

# Complaint to TGA – Swisse Wellness, Swisse Ultiboost Prostate

## 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: Swisse Ultiboost Prostate

Sponsor: Swisse Wellness Pty Ltd

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

ARTG no: 280774

Product Ingredients:

Colecalciferol 1.25 microgram

Cucurbita pepo 25 mg Equivalent: Cucurbita pepo (Dry) 500 mg

Curcuma longa 5 mg Equivalent: Curcuma longa (Dry) 100 mg

folic acid 250 microgram

Ganoderma lucidum 2.75 mg Equivalent: Ganoderma lucidum (Dry) 55 mg

Glycyrrhiza glabra 13.75 mg Equivalent: Glycyrrhiza glabra (Dry) 55 mg

Isatis tinctoria 11 mg Equivalent: Isatis tinctoria (Dry) 55 mg

Lycopersicon esculentum 10 mg

Panax ginseng 5.5 mg Equivalent: Panax ginseng (Dry) 55 mg

Selenomethionine 16.25 microgram

Serenoa repens 320.84 mg Equivalent: Serenoa repens (Dry) 4 g

Urtica dioica 62.5 mg Equivalent: Urtica dioica (Dry) 1 g

Zinc amino acid chelate 30 mg

## Advertisement type:

Internet – Web site

Accessed on:

06/01/2020

URL(s) listed (screen shots appended)

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

<https://www.priceline.com.au/swisse-ultiboost-prostate-50-tablets>

[https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=C697F23135C63DF1CA2583D900424C6F&agid=\(PrintDetailsPublic\)&actionid=1](https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=C697F23135C63DF1CA2583D900424C6F&agid=(PrintDetailsPublic)&actionid=1)

[https://www.mrvitamins.com.au/swisse-prostate-boost-50t?utm\\_source=google\\_shopping&gclid=Cj0KCQiAr8bwBRD4ARIsAHa4YyKrEqlo\\_x-1mzqoPes5CEltLdDkYdR-xlr8K30yKBcWXuN8NCcrzUaAjH-EALw\\_wcB](https://www.mrvitamins.com.au/swisse-prostate-boost-50t?utm_source=google_shopping&gclid=Cj0KCQiAr8bwBRD4ARIsAHa4YyKrEqlo_x-1mzqoPes5CEltLdDkYdR-xlr8K30yKBcWXuN8NCcrzUaAjH-EALw_wcB)

<https://www.amcal.com.au/swisse-ultiboost-prostate---50-tablets-p-9311770587600>

Etc.

## Complaint Summary

### Introduction

Benign Prostatic Hyperplasia (BPH) is an age-associated enlargement of the prostate gland that can produce urination difficulty. It requires assessment by a medical practitioner to exclude more serious

## Complaint to TGA – Swisse Wellness, Swisse Ultiboost Prostate

conditions such as prostate cancer. Prescription drugs may help but surgery is required for significant persisting symptoms, e.g. transurethral resection of the prostate (TURP).<sup>1</sup>

Extracts of the fruit of saw palmetto (*Serenoa repens*) are extensively promoted by the complementary medicine industry for the relief of the symptoms of BPH symptoms. However, there is no significant difference between saw palmetto and placebo treatment of urinary symptoms related to BPH.

The U.S. National Center for Complementary and Integrative Health (NCCIH) states, “High-quality scientific studies have shown that saw palmetto is no more effective than a placebo (an inactive substance) in relieving urinary tract symptoms caused by prostate enlargement.

NCCIH notes limited evidence that Nettle (*Urtica dioica*) alone or in combination with Saw palmetto (*Serenoa repens*) and may be efficacious for lower urinary tract symptoms associated with BPH.<sup>2</sup> However, the trials cited did not use comparable extracts to those contained in the Swisse product (which also has many additional ingredients of dubious validity).

More importantly, BPH is a restricted representation and should not be advertised to the general public. All products making these claims should be immediately delisted from the ARTG.

### Claims disputed

1. **“Promotes Health Prostate Function”, Maintains Healthy Urine Output’, ‘Formulated with Saw Palmetto and Nettle to help provide symptomatic relief of medically diagnosed Benign Prostatic Hypertrophy (prostate enlargement), including difficulties with urination, hesitant interrupted weak stream, urinary frequency and urgency, dribbling or leaking’.**

In 2012, a Cochrane Systematic Review assessed 32 randomised trials involving 5666 subjects and concluded that there was no significant difference existing between Saw Palmetto and placebo when it comes to the treatment of urinary symptoms related to BPH. The trial lengths varied from four to 72 weeks. Twenty-seven trials were double blinded and treatment allocation concealment was adequate in 14.<sup>3</sup>

The U.S. National Center for Complementary and Integrative Health (NCCIH) states, “High-quality scientific studies have shown that saw palmetto is no more effective than a placebo (an inactive substance) in relieving urinary tract symptoms caused by prostate enlargement”.<sup>4</sup>

NCCIH notes limited evidence that Nettle (*Urtica dioica*) alone or in combination with Saw palmetto (*Serenoa repens*) and may be efficacious for lower urinary tract symptoms associated with BPH.<sup>5</sup> However, the trials cited did not use comparable extracts to those contained in the Swisse product (which also has many additional ingredients of dubious validity).

