

Complaint to TGA – Natural Bio Pty Limited, Bioglan Ginkgo Biloba 2000mg

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: Bioglan Ginkgo Biloba 2000mg

Sponsor: Natural Bio Pty Limited

Address: 18 Jubilee Ave, Warriewood NSW, 2102

ARTG no: 112467

Product Ingredients: 40 mg of Ginkgo biloba which is equivalent to 2 g of Dry Ginkgo biloba (containing Ginkgo flavonglycosides 9.6 mg and Ginkgolides and bilobalide 2.4 mg)

Advertisement type:

Internet – Web site

Accessed on:

07/01/2020

URL(s) listed (screen shots appended)

- <https://www.bioglan.com.au/products/vitamins/ginkgo-biloba-2000/>
- <https://www.health365.com.au/bioglan-ginkgo-biloba-2000mg-100s>
- https://www.superpharmacy.com.au/products/bioglan-ginkgo-biloba-2000mg-100-tablets?gclid=EAlaIqobChMI8JrJtlvw5gIVESUrCh21uwFhEAQYASABEgKSc_D_BwE
- https://www.chemistwarehouse.com.au/buy/49121/bioglan-ginkgo-biloba-2000mg-100-tablets?gclid=EAlaIqobChMI8JrJtlvw5gIVESUrCh21uwFhEAQYAiABEgITF_D_BwE&gclsrc=aw.ds
- https://www.pharmacydirect.com.au/bioglan-ginkgo-biloba-2000mg-100-tablets?gclid=EAlaIqobChMI8JrJtlvw5gIVESUrCh21uwFhEAQYBSABEgItuvD_BwE
- https://www.ebay.com.au/p/1826404638?iid=322079115038&chn=ps&norover=1&mkevt=1&mkrid=705-139619-5960-0&mkcid=2&itemid=322079115038&targetid=834766631481&device=c&mktype=pla&googleloc=1000567&poi=&campaignid=7408627101&mkgroupid=86410135648&rlsatarget=pla-834766631481&abclid=1139226&merchantid=7364522&gclid=EAlaIqobChMI37KN7Izw5gIVzSMrCh3qaAbIEAYYBCABEgKei_D_BwE
- <https://www.goodpricepharmacy.com.au/bioglan-ginkgo-biloba-2000mg-100-tablets>
- <https://www.pharmacy4less.com.au/bioglan-ginkgo-biloba-2000mg-100-tablets-4.html>
- <https://www.chempro.com.au/BIOGLAN-GINKGO-BILOBA-2000MG-TAB-100>
- <https://www.yourdiscountchemist.com.au/bioglan-ginkgo-biloba-2000mg-tablets-100.html>
- <https://www.amazon.com.au/Bioglan-Ginkgo-2000mg-100s-Kilograms/dp/B00AQ7RKEQ>
- <https://discountchemist.com.au/product/bioglan-ginkgo-biloba-2000mg-100-tablets/>
- Etc.

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

It is claimed that Bioglan Ginkgo Biloba 2000mg helps memory, concentration, alertness and blood circulation. 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

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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 and the risk of having a heart attack or stroke.

It is alleged that the claims for Bioglan Ginkgo Biloba 2000mg breach s.9(a), 9(b), 10(a)(ii), 15(2)(b) and 15(3)(b) of the Therapeutic Goods Advertising Code (No.2), 2018.

Introduction

Bioglan Ginkgo Biloba 2000mg 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 helps memory, concentration and alertness as well as improving blood flow and circulation. This is not in accord with current scientific evidence.

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. In particular, they say there's no good evidence that ginkgo helps with memory enhancement in healthy people, intermittent claudication and the risk of having a heart attack or stroke.¹

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. **“Bioglan's Ginkgo Biloba 2000mg is beneficial in helping memory, concentration, alertness and blood circulation”.**

In 2007, Canter and Ernst² 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 majority of the studies tested 120 mg of active Ginkgo biloba which is also the recommended dose by Bioglan Ginkgo Biloba.

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 mostly 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.

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

² <https://onlinelibrary.wiley.com/doi/abs/10.1002/hup.843>

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Laws et al.³ (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. **“Ginkgo Biloba can improve blood circulation to the head, hands and feet, and therefore provide relief to those who suffer from poor circulation.”**

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.

3. **“Clinically trialled”**

Irrelevant, misleading and Deceptive given negative trial results.

In summary, it is alleged that both claims breach s.9(a), 9(b), 10(a)(ii), 15(2)(b) and 15(3)(b) of the Therapeutic Goods Advertising Code (No.2), 2018.

Signed and dated

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

³ <https://onlinelibrary.wiley.com/doi/abs/10.1002/hup.2259>

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

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Appendix (Screen shots with offending claims arrowed)

Ginkgo Biloba 2000mg 100s

BUY NOW ON **health 365**

Q  **Bioglan's Ginkgo Biloba 2000mg** is beneficial in helping memory, concentration, alertness and blood circulation*. 100 tablets

Always read the label. Follow the directions for use. If symptoms persist consult your healthcare professional.

 SENIORS CARD welcome here

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DETAILED INFORMATION DIRECTIONS INGREDIENTS

What is Bioglan Ginkgo Biloba 2000mg for?

