

# Complaint to TGA - Additional Fish Oil products (see AC-4HQEDT2E/2020)

## Acknowledgements:

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

## Background

It follows a recent complaint about [Swisse Omega-3 Fish Oil products](#) (AC-4HQEDT2E/2020). That complaint noted that the complementary medicine industry claim that omega-3 supplements reduce the risk of cardiovascular disease and alleviate the symptoms of arthritis (amongst other dubious claims). It was pointed out that these claims are not in accord with current scientific evidence.

In addition, the complaint noted that high dose omega-3 supplementation was often recommended for “joint support” but scientific evidence only supports this claim for rheumatoid arthritis, a restricted representation that is not allowed without prior TGA approval.

Furthermore, the complaint noted that concomitant use of high-dose fish oil with anticoagulant or antiplatelet drugs has been associated with increased bleeding. It can be argued that this dose should not be promoted to the general public without an appropriate warning.

Finally, it was pointed out that the ARTG Public Summary documents also contained problematic claims and need updated.

I now submit similar misleading and deceptive claims about fish oil products from additional sponsors. The list is illustrative only, but it does indicate a general problem with the claims made for these products and inconsistency in dose advice and warning messages. Only the Caruso’s product has what I would regard as an appropriate warning. A review of all these products is required.

I also note that the TGACRP has published seventeen upheld determinations about fish oil complaints, including Swisse and Caruso’s products.<sup>1</sup>

## Products, Sponsors, URLs and Claims (screen shots appended)

1. **Product name:** Caruso's Natural Fish Oil 1000, ARG: 234770  
**Sponsor:** Caruso's Natural Health Pty Ltd, PO Box 310, HORSLEY PARK, NSW, 2175

**Claims on web site:** <https://carusosnaturalhealth.com.au/natural-fish-oil-1000>

- “Relief of symptoms associated with mild osteoarthritis”
- “Maintenance of healthy Cardiovascular system function”
- “For mild osteoarthritis, cholesterol health, Joint health, cardiovascular health, skin conditions and pregnancy: Take 3 capsules 3 times a day with food or as advised by your healthcare profession”
- “Interactions: Consult your healthcare professional before use with anti-platelet and anti-coagulant medication”
- “Warnings and Contra-Indications: Discontinue use 2 weeks before surgery”

### Claims on ARTG Public Summary:

- “Fish oil supplementation may help to alleviate the symptoms associated with **rheumatoid arthritis** such a tender joints & morning stiffness”.
  - “Fish oil may assist the various symptoms of **arthritis**”
  - “Fish Oils may provide relief of and decrease joint pain, joint swelling and stiffness associated with **arthritis**”.
  - “May assist with the symptoms of Osteoarthritis and **Arthritis**”
  - “May assist morning stiffness and tender joints in people with **arthritis**”
- N.B. Arthritis unqualified is a restricted representation as is rheumatoid arthritis**

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<sup>1</sup> [https://www.tgacrp.com.au/complaint-register/?\\_search=fish](https://www.tgacrp.com.au/complaint-register/?_search=fish)

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- Helps maintain healthy heart or cardiovascular function
- Helps maintain healthy blood circulation
- Helps maintain healthy blood pressure in normal healthy individuals

2. **Product name:** Blackmores Odourless Fish Oil 1000, ARTG: 278574

**Sponsor:** Blackmores Ltd., PO Box 1725, WARRIEWOOD, NSW, 2102

**Claims on web site:** <https://www.blackmores.com.au/products/odourless-fish-oil-1000>

- “Maintains heart, brain eye and skin health”
- “For mild joint inflammation: Adults -Take up to 4 capsules 3 times a day with meals, or as professionally prescribed.”

**Claims on ARTG Public Summary:**

- “Helps maintain / support a healthy heart / cardiovascular system
- “Helps reduce inflammation and joint swelling”
- “Helps to relieve the pain of *rheumatoid arthritis*”

3. **Product name:** Nature's Way Odourless Fish Oil 1500mg, ARTG: 324088

**Sponsor:** Pharmacare Laboratories Pty Ltd, PO Box 384, MONA VALE, NSW, 1660

**Claims on web site:** <https://www.naturesway.com.au/product/nw-fish-oil-oil-1500mg-200s>

- "Nature's Way Odourless Fish Oil 1500 mg helps support heart health, brain function, eye health and joint health"
- "Fish oil supplementation can help: "Support heart health"
- "Therapeutic fish oil supplementation can help reduce: Mild joint aches and pains\*; Mild joint inflammation and swelling\*; \*Associated with symptoms of mild arthritis/mild osteoarthritis"
- "Therapeutic dose (adults) for joint health: 4 capsules spread over the course of the day, with food".

