

Complaint to TGA – Australian Naturalcare Products Pty Ltd, Saw Palmetto Prostate Formula

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: Saw Palmetto 3.2g Prostate Formula Once Daily Formula With Epilobium

Sponsor: Australian Naturalcare Products Pty Ltd

Address: PO Box 946, NORTH RYDE BC, NSW, 1670 Australia

ARTG no: 188955

Product Ingredients:

- Cucurbita pepo 600 mg
- Epilobium parviflorum 62.5 mg
- Lycopersicon esculentum 33.3 mg
- Panax notoginseng 50 mg
- selenomethionine 62.5 microgram
- Serenoa repens (Saw palmetto) 320 mg
- zinc amino acid chelate 51.25 mg

Advertisement type:

Internet – Web site

Accessed on:

06/01/2020

URL(s) listed (screen shots accessed 05/01/2020 appended)

<https://www.ausnaturalcare.com.au/vitamins/saw-palmetto>

https://youtu.be/j_XAB8bRF_s (advertised video)

<https://www.amazon.com.au/Australian-NaturalCare-Palmetto-Prostate-Formula/dp/B07CKZZYV7>

https://shopping.rewardia.com.au/Saw_Palmetto_3_2g_Prostate_Formula_45_Caps?pk=zm&pi=1287691018

<https://www.ebay.com.au/itm/Australian-NaturalCare-Saw-Palmetto-3-2g-Prostate-Formula-Once-Daily-Formula-Wit-/362637949602>

<https://issuu.com/ausnaturalcare/docs/australian-naturalcare-health-catal>

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 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).¹

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

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

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is no significant difference between saw palmetto and placebo treatment of urinary symptoms related to BPH.

In addition, BPH is a restricted representation and should not be advertised to the general public without permission from the TGA.

Claims disputed

“Clinically proven to reduce Benign Hyperplasia (BPH) symptoms” and “Relieves impaired urinary flow, delayed onset of urination and the frequent need to urinate during the day and night – as well as other symptoms of medically diagnosed BPH”

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 14.²

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”.³

In addition, the Therapeutic Goods (Permissible Indications) Determination (No.1) 2019 relating to prostate indications state, “Product presentation must not imply or refer to serious genitourinary conditions like Benign Prostatic Hypertrophy”.⁴ In short BPH is a *restricted representation* and should not be advertised to the general public without permission from the TGA.

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

² <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001423.pub3/full>

³ <https://nccih.nih.gov/health/palmetto/ataglance.htm>

⁴ <https://www.legislation.gov.au/Details/F2019L00262>

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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
7 January 2020

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Appendix (Screen shots with offending claims arrowed)

Saw Palmetto 3.2g Prostate Formula Once Daily Formula With Epilobium

Delivers a high potency dose of saw palmetto with added herbs and nutrients that specifically target the health of the prostate gland.

SKU: 4360 Share: [social icons] ★★★★★ (1)

\$22.95
\$32.95 **Save 30%** In Stock

1 **ADD TO CART** [heart icon]

- ✓ Helps relieve the urinary symptoms associated with BPH.
- ✓ Contains nutrients targetting the health of the prostate gland.
- ✓ Supports male physiology, sexual health & function.

<https://www.ausnaturalcare.com.au/vitamins/saw-palmetto>

Information:

Prostate problems? Saw Palmetto 3.2g Prostate Formula relieves impaired urinary flow, delayed onset of urination and the need to urinate during the day and night – as well as other symptoms of medically diagnosed benign prostatic hyperplasia (BPH).

In addition to saw palmetto, which has been clinically proven to reduce BPH symptoms, [redacted] and tienchi ginseng, which have traditionally been used to assist BPH symptoms and men's urinary disorders. Also includes [redacted] oil and the antioxidant nutrients zinc, selenium and lycopene to support healthy male physiology.

You can read more about how saw palmetto can assist with prostate health on our lifestyle blog.

Check out our video below:

How Does Saw Palmetto Help With BPH ... Watch later Share

Angela Fleming Emily Seddon

<https://www.ausnaturalcare.com.au/vitamins/saw-palmetto>

