and percentage index of speech recognition. There was no statistically significant change in the hearing threshold after treatment with any of the tested drugs, during the study period.

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

4. Used to reduce tinnitus and vertigo

An updated Cochrane review (2013) assessed the effect of Ginkgo biloba in patients who are troubled by tinnitus.¹³ Four trials with a total of 1543 participants were included in the review; we assessed all the included studies as having a low risk of bias. 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.

One small study was found suggesting that Ginkgo biloba (EGb 761) might be useful in the treatment vertigo, dizziness, or both, caused by vascular vestibular disorders.¹⁴ It has yet to be replicated with larger number of patients.

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

5. Used for problems relating to poor blood flow in the body, including leg pain when walking (claudication), and Raynaud's syndrome (a painful response to cold, especially in the fingers and toes).

A Cochrane review (2013) assessed the effect of Ginkgo biloba on walking distance in people with intermittent claudication.¹⁵ Fourteen trials with a total of 739 participants were included. Eleven trials involving 477 participants compared Ginkgo biloba with placebo and assessed the

¹² <https://www.cambridge.org/core/journals/journal-of-laryngology-and-otology/article/evaluation-of-antioxidant-treatment-in-presbycusis-prospective-placebocontrolled-doubleblind-randomised-trial/BFCA60DB5B259CC858F607A3C1935145>

¹³ <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003852.pub3/full>

¹⁴ <https://www.ncbi.nlm.nih.gov/pubmed/10345150>

¹⁵ <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006888.pub3/full>

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absolute claudication distance. The authors concluded that, overall, there was no evidence that Ginkgo biloba has a clinically significant benefit for patients with peripheral arterial disease.

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

Previous complaints:

Five complaints upheld complaints were found on the CRP web site concerning Ginkgo products including one referral to the Secretary of the TGA.¹⁶

Typically, no information about the outcome of this referral is available at the TGA, "Outcomes of advertising complaints - compliance following TGA intervention"¹⁷ or "Decisions in relation to complaints about advertisements".¹⁸

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28/11/18

¹⁶ http://www.tgacrp.com.au/complaint-register/?_search=Ginkgo

¹⁷ <https://www.tga.gov.au/ws-rec2sec-index?page=1>

¹⁸ <https://www.tga.gov.au/decisions-relation-complaints-about-advertisements#summary-h>