More importantly, the ARTG Public Summary for this product states, “Product presentation must not imply or refer to serious genitourinary conditions like Benign Prostatic Hypertrophy”.<sup>6</sup> In

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<sup>1</sup> <https://www1.racgp.org.au/ajgp/2018/july/benign-prostatic-hyperplasia>

<sup>2</sup> <https://jamanetwork.com/journals/jama/article-abstract/1104439>

<sup>3</sup> <https://www.nejm.org/doi/full/10.1056/NEJMoa053085>

<sup>4</sup> <https://nccih.nih.gov/health/providers/digest/BPH-science>

<sup>5</sup> <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001423.pub3/full>

<sup>6</sup> <https://nccih.nih.gov/health/palmetto/ataglace.htm>

<sup>7</sup> <https://nccih.nih.gov/health/providers/digest/BPH-science>

<sup>8</sup> <https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/>

<sup>9</sup> [https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=C697F23135C63DF1CA2583D900424C6F&agid=\(PrintDetailsPublic\)&actionid=1](https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=C697F23135C63DF1CA2583D900424C6F&agid=(PrintDetailsPublic)&actionid=1)

## Complaint to TGA – Swisse Wellness, Swisse Ultiboost Prostate

short BPH is a *restricted representation* and must not be advertised to the general public without permission from the TGA. This is a serious breach of the Therapeutic Goods Act.

All products making these claims should be immediately delisted from the ARTG.

### 2. 'Based on Scientific Evidence'

Swisse claims their product is 'based on scientific evidence' and Priceline state, 'Modern studies support the use of Saw palmetto for the symptomatic relief of prostate enlargement' but the evidence cited above does not support these statements. No clinical trial of the multiple ingredient Swisse product could be found.

### Alleged regulatory breaches:

Therapeutic Goods Act 1989 (Compilation 72, 2019)	
s.42DL(7)(a)	Advertisement contains a <i>restricted representation</i> and neither an approval under section 42DF nor a permission under section 42DK is in force in relation to the restricted representation
Therapeutic Goods Advertising Code (No 2) 2018	
s.9(a),	Claims in the advertising must be valid and accurate, and all information presented must be substantiated before the advertising occurs
s.9(b)	Advertisements must be truthful, balanced and not misleading or likely to mislead, including in its claims, presentations, representations and comparisons
s.10(a)(ii)	Advertising for therapeutic goods must support the safe and proper use of therapeutic goods by not exaggerating product efficacy or performance
s.10(b)	Advertising for therapeutic goods must not be likely to lead to people delaying necessary medical attention
s.15(2)(b)	Any scientific or clinical representation must be consistent with the body of scientific or clinical evidence applicable to the advertised therapeutic goods
s.16(2)(c)	An advertisement for therapeutic goods must not contain an endorsement from, or imply that the therapeutic goods are endorsed by a health practitioner, health professional, medical researcher or a group of such persons (the video)
s.28(1)(a)	An advertisement must not refer to serious forms of a disease, condition, ailment or defect if it is medically accepted that the form requires diagnosis or treatment or supervision by a suitably qualified health professional,

### Signed and dated

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

# Complaint to TGA – Swisse Wellness, Swisse Ultiboost Prostate

Appendix (Screen shots with offending claims arrowed)

The screenshot shows the product page for Swisse Ultiboost Prostate. The page includes a navigation bar with the Swisse logo and links for 'THE Quest CONTINUES', 'Our Products', 'About Swisse', and 'Wellness Hub'. The product title is 'SWISSE ULTIBOOST PROSTATE'. Below the title, a description states: 'Swisse Ultiboost Prostate is a premium quality formula containing ingredients to support healthy prostate function.' To the right is an image of the product container, which is a white jar with a green lid. The label on the jar features the Swisse logo and lists benefits: 'PROMOTES HEALTHY PROSTATE FUNCTION', 'MAINTAINS HEALTHY URINE OUTPUT', and 'SUPPORTS REPRODUCTIVE HEALTH'. Below these, it says 'BASED ON SCIENTIFIC EVIDENCE' and 'MEN'S HEALTH 50 TABLETS'. The page also shows a quantity selector set to '1' of '50 Tabs', a price of '\$46.99', and an 'ADD TO CART' button. A disclaimer at the bottom reads: '\*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.'

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


## BENEFITS


Formulated with Saw Palmetto and Nettle to help provide symptomatic relief of medically diagnosed Benign Prostatic Hypertrophy (prostate enlargement), including difficulties with urination, hesitant interrupted weak stream, urinary frequency and urgency, dribbling or leaking. Zinc is essential for male reproductive health.

Swisse Ultiboost Prostate has been formulated based on scientific evidence to provide ingredients beneficial to prostate health.

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

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CLICK ON IMAGE TO ZOOM 


**SWISSE Ultiboost Prostate 50 Tablets**

Be the first to [review](#) this product

SKU: 287083

**\$36.99**

1 **ADD TO CART** 

**ADD TO WISHLIST** 

Swisse Ultiboost Prostate has been formulated specifically to help promote healthy prostate function.

Always read the label. Follow the directions for use. If symptoms persist, talk to your health professional.  
Vitamins and supplements may be of assistance if dietary intake is inadequate.

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▼ **More Product Information**

The main herbal ingredient is a standardised extract of Saw Palmetto. Saw Palmetto has been used for male urinary conditions and was described as 'old man's friend'. Modern studies support the use of Saw palmetto for the symptomatic relief of prostate enlargement.

Product Swisse Ultiboost Prostate 50 Tablets

<https://www.priceline.com.au/swisse-ultiboost-prostate-50-tablets>