

Complaint to TGA - Swisse Wellness Pty Ltd, Swisse Ultiboost Menopause Balance

Acknowledgements:

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

Product and Sponsor

Product name: Swisse Ultiboost Menopause Balance

Sponsor: Swisse Wellness Pty Ltd

Address: 111 Cambridge Street, Collingwood, VIC, 3066 Australia

ARTG no: 214541

Product Ingredients (from Swisse site):

- SOYBEAN (Glycine max) standardised extract equiv. dry seed 13.8 g (equiv. to isoflavones calculated as daidzin/ein, genistin/ein, glycitin/ein 34.5 mg)
- SAGE (Salvia officinalis) extract equiv. dry leaf 1.3 g
- BLACK COHOSH (Actaea racemosa) extract equiv. dry root & rhizome 20 mg
- CALCIUM (from calcium citrate 770.14 mg) 162.5 mg
- VITAMIN D3 (as cholecalciferol 12.5 mcg) 500 IU

Permitted indication (selection relevant to claims):

- Helps decrease/reduce/relieve night sweats associated with menopause
- Decrease/reduce/relieve symptoms of menopause
- Helps reduce occurrence of menopausal symptoms
- Decrease/reduce/relieve hot flushes associated with menopause
- Decrease/reduce/relieve aggression/irritability associated with menopause

Warnings

- If symptoms persist consult your healthcare practitioner (or words to that effect).
- Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
- Warning: 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:

14/01/2020

URL(s) listed (screen shots appended)

- <https://swisse.com.au/our-products/swisse-ultiboost-menopause-balance>
- <https://www.chemistwarehouse.com.au/buy/70153/swisse-ultiboost-menopause-balance-60-tablets>
- <https://www.amcal.com.au/swisse-ultiboost-menopause-balance---60-tablets-p-9311770595742>
- <https://www.priceline.com.au/swisse-ultiboost-menopause-balance-60-tablets>
- <https://www.goodpricepharmacy.com.au/swisse-ultiboost-menopause-balance-60-tablets>
- <https://www.amazon.com.au/Swisse-Ultiboost-Menopause-Balance-Tab/dp/B076VW3RDB>

Complaint to TGA - Swisse Wellness Pty Ltd, Swisse Ultiboost Menopause Balance

- <https://www.pharmacy4less.com.au/swisse-ultiboost-menopause-balance-60-tablets-4.html>
- <https://www.nationalpharmacies.com.au/product/swisse-menopause-balance-60-tablets/>
- <https://www.discountdrugstores.com.au/swisse-ultiboost-menopause-balance---60-tablets-p-9311770595742>
- https://natic.com.au/en/swisse-ultiboost-menopause-balance-60-tablets?gclid=EAlalQobChMIIn5iZ7MKE5wIVEA4rCh3BkQZeEAMYASAAEgKKVfD_BwE
- <https://www.ebay.com.au/p/6031262676>
- <https://www.pharmacyselectonline.com.au/productdetail.aspx>
- <https://www.canberradiscountpharmacy.com.au/productdetail.aspx>
- <https://vitaminonly.com.au/collections/swisse/products/swisse-menopause-balance-60-tablets>
- <https://www.healthpost.com.au/swisse-menopause-balance-swmb-p>
- Etc.

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

It is claimed that Swisse Ultiboost Menopause Balance is, 'a premium quality, comprehensive formula with nutrients and herbs to assist reduce symptoms such as hot flushes, night sweats, trouble sleeping and nervous irritability when associated with menopause', 'Based on scientific evidence.'

These claims are not in accordance with current scientific evidence. For example, the U.S. National Center for Complementary and Integrative Health (NCCIH) states that studies that tested black cohosh (*Actaea racemosa*) for menopause symptoms have had inconsistent results. The overall evidence is insufficient to support using black cohosh for this purpose. Soy isoflavone supplements may help to reduce the frequency and severity of menopausal hot flashes, but the effect may be small. Sage (*Salvia officinalis*) has not been clearly shown to be helpful for any health condition.

In addition, active constituents of herbal products vary depending on how they 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. Herbal combinations may be additive, synergistic or antagonistic. We could find no clinical trials that used the specific combination of ingredients found in the Swisse product.

It is alleged that the claims for Swisse Ultiboost Menopause Balance breach s.9(a), 9(b), 10(a)(ii), 10(b), and 15(2)(b) of the Therapeutic Goods Advertising Code (No.2), 2018. Some online sites such as ebay.com.au also lacked required information, a s.12(3) Code breach. This product should be delisted from the ARTG.

Introduction

Swisse Ultiboost Menopause Balance is a supplement that contains soy, sage (*Salvia officinalis*), and black cohosh (*Actaea racemosa*). There is a common belief (extensively promoted by the complementary medicine industry) that these ingredients reduce menopausal symptoms such as hot flushes and night sweats, trouble sleeping, and excessive perspiration. This is not in accord with current scientific evidence.

Complaint to TGA - Swisse Wellness Pty Ltd, Swisse Ultiboost Menopause Balance

Claims disputed

1. 'Black cohosh helps relieve hot flushes and night sweats'

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. 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 black cohosh in the Swisse product 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.³

2. 'Soy isoflavones help to reduce the severity and frequency of occurrence (of hot flushes and night sweats)'

Lee et al., (2017) examined the effects of soy isoflavones on climacteric symptoms in Korean postmenopausal women.⁴ They used a randomized, double-blind study design. Eighty-seven participants who had undergone natural menopause were randomly administered either 70 mg/day isoflavones (n = 43) or placebo (n = 41) for 12 weeks. The Kupperman index for climacteric symptoms was assessed. No significant difference was found between the isoflavones or placebo group. The authors concluded that isoflavones supplement showed no benefit compared to the placebo on climacteric symptoms or quality of life.

