

Complaint to TGA - Nature's Sunshine Products of Australia Pty Ltd, Nature's Sunshine Black Cohosh

Acknowledgements:

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

Product and Sponsor

Product name: Nature's Sunshine Black Cohosh

Sponsor: Nature's Sunshine Products of Australia Pty Ltd

Address: PO Box 6884, BAULKHAM HILLS BUSINESS CENTRE, NSW, 2153 Australia

ARTG no: 25150

Product Ingredients: Actaea racemosa, synonym Cimicifuga racemosa (525 mg)

Permitted indication:

- Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Western herbal medicine to uterine tonic/Enhance uterine health
- Traditionally used in Western herbal medicine to haemagogue/emmenagogue/promotes menstrual flow
- Traditionally used in Western herbal medicine to maintain/support/regulate healthy menstrual cycle
- Traditionally used in Western herbal medicine to decrease/reduce/relieve menstruation pain/dysmenorrhoea
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of menopause.

Warnings:

- In very rare cases, black cohosh has been associated with liver failure
- If you are experiencing yellowing of the skin or whites of the eyes, dark urine, nausea, vomiting, unusual tiredness, weakness, stomach or abdominal pain, and/or loss of appetite, you should stop using this product and see your doctor.

Advertisement type:

e.g. Internet – Web site

Accessed on:

22/01/2020

URL(s) listed (screen shots appended)

- <https://www.naturessunshine.com.au/products/black-cohosh>
- <https://return2health.com.au/black-cohosh/nature-s-sunshine-black-cohosh>
- <https://www.chempro.com.au/Natures-Sunshine-Black-Cohosh-100-Capsules>
- <https://www.amazon.com.au/Natures-Sunshine-Black-Cohosh-Capsules/dp/B07GDH1QY6>
- <https://www.obornehealth.com.au/Natures-Sunshine-Black-Cohosh-525mg-100c>
- <https://www.ebay.com.au/itm/NATURES-SUNSHINE-Black-Cohosh-525mg-100-capsules-period-pain-cramps-menopause-/300935877076>
- <https://myhealthwarehouse.com.au/natures-sunshine-black-cohosh-100-capsules/>
- <https://www.healthpost.com.au/natures-sunshine-black-cohosh-nsbco-p>
- <https://gr8health.com.au/nature-s-sunshine-black-cohosh-100-caps.html>
- <https://www.naturalchemist.com.au/natures-sunshine-black-cohosh-525mg-100-capsules/>

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- <https://www.mynaturalhealth.com.au/products/view/nature-s-sunshine-black-cohosh>
- Etc.

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

A number of web sites listed above make scientific claims for this product, e.g. 'Nature's Sunshine Black Cohosh 100 Capsules is highly effective in managing the symptoms of menopause by encouraging the normalisation of female hormones. This supplement also helps to relieve menstrual pain and cramping due to its relaxant and anti-spasmodic actions'. Other claims include 'anti-inflammatory' and 'temporary relief of the pain of osteoarthritis' (unqualified).

The above claims are not in accord with the ARTG Public summary (25150) which has, 'Traditionally used in Western Herbal Medicine' indications.

In addition, there is no good scientific evidence that Black Cohosh is 'highly effective in managing the symptoms of menopause' or can 'relieve menstrual pain and cramping'.

Other sites base their claims on 'traditional evidence. TGA Evidence Guidelines state:

If you are aware that there is conflicting evidence between the history of traditional use and contemporary scientific evidence for your medicine, then it is advisable to include a statement to this effect in any labelling and advertising associated with the medicine, for example: 'this traditional use is not supported by scientific evidence'. This will ensure that the advertised information relating to your medicine is truthful, valid and not misleading.

These sites lack this important caveat.

Finally, some web sites lack important warnings thereby putting the public at risk.

In summary we allege breaches of s.9(a), 9(b), 9(d), 10(a)(i)(ii), 10(c), 12(3) & 28(1) of the Therapeutic Goods Advertising Code (No.2), 2018.

Introduction

Nature's Sunshine Black Cohosh is a capsule form of supplement that containing Black Cohosh (*Cimicifuga racemosa*). There is a common belief (extensively promoted by the complementary medicine industry) that Black Cohosh helps relieve menopausal symptoms. This is not in accord with current scientific evidence.

