

Complaint to TGA – Natural Bio Pty Limited, Bioglan Healthy Kids Eye Guard Chewable

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 Healthy Kids Eye Guard Chewable

Sponsor: Natural Bio Pty Limited

Address: PO Box 384, MONA VALE, NSW, 1660 Australia

ARTG no: 272544

Specific Indications:

- The yellow coloured carotenoids of lutein combined with beta Carotene are found in high concentration in the eye and thought to/ help/ may help/ absorb blue light and/block/ UV Rays/from sunlight/ and help provide/form/a protective filter/barrier. Lutein is thought to be/know to be/ important for eye health.
- Lutein shield/may/help/ helps protect/shield/ the retina from blue light/Help protect /shield/eyes against blue light.
- Lutein which helps to/that are thought to/ filter blue light/act as/ and acts as /'natural sunglasses'/in the eyes/ to help protect the eye/s from sunlight and digital device screens
- Lutein is thought to block UV light and resist breakdown by sunlight
- Help support/children's/kids/ healthy eyesight/eyes/early in life/with this product.

Warnings:

- Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
- (If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect]

Product Ingredients:

- Betacarotene 0.5mg
- D-alpha-tocopheryl acid succinate 4.5mg
- Lutein 5mg

Advertisement type:

Internet – Website

Accessed on:

13/01/20

URL(s) listed (screen shots appended)

- <https://www.bioglan.com.au/products/vitamins/eye-guard-chewable/>
- <https://www.chemistwarehouse.com.au/buy/80303/bioglan-kids-eye-guard-chewable-50-tablets?>
- <https://www.amazon.com.au/Bioglan-Eye-Guard-Chewable-0-07kg/dp/B07BPPPGC7>
- <https://www.chempro.com.au/Bioglan-Healthy-Kids-Eye-Guard-Chewable-50-Tablets>
- <https://www.superpharmacy.com.au/products/bioglan-kids-eye-guard-chewable-50-tablets?>
- <https://www.pharmacyonline.com.au/bioglan-kids-eye-guard-chewable-tab-x-50?>

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- https://www.chemistdiscountcentre.com.au/?gclid=CjwKCAiApOvwBRBUEiwAcZGdGJLwxRvtVBp5wl2VrsXBiqy651aClWv623OcKzExINdyKB7UCgxISxoCGxYQAvD_BwE#/prod/136185/bioglan-healthy-kids-eye-guard-50-chewable-tablets
- <https://www.yourchemistshop.com.au/bioglan-kids-eye-guard-chewable-50-tablets-2.html>
- <https://www.ebay.com.au/itm/Bioglan-Kids-Eye-Guard-Chewable-50-Tablets-/322204623262>
- <https://www.chemistdirect.com.au/bioglan-kids-eye-guard-chewable-tab-x-50>
- <https://www.pharmacy4less.com.au/bioglan-eye-guard-chewable-50s-4.html>
- <https://vitaminsforall.com.au/product/bioglan-healthy-eye-guard-chewable-50s/>
- <https://www.goodpricepharmacy.com.au/bioglan-kids-eye-guard-50-chewable-tablets>
- Etc.

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

Bioglan Healthy Kids Eye Guard Chewable claim to be able to block UV light/ blue light and protect kid's eyes, therefore working as a pair of sunglasses. These claims are not supported by scientific evidence and exploit parents concern about their children.

In addition, a number of web sites lack information required for therapeutic goods that are not available for physical examination before purchase.

It is alleged the advertisements illustrated breach s.9(a), 9(b), 10(a)(ii), 10(c), 12(3)f),13(6) & (7), 19(2) of the Therapeutic Goods Advertising Code (No.2) 2018.

The ARTG Public Summary information (appended) and the advertisements needs drastic revision. Alternatively, and preferably, this product should be delisted from the ARTG.

Introduction

Parents always want the best for the kids and easily seduced into buying products which claim to protect kid's eyes from alleged dangers of phone and computer screens. Bioglan Healthy Kids Eye Guard Chewable claims 'protect eyes against blue light'. Unfortunately, studies show no significant evidence in promoting eye health.