**Claims on ARTG Public Summary:**

- “Decrease/reduce/relieve mild *rheumatic* aches and pains”
- “Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis”
- “Maintain/support joint health”
- “Decrease/reduce/relieve mild joint inflammation/swelling”
- “Decrease/reduce/relieve mild joint pain/soreness”

4. **Product name:** Herbs of Gold - Fish Oil 1000, ARTG: 94756

**Sponsor:** Herbs of Gold Pty Ltd, PO Box 3143, KIRRAWEE, NSW, 2232

**Claims on web site:** <https://www.herbsofgold.com.au/products/nutritional-oils/fish-oil-1000>

- “Fish Oil 1000 supports healthy blood circulation and cardiovascular system function”
- “Fish Oil 1000 relieves inflammation and supports joint health.”

**Claims on ARTG Public Summary:**

- “Maintain/support joint health”
- “Maintain/support healthy blood circulation”
- “Maintain/support cardiovascular system health”
- “Maintain/support healthy cardiovascular system function”
- “Maintain/support heart health”

**Advertisement type:**

Internet – Web site

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Accessed on:

05/12/19

## Complaint Summary (all products)

The complementary medicine industry claims that omega-3 supplements reduce the risk of cardiovascular disease and alleviates the symptoms of arthritis. This is not in accord with current scientific evidence.

### Disputed claims (screen shots appended):

1. **“Heart and cardiovascular health:** Omega-3 fatty acids support a healthy heart and cardiovascular system. EPA and DHA also help maintain normal blood pressure and triglyceride levels in healthy individuals. Based on scientific evidence”.

In 2019, Manson et al., reported a randomized, placebo-controlled trial, with marine n-3 fatty acids (at a dose of 1 g per day) in the primary prevention of cardiovascular disease among men 50 years of age or older and women 55 years of age or older in the United States. The authors concluded that supplementation with n-3 fatty acids did not result in a lower incidence of major cardiovascular events than placebo.

A 2018 Cochrane review also concluded that taking omega-3 capsules did not reduce heart disease, stroke or death. This aligns with the Australian Heart Foundation’s current position, which does not advise that health professionals routinely recommend omega-3 supplements for heart health.

2. **“Joint Health:** Omega-3 fatty acids have anti-inflammatory properties. Studies show that fish oil may assist with the symptomatic relief of mild arthritis such as joint pain and inflammation”.

Arthritis patients often take fish oil supplements to alleviate symptoms, but the evidence only relates to rheumatoid arthritis. A 2017 Systematic Review and Meta-Analysis of Randomized Trials of Marine Oil Supplements for Arthritis by Senftleber et al., concluded, "A significant effect was found in patients with rheumatoid arthritis but not in osteoarthritis patients.

3. **“Blood Pressure and Joint Support:** 3 capsules 3 times a day (Caruso’s), 4 capsules 3 times a day (Blackmores).

There is no good evidence to support this dose for blood pressure in normotensive healthy people and the effect on hypertensive patients is small and not recommended as an alternative to BP-lowering drugs.

There is evidence that high dose fish-oil supplements may be beneficial for rheumatoid arthritis, but rheumatoid arthritis is a restricted representation and data from studies of this condition are not applicable to claims for “joint support”.

In addition, concomitant use of high-dose fish oil with anticoagulant or antiplatelet drugs has a theoretical risk of increased bleeding. In my opinion, this dose should not be promoted to the general public; it should only be taken under medical supervision.

It is alleged these claims breach s.9(a), 9(b), 10(a)(ii), 10(c), 15(2)(b) and 15(3)(c) of the Therapeutic Goods Advertising Code (No. 2), 2018.

## Introduction

Omega-3 fats are essential; to stay healthy we must obtain some from food. The main types of omega-3 fats are alpha-linolenic acid (ALA), a fat found in plant foods, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), both found in fish. There is a common belief (promoted by the complementary medicine

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industry) that taking omega-3 supplements reduces the risk of heart disease, stroke and death and also alleviates the symptoms of arthritis.

### Claims disputed

4. **“Heart and cardiovascular health:** Omega-3 fatty acids support a healthy heart and cardiovascular system. EPA and DHA also help maintain normal blood pressure and triglyceride levels in healthy individuals Based on scientific evidence”.

The clear implication of these claims is that taking Omega-3 fatty acids supplements will reduce the risk of cardiovascular disease in healthy people.