The major active constituents of Black Cohosh vary depending on how it is grown, harvested and extracted. Extracts need to be standardised and different extracts are not comparable; one of the reasons for varied clinical trial results. We could find no clinical trials that used the specific Nature's Sunshine product.

Claims disputed

1. 'Nature's Sunshine Black Cohosh 100 Capsules is highly effective in managing the symptoms of menopause by encouraging the normalisation of female hormones. This supplement also helps to relieve menstrual pain and cramping due to its relaxant and anti-spasmodic actions.'

A 2012 Cochrane review (Leach and Moore) analysed sixteen randomised controlled trials that recruited a total of 2027 perimenopausal or postmenopausal women.¹ All studies used oral mono-preparations of black cohosh at a median daily dose of 40 mg, for a mean duration of 23 weeks. Comparator interventions included placebo, hormone therapy, red clover and fluoxetine.

¹ <https://pubmed.ncbi.nlm.nih.gov/22972105-black-cohosh-cimicifuga-spp-for-menopausal-symptoms/>

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Reported outcomes included vasomotor symptoms, vulvovaginal symptoms, menopausal symptom scores and adverse effects.

There was no significant difference between black cohosh and placebo in the frequency of hot flushes or in menopausal symptom scores. The authors concluded there is currently insufficient evidence to support the use of black cohosh for menopausal symptoms.

This review has been criticised because the pharmaceutical quality of the different black cohosh extracts was not critically discussed by Leach and Moore.² However, there is no evidence that Nature's Sunshine Black Cohosh is of pharmaceutical quality and we could find no clinical trials that used this specific product.

The U.S National Center for Complementary and Integrative Health (NCCIH) notes that studies that tested black cohosh for menopause symptoms have had inconsistent results. They state that overall evidence is insufficient to support using black cohosh for this purpose. They also state there is not enough reliable data to show whether black cohosh is effective for other uses (such as menstrual pain and cramping).³

In summary, there is no good scientific evidence that Black Cohosh is 'highly effective in managing the symptoms of menopause' or 'helps to relieve menstrual pain and cramping due to its relaxant and anti-spasmodic actions'.

These claims breach s.9(a), 9(b), 9(d), 10(a)(i) & 10(c) of the Code

2. Other claims include 'anti-inflammatory' and 'temporary relief of the pain of osteoarthritis' (unqualified). No scientific evidence was found to support these claims. In addition, the claim for osteoarthritis (unqualified) is a s.28(1) breach of the Code.

Furthermore, the above claims are not in accord with the ARTG Public summary (25150) which uses, 'Traditionally used in Western Herbal Medicine' indications, a breach of s.9(d) of the Code.

Some sites base their claims on 'traditional' evidence. TGA Evidence Guidelines state:

If you are aware that there is conflicting evidence between the history of traditional use and contemporary scientific evidence for your medicine, then it is advisable to include a statement to this effect in any labelling and advertising associated with the medicine, for example: 'this traditional use is not supported by scientific evidence'. This will ensure that the advertised information relating to your medicine is truthful, valid and not misleading.

These sites lack this disclaimer and thus breach s.9(b) of the Code

Finally, some web sites lack important warnings putting the public at risk, a breach of s.12(3) of the Code.

In summary, we allege breaches of s.9(a), 9(b), 9(d), 10(a)(i)(ii) & 10(c), 12(3) & 28(1) of the Therapeutic Goods Advertising Code (No.2), 2018.

² <https://pubmed.ncbi.nlm.nih.gov/23992293-efficacy-of-black-cohosh-cimicifuga-racemosa-medicines-for-treatment-of-menopausal-symptoms-comments-on-major-statements-of-the-cochrane-collaboration-report-2012-black-cohosh-cimicifuga-spp-for-menopausal-symptoms-review/>

³ <https://nccih.nih.gov/health/blackcohosh/ata glance.htm>

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Signed and dated

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

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Appendix (Screen shots with offending claims arrowed)

Black Cohosh

This herb was traditionally used by the North American Indians to relieve menstrual pain and cramping due to its relaxant and antispasmodic actions.

- ✓ Antispasmodic
- ✓ Traditionally used to aid in the relief of menstrual pain and cramping

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

Retail Cost: \$45.95

Qty: 1

Description

INDICATIONS FOR USE

- Traditionally used for the relief of menstrual pain and cramping.
- Black cohosh has anti-inflammatory properties and may provide temporary relief of the pain of osteoarthritis.