Claims disputed

List citing relevant literature, rationale and details of alleged regulatory breaches

1. **"Lutein help protect eyes against blue light" & "act as 'natural sunglasses' to help protect the eye from sunlight and digital device screens"**

A 2017 ABC article was titled, 'Can a vitamin product protect kids' eyes from a tablet's blue light?'¹

Key points:

- The Royal Australian and New Zealand College of Ophthalmologists said there was no scientific evidence that blue light was damaging to the eye or caused disease.
- 'The idea that a vitamin might stop blue light absorption to me is ludicrous,' the college's Dr Shanel Sharma said.

¹ <https://www.abc.net.au/news/2017-10-11/can-a-vitamin-protect-kids-eyes-from-blue-light/9011890>

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- Marketing expert Debra Grace, from Griffith University in Queensland, said the ads were aimed at the biggest and most captive market.
- ‘These ads are perfect examples of marketers targeting parents, based on their guilt feelings,’ Professor Grace said.
- The Royal Australian and New Zealand College of Ophthalmologists said the only evidence of vitamins helping eye health applied to the aging-related condition macular degeneration.
- Dr Sharma said a very specific combination of vitamins, known as the AREDS formulation, slowed the rate of macular degeneration in one out of four aged people whose disease was in an advanced stage.
- ‘But in patients who have macular degeneration in a milder form, there is no evidence that even if they took the full vitamin complement for five years that there is any reduction in the rate of development of macular degeneration. So, I would not prescribe it for children,’ she said.
- The Bioglan product also contains vitamin E, which is part of the AREDS formulation, and beta-carotene. Dr Sharma said there was scientific evidence linking beta-carotene to an increased incidence of lung cancer in smokers. ‘I would be concerned about children being given this, particularly those exposed to second-hand smoke,’ she said.

A 2017 Cochrane systematic review (Evans et al., 2017) concluded that lutein/vitamin E/ beta-carotene supplements cannot prevent age macular degeneration (AMD). The Cochrane researchers found studies relating to the effects of these supplements on healthy people who did not yet have AMD. The studies were large and included a total of 76,756 people. They took place in Australia, Finland, and the USA.

The studies comparing vitamin C, vitamin E, beta-carotene, and multivitamin supplements with placebo all showed little or no difference or even increase the chance of developing AMD.

Some large studies showed evidence that beta-carotene increases the risk of developing lung cancer in people who have been exposed to asbestos. The authors concluded beta-carotene supplements and antioxidant supplements (lutein) cannot prevent the damage to macula. ²

Other studies carried out may show a significant difference increase in the Macular Pigment Optical Density but they either have a conflict of interest or bias. The clinical trial done by Rodriguez-Carmona et al. (2006) is an example as the study was supported by DSM Nutritional Products Ltd, a manufacturer and supplier of vitamins and nutritional supplements, suggesting the subjectively biased results. ³

Other matters:

A number of web sites lack information required for therapeutic goods that are not available for physical examination before purchase (identified below).

² https://www.cochrane.org/CD000253/EYES_antioxidant-vitamin-and-mineral-supplements-prevent-development-age-related-macular-degeneration-amd

³ <https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1475-1313.2006.00386.x>

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The phrase ‘contain sulfites’ is not on the ARTG summary but some advertisements included this in the warnings section. It is suspected that the advertisers misplaced the warnings for another product here instead of ‘contain sugars’.

We also allege a s.19(2) Code breach as the cartoons on the product are targeting the kids aged under 12. Kids can demand a product that appeals to them and place significant pressure (‘pester power’) on parents.

Conclusion:

It is alleged the advertisements illustrated breach s.9(a), 9(b), 10(a)(ii), 10(c), 12(3)f),13(6) & (7), 19(2) of the Therapeutic Goods Advertising Code (No.2) 2018.

In addition, a number of web sites lack information required for therapeutic goods that are not available for physical examination before purchase (identified below).

The ARTG Public Summary information (appended) and the advertisements needs drastic revision.