The NCCIH state that soy isoflavone supplements may help reduce the frequency and severity of menopausal hot flashes, but the effect may be small.⁵

3. 'Sage has antihidrotic properties to help reduce excessive sweating and perspiration.'

NCCIH states that sage has not been clearly shown to be helpful for any health condition, and that little research has been done on it.⁶

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

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>

⁴ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5449379/>

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

⁶ <https://nccih.nih.gov/health/sage>

Complaint to TGA - Swisse Wellness Pty Ltd, Swisse Ultiboost Menopause Balance

Active constituents of herbal products vary depending on how they 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. Herbal combinations may be additive synergistic or antagonistic. We could find no clinical trials that used the specific combination of ingredients found in the Swisse product.

In summary, it is alleged that the claims for Swisse Ultiboost Menopause Balance breach s.9(a), 9(b), 10(a)(ii), 10(b), and 15(2)(b) of the Therapeutic Goods Advertising Code (No.2), 2018. Some online sites such as ebay.com.au lacked required information, a s.12(3) Code breach.

Signed and dated

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

Complaint to TGA - Swisse Wellness Pty Ltd, Swisse Ultiboost Menopause Balance

Appendix (Screen shots with offending claims arrowed)

SWISSE ULTIBOOST MENOPAUSE BALANCE

Swisse Ultiboost Menopause Balance is a premium quality, comprehensive formula with nutrients and herbs to help reduce symptoms such as hot flushes, night sweats, trouble sleeping and nervous irritability when associated with menopause.


- 1 + Of 60 Tabs

RRP
\$41.99

ADD TO CART


*Inc GST. Price may vary between retailers. Australian orders delivered in 3 business days.

⚠ Always read the label. Follow the directions for use. If symptoms persist, talk to your healthcare professional. Supplements may only be of assistance if dietary intake is inadequate.



BENEFITS

Swisse Ultiboost Menopause Balance has been formulated based on scientific evidence to provide key ingredients beneficial during menopause.




KEY BENEFITS

Hot Flushes & Night Sweats Black cohosh helps relieve hot flushes and night sweats. Soy isoflavones help to reduce the severity and frequency of occurrence.	Excessive Perspiration Sage has antidiuretic properties to help reduce excessive sweating and perspiration.
Trouble Sleeping Black Cohosh helps relieve sleeplessness. Nervous Irritability Black Cohosh helps relieve nervous irritability.	Bone Health Calcium requirements increase post menopause. Swisse Ultiboost Menopause Balance contains calcium to help in the maintenance of healthy bones and teeth. Vitamin D is included to assist with the absorption and delivery of calcium to the bone.

<https://swisse.com.au/our-products/swisse-ultiboost-menopause-balance>

Complaint to TGA - Swisse Wellness Pty Ltd, Swisse Ultiboost Menopause Balance



Swisse-Ultiboost Menopause Balance 60 Tablets

Regular Price: \$34.99
Special Price: \$27.95

Total Sold:
Availability: In stock

☆☆☆☆☆

A supplement that relieves problems related to menopause!

- Reduces symptoms of night sweats and flushes.
- Aids in boosting bone health.
- Relieves tenseness, restlessness and irritability.

FREE SHIPPING
within Australia
OVER \$150
Excluding infant formula

1 + ADD TO CART

<https://natic.com.au/en/swisse-ultiboost-menopause-balance-60-tablets>

Complaint to TGA - Swisse Wellness Pty Ltd, Swisse Ultiboost Menopause Balance

[Home](#) / [Health](#) / [Vitamins](#) / [Swisse](#) / [Swisse Women's Health](#)



Swisse Ultiboost Menopause Balance 60 Tablets

Product ID: 2640906

★★★★★ 4.8 (25) [Write a review](#)

\$28.49

\$13.50 Off RRP

Don't Pay RRP: \$41.99



QTY

1 ▼



Click & Collect
Search For A Pickup Store
[CLICK HERE](#) ▼

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.

Swisse is currently undergoing a package refresh. Please [click here](#) for more information.

General Information

Swisse Ultiboost Menopause Balance is a premium quality, comprehensive formula with nutrients and herbs to help reduce symptoms such as hot flushes, night sweats, trouble sleeping and nervous irritability when associated with menopause.

Hot Flushes & Night Sweats: Black cohosh helps relieve hot flushes and night sweats. Soy isoflavones help to reduce the severity and frequency of occurrence.

Excessive Perspiration: Sage has antihidrotic properties to help reduce excessive sweating and perspiration.

Trouble Sleeping: Black Cohosh helps relieve sleeplessness. **Nervous Irritability:** B helps relieve nervous irritability.

<https://www.chemistwarehouse.com.au/buy/70153/swisse-ultiboost-menopause-balance-60-tablets>

Complaint to TGA - Swisse Wellness Pty Ltd, Swisse Ultiboost Menopause Balance



Brand new: lowest price ⓘ

AU \$29.90

+ AU \$6.95 postage

Get it by **Mon, 20 Jan - Tue, 21 Jan** from Sydney, Australia

- **New** condition
- 30-day returns - Buyer pays return postage

"Each country has different laws and regulations about buying products from other countries."

[See details](#)
[See all 7 brand new lis](#)

Lacks required information

<https://www.ebay.com.au/p/6031262676>