

Complaint to TGA – Blackmores Ltd, Blackmores Proseren Capsules

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: BLACKMORES PROSEREN CAPSULES

Sponsor: Blackmores Ltd

Address: PO Box 1725, WARRIEWOOD, NSW, 2102 Australia

ARTG no: 298805

Product Ingredients:

- Serenoa repens 160 mg (ARTG)
- Serenoa serrulata (saw palmetto) extract equivalent to dry fruit 1.6 g (1600 mg) standardised to contain fatty acids 144 mg (Blackmores advertisement)

Specific Indications:

- Traditionally used in western herbal medicine for the symptomatic relief of mild prostate complaints such as: Frequent urination especially at night, weak or interrupted urinary flow, or the feeling of not being able to empty the bladder completely.
- Supports healthy prostate function.

Advertisement type:

Internet – Web site

Accessed on:

09/01/2020

URL(s) listed (screen shots accessed 08/01/2020 appended)

- <https://www.blackmores.com.au/products/proseren-saw-palmetto>
- <https://www.chemistwarehouse.com.au/buy/42745/blackmores-proseren-prostate-support-120-capsules>
- <https://www.ebay.com.au/p/1326434525>
- <https://www.priceline.com.au/blackmores-proseren-saw-palmetto-120-capsules>
- <https://www.amazon.com.au/Blackmores-Proseren-Saw-Palmetto-Capsules/dp/B074QDT1TX>
- <https://www.chemistaustralia.com.au/blackmores-proseren-saw-palmetto-capsules-120>
- <https://www.cincottachemist.com.au/blackmores-proseren-120-capsules>
- Etc.

Complaint Summary

Blackmores Proseren® Saw Palmetto claims to be, 'traditionally used in Western Herbal Medicine for the symptomatic relief of mild prostate complaints such as frequent urination, weak or interrupted urinary flow, or the feeling of not being able to empty the bladder completely'.

These symptoms can be caused by serious genitourinary conditions such as Benign Prostatic Hypertrophy (BPH) or prostatic cancer.

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".

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In addition, 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’.

It is alleged these claims breach the Therapeutic Goods Act 1989, s.42DL(7)(a) and the Therapeutic Goods Advertising Code (No 2) 2018, s.9(a), s.9(b), s.10(a)(ii), s.10(b) and s.28(1)(a).

This product should be delisted from the ARTG.

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 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

1. **“Traditionally used in Western Herbal Medicine for the symptomatic relief of mild prostate complaints such as frequent urination, weak or interrupted urinary flow, or the feeling of not being able to empty the bladder completely”**

These symptoms can be caused by serious genitourinary conditions such as Benign Prostatic Hypertrophy (BPH) or prostatic cancer.

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”.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

A 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 14.⁴

When asked from LiveChat provided by Blackmores whether the product would help with BPH, the attendant of the LiveChat replied ‘Yes, this product contains the herb Saw palmetto which is used to help with symptoms of BPH’ (see Appendix).

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

² <https://www.legislation.gov.au/Details/F2019L00262>

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

⁴ <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD001423.pub3/full>

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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.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,

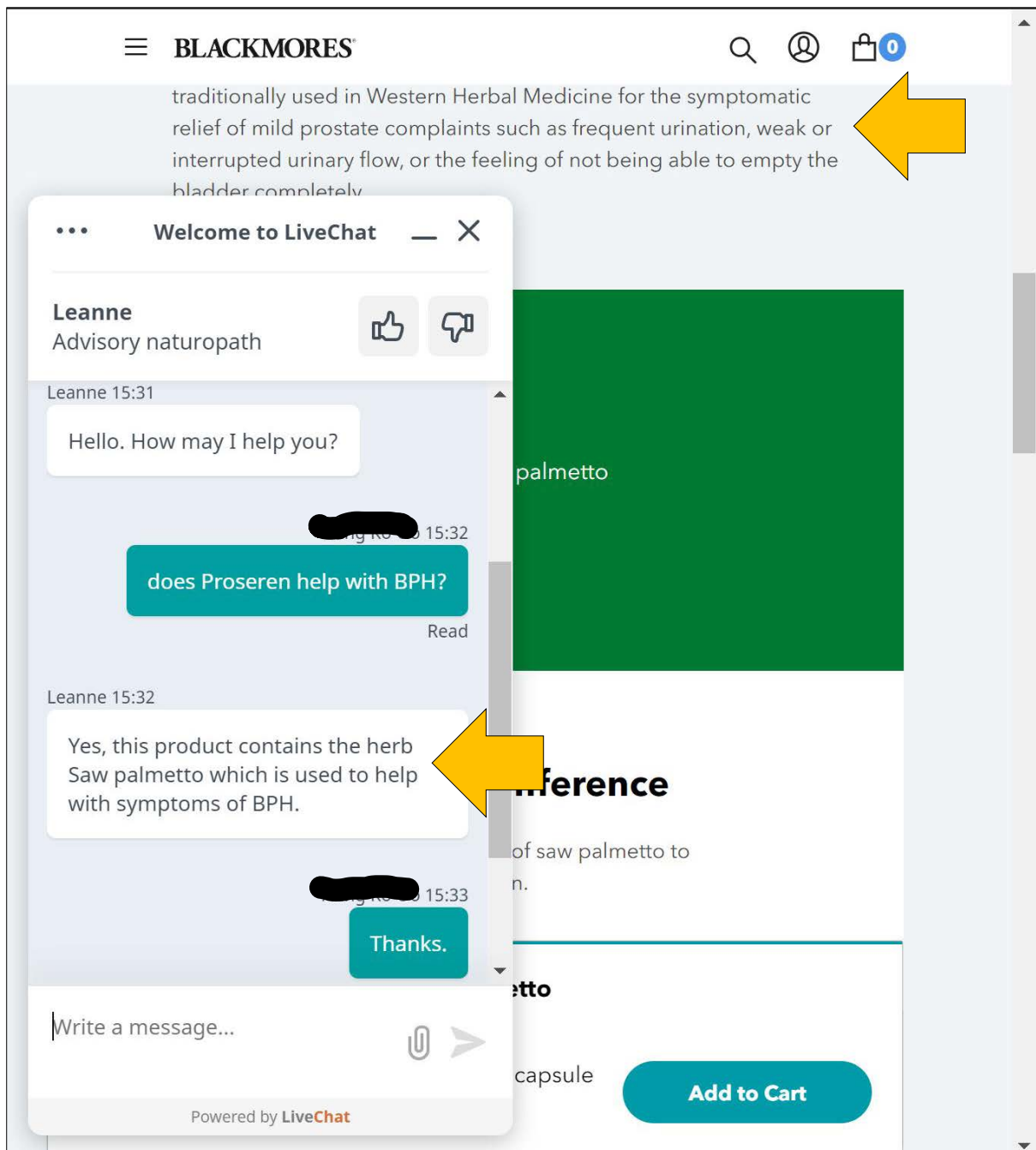
This product must be delisted from the ARTG.