Alternatively, and preferably, 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
15 January 2020

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Appendix (Screen shots with offending claims arrowed)

Healthy Kids Eye Guard Chewable 50s

Q



BUY NOW ON 

Bioglan Healthy Kids Eye Guard Chewables contain ingredients which support kids eye health.

Contains sulfites.

Always read the label. Follow the directions for use. Vitamin supplements should not replace a balanced diet.

*With digital devices a mainstay for Aussie kids today, concern about prolonged exposure to the high energy blue light they emit is a common concern for parents, so it's fitting that they have voted Bioglan Kids Eye Guard Chewable the **2019 Kids Health and Wellbeing Product of the Year.***

**WINNER KIDS HEALTH AND WELLBEING CATEGORY. SURVEY OF 14,000 PEOPLE BY NIELSEN.*

Share



Lacks required information 13(6),(7)

DETAILED INFORMATION

DIRECTIONS

FORMULATION

WHAT IS BIOGLAN HEALTHY KIDS EYE GUARD CHEWABLE FOR?

Bioglan Healthy Kids Eye Guard Chewables contain three key eye health ingredients that support kids eye health.

WHY SHOULD I CHOOSE BIOGLAN HEALTHY KIDS EYE GUARD CHEWABLE?

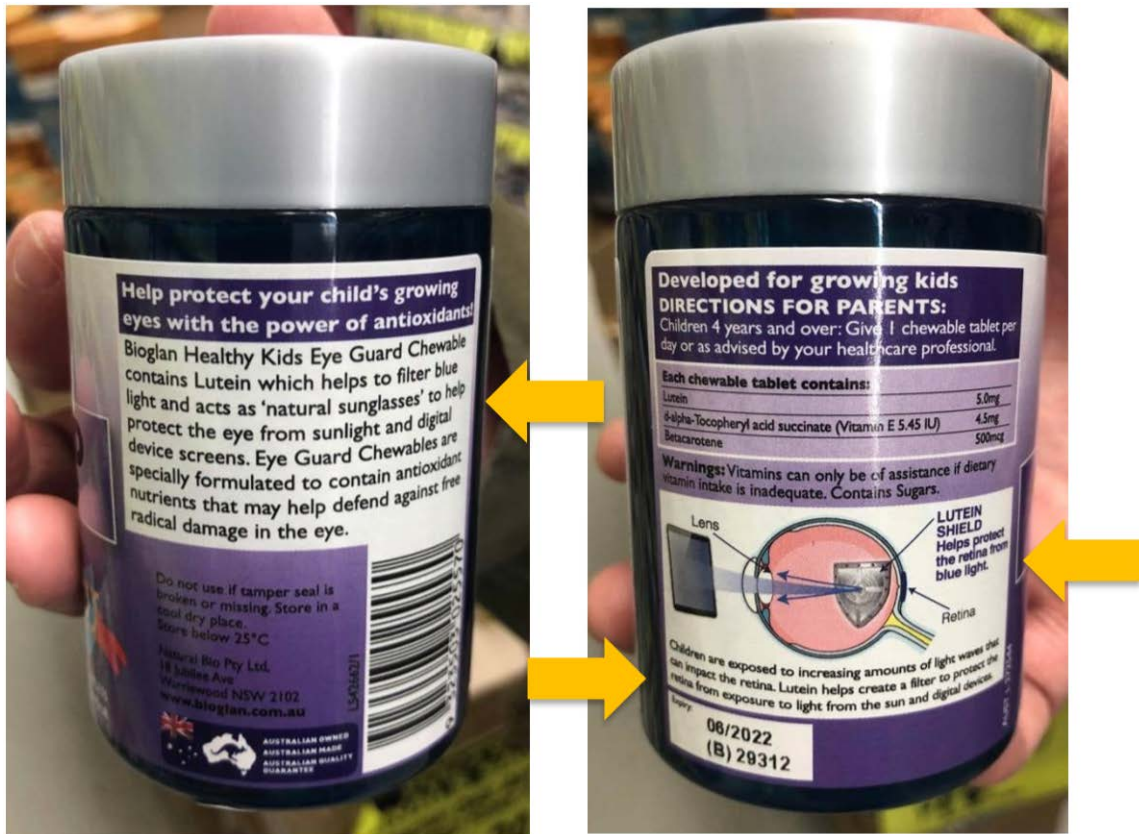
Bioglan Healthy Kids Eye Guard Chewable contain lutein to help support the healthy eye functions during excessive digital device screen time. Eye guard chewables are specially formulated to contain antioxidant nutrients which can reduce free radical damage.