Healthy Brain Function – Oxygen supply to the brain is important to memory and concentration, the Ginkgo herb contains key alkaloids that can assist to increase blood flow and increase circulation.

Circulation Ginkgo Biloba can improve blood circulation to the head, hands and feet, and therefore provide relief to those who suffer from poor circulation*.

Who is Bioglan Ginkgo Biloba 2000mg for?

Are you looking to maintain healthy memory and boost memory and concentration? Ginkgo Biloba 2000mg helps concentration, alertness and overall blood circulation.

When should I take Bioglan Ginkgo Biloba 2000mg?

If you're feeling as though your memory or concentration aren't as great as they used to be, Ginkgo Biloba could be product great choice for you. With the clinically trialled dose of Ginkgo Biloba this product provides the benefits of increased circulation and brain health.

Why should I take Bioglan Ginkgo Biloba 2000mg?

Blood circulation Concentration and alertness Memory and Recall

<https://www.bioglan.com.au/products/vitamins/ginkgo-biloba-2000/>

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Bioglan Ginkgo Biloba 2000mg 100s

SKU 543149
In stock

\$19.76 Sign in to view members price
Save \$2.19
RRP: \$21.95

QTY 1

Bioglan's Ginkgo Biloba 2000mg is beneficial in helping memory, concentration, alertness and blood circulation*.

100 tablets

<https://www.health365.com.au/bioglan-ginkgo-biloba-2000mg-100s>

DETAILED INFORMATION	DIRECTIONS	INGREDIENTS
<p>What is Bioglan Ginkgo Biloba 2000mg for?</p> <p><u>Healthy Brain Function</u> – Oxygen supply to the brain is important to memory and concentration, the Ginkgo herb contains key alkaloids that can assist to increase blood flow and increase circulation.</p> <p><u>Circulation</u> Ginkgo Biloba can improve blood circulation to the head, hands and feet, and therefore provide relief to those who suffer from poor circulation*.</p> <p>Who is Bioglan Ginkgo Biloba 2000mg for?</p> <p>Are you looking to maintain healthy memory and boost memory and concentration? <u>Ginkgo Biloba 2000mg helps concentration, alertness and overall blood circulation.</u></p>		

<https://www.bioglan.com.au/products/vitamins/ginkgo-biloba-2000/>

Overview

Bioglan's Ginkgo Biloba 2000mg is beneficial in helping to improve memory, concentration, alertness and blood circulation. Healthy Brain Function – Compromised oxygen supply to the brain can contribute to poor memory and concentration, Ginkgo improved blood circulation and oxygen supply to the brain. Circulation – Ginkgo Biloba can improve blood circulation to the head, hands and feet, and therefore provide relief to those who suffer from poor circulation.

https://www.superpharmacy.com.au/products/bioglan-ginkgo-biloba-2000mg-100-tablets?gclid=EAlaIqobChMI8JrJtlvw5gIVESUrCh21uwFhEAQYASABEgKSc_D_BwE

WHO IS BIOGLAN GINKGO BILOBA 2000MG FOR?

Are you looking to maintain healthy memory and boost memory and concentration? Ginkgo Biloba 2000mg provides the clinically trailed dose of Ginkgo Biloba to help concentration, alertness and overall blood circulation.

https://www.pharmacydirect.com.au/bioglan-ginkgo-biloba-2000mg-100-tablets?gclid=EAlaIqobChMI8JrJtlvw5gIVESUrCh21uwFhEAQYBSABEgltuvD_BwE

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Home / Health / Vitamins / Bioglan / Bioglan Brain, Memory & Sleep Health



Bioglan Ginkgo Biloba 2000mg 100 Tablets

Product ID: 2500925
★★★★★ 5.0 (4) Write a review

\$15.49

\$6.46 Off RRP
Don't Pay RRP: \$21.95

QTY: 1

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THIS PRODUCT MAY NOT BE RIGHT FOR YOU. ALWAYS READ THE LABEL, WARNINGS AND INSTRUCTIONS FOR USE, BEFORE PURCHASE. VITAMIN AND MINERAL SUPPLEMENTS SHOULD NOT REPLACE A BALANCED DIET.

General Information

Bioglan's Ginkgo Biloba 2000mg is beneficial in helping memory, concentration, alertness and blood circulation*.
100 tablets

What is Bioglan Ginkgo Biloba 2000mg for?

Healthy Brain Function - Oxygen supply to the brain is important to memory and concentration, the Ginkgo herb contains key alkaloids that can assist to increase blood flow and increase circulation.

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Who is Bioglan Ginkgo Biloba 2000mg for?
Are you looking to maintain healthy memory and boost memory and concentration?
Bioglan 2000mg helps concentration, alertness and overall blood circulation.
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If you're feeling as though your memory or concentration aren't as great as they used to be, Ginkgo Biloba could be product great choice for you. With the clinically trialed dose of Ginkgo Biloba this product provides the benefits of increased circulation and brain health.

Why should I take Bioglan Ginkgo Biloba 2000mg?
Blood circulation Concentration and alertness Memory and Recall

Warnings

Always read the label. Use only as directed. If symptoms persist consult your healthcare professional.

<https://www.chemistwarehouse.com.au/buy/49121/bioglan-ginkgo-biloba-2000mg-100-tablets>