In 2019, Manson et al., reported a randomized, placebo-controlled trial, with marine n-3 fatty acids (at a dose of 1 g per day) in the primary prevention of cardiovascular disease and cancer among men 50 years of age or older and women 55 years of age or older in the United States.<sup>2</sup>

Primary end points were major cardiovascular events (a composite of myocardial infarction, stroke, or death from cardiovascular causes). Secondary end points included individual components of the composite cardiovascular end point, the composite end point plus coronary revascularization (expanded composite of cardiovascular events),

A total of 25,871 participants, including 5106 black participants, underwent randomization. During a median follow-up of 5.3 years, a major cardiovascular event occurred in 386 participants in the n-3 group and in 419 in the placebo group (hazard ratio, 0.92; 95% confidence interval [CI], 0.80 to 1.06; P=0.24). In the analyses of key secondary end points, the hazard ratios were as follows: for the expanded composite end point of cardiovascular events, 0.93 (95% CI, 0.82 to 1.04); for total myocardial infarction, 0.72 (95% CI, 0.59 to 0.90); for total stroke, 1.04 (95% CI, 0.83 to 1.31); for death from cardiovascular causes, 0.96 (95% CI, 0.76 to 1.21).

It was concluded that supplementation with n-3 fatty acids did not result in a lower incidence of major cardiovascular events than placebo. (Funded by the National Institutes of Health and others; VITAL ClinicalTrials.gov number, NCT01169259).

A 2018 Cochrane review also concluded that taking omega-3 capsules does not reduce heart disease, stroke or death.<sup>3</sup> This aligns with the Australian Heart Foundation’s current position, which does not advise that health professionals routinely recommend omega-3 supplements for heart health.<sup>4</sup>

Furthermore, a 2012 systematic review of fish-oil supplements for the prevention and treatment of hypertension by Campbell et al., found nine studies in normotensive participants that showed a non-significant reduction in both systolic and diastolic BP.<sup>5</sup>

5. **“Joint Health:** Omega-3 fatty acids have anti-inflammatory properties. Studies show that fish oil may assist with the symptomatic relief of mild arthritis such as joint pain and inflammation”.

Arthritis patients often take fish oil supplements to alleviate symptoms, but the evidence only relates to rheumatoid arthritis. For example, a 2017 Systematic Review and Meta-Analysis of Randomized Trials of Marine Oil Supplements for Arthritis by Senftleber et al., concluded, "A significant effect was found in patients with rheumatoid arthritis (22 trials; -0.21; 95% CI, -0.42 to -0.004) and other or mixed

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<sup>2</sup> <https://www.nejm.org/doi/full/10.1056/NEJMoa1811403>

<sup>3</sup> <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD003177.pub4/full>

<sup>4</sup> <https://www.heartfoundation.org.au/news/omega-3-supplements-and-fish-oil-dont-help-hearts-new-evidence>

<sup>5</sup> <https://pubmed.ncbi.nlm.nih.gov/22345681-a-systematic-review-of-fish-oil-supplements-for-the-prevention-and-treatment-of-hypertension/>

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diagnoses (3 trials;  $-0.63$ ; 95% CI,  $-1.20$  to  $-0.06$ ), but not in osteoarthritis patients (5 trials;  $-0.17$ ; 95% CI,  $-0.57$ – $0.24$ ).<sup>6</sup> See also Abdulrazaq, et al (2017).<sup>7</sup>

6. **“Blood Pressure and Joint Support: 3 capsules 3 times a day”** (Caruso's); 4 capsules 3 times a day (Blackmores).

The studies cited above do not support this dose for “maintaining normal blood pressure” in normotensive healthy people. While there is evidence (above) that high dose fish-oil supplements may be beneficial for rheumatoid arthritis, this condition is a restricted representation and data from studies of this condition are not applicable to claims for “joint support” and the “symptomatic relief of mild arthritis”.<sup>8</sup>

In addition, concomitant use of high-dose fish oil with anticoagulant or antiplatelet drugs has a theoretical risk of increased bleeding.<sup>9</sup> In my opinion, this dose should not be promoted to the general public; it should only be taken under medical supervision.

Swisse responded to a request for evidence supporting their claims for Swisse Ultiboost Odourless High Strength Wild Fish Oil by referring the student to their New Zealand web site (Appendix). The evidence cited was published 10 or more years ago. These studies were then removed but the claim, “Based on scientific evidence” remains.