Bioglan Healthy Kids Eye Guard Chewables have a delicious blueberry flavour which your kids will love!

A balanced diet and sufficient intake of vitamins and minerals from food, is essential for children.

<https://www.bioglan.com.au/products/vitamins/eye-guard-chewable/>

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(Photos of the back labels of product were taken in person on 13/9/2019)



Bioglan Eye Guard Chewable
50S, 0.07kg
by Bioglan

Price: **\$10.99** & **FREE Delivery** on orders over \$39.00. [Details](#)

- Help Protect Against Blue Light
- Antioxidants Support Eye Health
- Great Tasting

2 new from \$10.99

New Year New You Kick start the new year with health, fitness and fashion products. [Shop now](#)

Lacks required information

<https://www.amazon.com.au/Bioglan-Eye-Guard-Chewable-0-07kg/dp/B07BPPPGC7>


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Bioglan Healthy Kids Eye Guard Chewable 50 Tablets

\$16.95

\$14.95

Buy Now, Pay Later  [more info »](#)

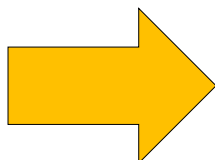
Price includes GST

Bioglan Healthy Kids Eye Guard Chewables contain three key eye health ingredients that may help protect children's eyes from blue light damage and UV sunlight.

What is Bioglan Healthy Kids Eye Guard Chewable for?

Bioglan Healthy Kids Eye Guard Chewables contain three key eye health ingredients that may help protect children's eyes from blue light damage and UV sunlight.

Why should I choose Bioglan Healthy Kids Eye Guard Chewable?



Bioglan Healthy Kids Eye Guard Chewable contains lutein which helps to filter blue light and acts as 'natural sunglasses' to help support healthy eye functions during excessive digital device screen time. Eye Guard Chewables are specially formulated to contain antioxidant nutrients that may help defend against free radical damage in the eye associated with UV sunlight.

Help protect your child's eyes from the blue light waves from digital devices with Bioglan Healthy Kids Eye Guard Chewable. Bioglan Healthy Kids Eye Guard Chewable has a delicious Blueberry flavour which your kids will love!

<https://www.chempro.com.au/Bioglan-Healthy-Kids-Eye-Guard-Chewable-50-Tablets>

Overview

Bioglan Healthy Kids Eye Guard Chewables contain antioxidant nutrients, lutein, beta-carotene and Vitamin E, three key eye health ingredients to help support your child's developing eyes. Bioglan Healthy Kids Eye Guard Chewable contains lutein and beta-carotene which are thought to help form a filter in the eyes which act as 'natural sunglasses' to help protect the eye from sunlight and the 'blue light' from digital device screens. Eye guard chewables are specially formulated to contain antioxidant nutrients that may help defend against free radical damage in the eye.

<https://www.superpharmacy.com.au/products/bioglan-kids-eye-guard-chewable-50-tablets?>

Bioglan Healthy Kids Eye Guard Chewables contain ingredients which support kids eye health.

WHAT IS BIOGLAN HEALTHY KIDS EYE GUARD CHEWABLE FOR?

- Bioglan Healthy Kids Eye Guard Chewables contain three key eye health ingredients that support kids eye health.

WHY SHOULD I CHOOSE BIOGLAN HEALTHY KIDS EYE GUARD CHEWABLE?

- Bioglan Healthy Kids Eye Guard Chewable contain lutein to help support healthy eye functions during excessive digital device screen time.
- Eye guard chewables are specially formulated to contain antioxidant nutrients that may help defend against free radical damage.