<https://www.naturessunshine.com.au/products/black-cohosh>

Home /Supplements /Herbal Supplements /Black Cohosh /Black Cohosh

Black Cohosh

by Nature's Sunshine

★★★★★ 4 Review(s)

Nature's Sunshine Black Cohosh provides 525 mg black cohosh per capsule to support the female reproductive and hormonal systems.

Benefits:

- > Promotes hormonal balance.
- > Assists in easing menopause symptoms.
- > Helps to calm menstrual & premenstrual symptoms.
- > Supports female reproductive system.

Ask a question

Availability: **IN STOCK**

Product Name	Price	Qty
100 Caps	AU\$34.98 Special Price AU\$26.24	1

Related Categories

- Women's Health (65)
- Menopause (16)
- Black Cohosh (14)

<https://return2health.com.au/black-cohosh/nature-s-sunshine-black-cohosh?>

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Product Description

Directions
Ingredients
Additional Information

Lacks warnings

Product Questions

Black cohosh is well known for supporting female reproductive health. Poor hormonal balance is commonly seen with female reproductive problems. Black cohosh has mild estrogenic actions (phytoestrogens) and may help to balance hormone levels by binding with receptors.

Black cohosh also has antispasm actions which may help relax muscle spasms associated with the menstrual and premenstrual phases. ➔

<https://return2health.com.au/black-cohosh/nature-s-sunshine-black-cohosh?>

Health, Household & Personal Care › Vitamins & Supplements › Vitamins, Minerals & Supplements



Roll over image to zoom in

Nature's Sunshine 525mg Black Cohosh 100 Capsules, 100 count

by Nature's Sunshine

Price: **\$34.96** & **FREE Delivery** on orders over \$39.00 . [Details](#)

- Supports the female glandular system
- Supports the reproductive health
- Promotes balanced hormone levels
- Calms premenstrual and menstrual symptoms
- Helps ease common symptoms of menopause

2 new from \$34.96

New Year New You

Kick start the new year with health, fitness and fashion products. Shop now

\$34.96

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

Get it Tue, Feb. 4 - Wed, Feb. 5 with FREE delivery.

Get it Tomorrow if you order

Lacks warnings

Add to Cart

Buy Now

Ships from and sold by Amazon AU.

<https://www.amazon.com.au/Natures-Sunshine-Black-Cohosh-Capsules/dp/B07GDH1QY6>

Description
Ingredients
Directions + Precautions
About Nature's Sunshine

Nature's Sunshine Black Cohosh supports a healthy female reproductive system and hormone levels. Women of all ages experience conditions relating to the glandular and reproductive systems.

Healthy hormone levels support healthy reproductive function in every stage of a woman's life. Black cohosh supports healthy premenstrual and menstrual cycles and a balanced transition through menopause. temperature balance.

Lacks warnings

Highlights

- Supports the female reproductive system
- Supports healthy hormone levels
- Support for healthy premenstrual, menstrual & menopausal women

<https://www.healthpost.com.au/natures-sunshine-black-cohosh-nsbco-p>

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Nature's Sunshine Black Cohosh 525mg 100c

RRP: **\$45.95**

SKU: **NSBLAC**

BARCODE:# 99904170094

DF Dairy Free

GF Gluten Free

[Add to Wishlist](#)

[Details](#) [Ingredients & Excipients](#) [Dose & Administration](#) [Cautions/Contra-Indications](#)

Storage Conditions

Nature's Sunshine Products perfectly meet the growing worldwide need for products that take a natural, holistic approach to wellness by marrying time-honoured wisdom with cutting edge technology. Since becoming the first company to encapsulate herbs in 1972, Nature's Sunshine has grown from a small, family-owned business to one of the leading health and wellness companies in the world. By placing in your hands the finest quality herbs and nutritional supplements, Nature's Sunshine gives you the tools you need to take responsibility for your health to look and feel your best.

Black Cohosh was traditionally used by the North American Indians to relieve menstrual pain and cramping due to its relaxant and antispasmodic actions.

Nature's Sunshine Black Cohosh may be indicated for:

- Traditionally used for the relief of menstrual pain and cramping.
- Black cohosh has anti-inflammatory properties and may provide temporary relief of the pain of osteoarthritis.

<https://www.obornehealth.com.au/Natures-Sunshine-Black-Cohosh-525mg-100c>