It is alleged these claims breach s.9(a), 9(b), 10(a)(ii), 10(c), 15(2)(b) and 15(3)(c) of the Therapeutic Goods Advertising Code (No. 2), 2018.

In addition, the ARTG public summary documents also contains the disputed claims and needs to be updated in the light of recent evidence.

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

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<sup>6</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5295086/>

<sup>7</sup> <https://www.ncbi.nlm.nih.gov/pubmed/28606571>

<sup>8</sup> <https://www.tga.gov.au/book-page/part-4-restricted-representations-and-prohibited-representations>

<sup>9</sup> <https://www.tga.gov.au/publication-issue/medicines-safety-update-no2-2010>

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## Appendix (screen shots)



### Caruso's Natural Fish Oil 1000 Health Benefits:

- Relief of symptoms associated with mild osteoarthritis
- Maintenance of healthy Cardiovascular system function



#### Formulation:

**Each capsule contains:**  
Natural Fish Oil 1g (1000mg)  
Containing Omega 3 Marine  
Triglycerides 300mg as:  
Eicosapentaenoic acid (EPA) 180mg  
Docosahexaenoic Acid (DHA) 120mg

#### Dosage:

For general health and wellbeing:  
Adults take 1 capsule 3 times a day with food.

For mild osteoarthritis, cholesterol health, Joint health, cardiovascular health, skin conditions and pregnancy:  
Take 3 capsules 3 times a day with food or as advised by your healthcare professional



#### Warnings and Contra-Indications:

Always read the label and follow directions for use. If symptoms persist, worsen or change unexpectedly, consult your healthcare professional.

Not suitable for those with seafood allergies

Discontinue use 2 weeks before surgery



#### Interactions:

Consult your healthcare professional before use with anti-platelet and anti-coagulant medication.

Take at least two hours away from pharmaceutical medications



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<https://carusosnaturalhealth.com.au/natural-fish-oil-1000>

	<p><b>Why use</b></p> <ul style="list-style-type: none"><li>• Ideal for people who don't eat 2-3 serves of fish per week</li><li>• Maintains heart, brain eye and skin health</li><li>• Reduces inflammation</li></ul> <p><b>For mild joint inflammation:</b> <b>Adults</b> - Take up to 4 capsules 3 times a day with meals, or as professionally prescribed.</p>
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<https://www.blackmores.com.au/products/odourless-fish-oil-1000>

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SHARE    



BRAIN, MEMORY & SLEEP, BRAIN, MEMORY & SLEEP, HEART HEALTH, HEART HEALTH, JOINTS & MILD ARTHRITIS, JOINTS & MILD ARTHRITIS, NATURE'S WAY, PRODUCTS, PRODUCTS, VITAMINS,

## NW FISH OIL O/L 1500MG 180+20S

Nature's Way Odourless Fish Oil 1500 mg helps support heart health, brain function, eye health and joint health.

Contains soya, sulfites.

Always read the label. Follow the directions for use. If symptoms persist, talk to your healthcare professional.

BUY NOW ON 

### OVERVIEW

### DIRECTIONS

### INGREDIENTS

Nature's Way Odourless fish oil provides a 1500 mg dose of fish oil, with no fishy aftertaste.

Fish oil supplementation can help:

- Support healthy cholesterol
- Support brain and eye health
- Support heart health

Therapeutic fish oil supplementation can help reduce:

- Mild joint aches and pains\*
- Mild joint inflammation and swelling\*

\*Associated with symptoms of mild arthritis/mild osteoarthritis

Adults: One capsule daily with food, or as recommended by your healthcare professional.

Therapeutic dose (adults) for joint health: 4 capsules spread over the course of the day, with food. E.g. one capsule in the morning, followed by another two at lunch, and the final one at dinner.

<https://www.naturesway.com.au/product/nw-fish-oil-oil-1500mg-200s>



## Fish Oil 1000

**\$31.45**

200 CAPSULES

**Omega-3 essential fatty acids**  
Herbs of Gold Fish Oil 1000 is a high-quality fish oil supplement that contains eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

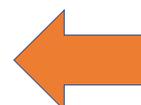
- ✓ Small wild cold water fish
- ✓ Mercury & heavy metal tested
- ✓ Low reflux

**Always read the label. Follow the directions for use. If symptoms persist, talk to your health professional. Contains sulfites.**



Size                      Quantity

- Fish Oil 1000 supports healthy blood circulation and cardiovascular system function.
- Fish Oil 1000 relieves inflammation and supports joint health.



<https://www.herbsofgold.com.au/products/nutritional-oils/fish-oil-1000>