Bioglan Healthy Kids Eye Guard Chewables have a delicious blueberry flavour which your kids will love!

A balanced diet and sufficient intake of vitamins and minerals from food, is essential for children.

<https://www.pharmacyonline.com.au/bioglan-kids-eye-guard-chewable-tab-x-50?>

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DESCRIPTION **REVIEWS**

Bioglan Kids Eye Guard chewable contains Lutein and is full with powerful antioxidants nutrients
Bioglan Kids Eye Guard chewable may help protect against free radical damage in the eye
Bioglan Kids Eye Guard contains Lutein. Lutein is a natural yellow pigment that helps protect the eyes retina from exposure to sunlight and digital device screens etc. Bioglan Kids Eye Guard are chewable blueberry flavour tablets your child will just love.

Key Benefits:

- Antioxidants to support eye health
- Contains Lutein
- Delicious Blueberry Flavour
- Help protect against blue light


Directions:
Children 4 years and over: 1 chewable tablet per day or as advised by your healthcare professional.

Ingredients: Each tablet contains – Lutein 5.0mg, d-alpha-Tocopheryl acid succinate (Vitamin E 5.45 IU) 4.5mg, Betacarotene 500mcg.

Precautions: Vitamins can only be of assistance if dietary vitamin intake is inadequate. Contains sugars

<https://www.yourchemistshop.com.au/bioglan-kids-eye-guard-chewable-50-tablets-2.html>

SALE



Bioglan Eye Guard Chewable 50s

RRP \$16.99 - Save 6% or \$1.00 off RRP
\$15.99

RATINGS:

AVAILABILITY:
In store and online

- 1 + **ADD TO CART**

Lacks required information

Description

Bioglan Healthy Kids Eye Guard Chewables contain three key eye health ingredients that may help protect your child's eyes from blue light damage caused by digital devices. Children 4 years and over: 1 chewable tablet per day or as advised by your healthcare professional. Lutein 5mg, Vitamin E 4.5mg, Beta-carotene 500mcg. Do not use if tamper evident seal is missing or broken. Store below 25°C. Vitamins can only be of assistance if dietary vitamin intake is inadequate.

<https://www.pharmacy4less.com.au/bioglan-eye-guard-chewable-50s-4.html>

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Overview

Bioglan Healthy Kids Eye Guard Chewables contain antioxidant nutrients, Vitamin E, three key eye health ingredients to help support your child's development. Bioglan Healthy Kids Eye Guard Chewable contains lutein and zeaxanthin which act as a natural filter in the eyes which act as 'natural sunglasses' to protect the eye from 'blue light' from digital device screens. Eye guard chewables are specially formulated to contain antioxidant nutrients that may help defend against free radical damage in the eye.

Lacks required information 12(3)(f)

<https://www.superpharmacy.com.au/products/bioglan-kids-eye-guard-chewable-50-tablets>

Product Details

Ingredients

Warnings

Directions for use

Bioglan Healthy Kids Eye Guard Chewables contain lutein, beta-carotene and Vitamin E, three key eye health ingredients to help protect your children's retina from sunlight and the blue light from digital devices. Bioglan Healthy Kids Eye Guard Chewable contains lutein which helps to filter blue light and acts as 'natural sunglasses' to protect the eye from sunlight and digital device screens. Eye guard chewables are specially formulated to contain antioxidant nutrients that may help defend against free radical damage in the eye.

Key Benefits:

- Antioxidants to support eye health
- Contains Lutein
- Delicious Blueberry Flavour
- Help protect against blue light

Lacks required information 13(6),(7)

https://www.chemistdiscountcentre.com.au/?gclid=CjwKCAiApOvwBRBUEiwAcZGdGJLwxRvtVBp5wI2VrsXBiqy651aClWv623OcKzExINdyKB7UCgxISxoCGxYQAvD_BwE#!/prod/136185/bioglan-healthy-kids-eye-guard-50-chewable-tablets