Signed and dated

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

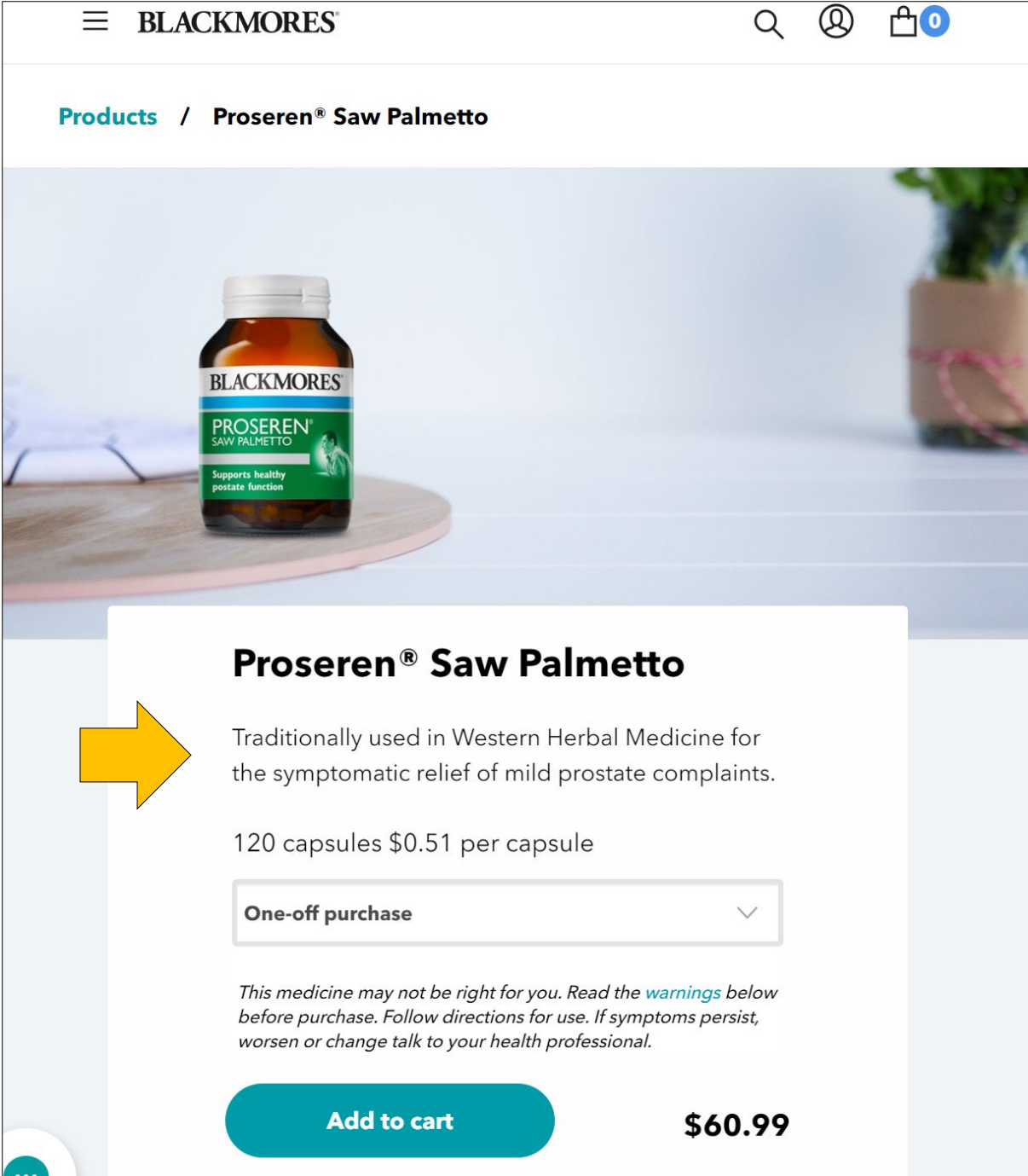
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Appendix (Screen shots with offending claims arrowed)



<https://www.blackmores.com.au/products/proseren-saw-palmetto#Comments>

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BLACKMORES

Products / Proseren® Saw Palmetto

Proseren® Saw Palmetto

Traditionally used in Western Herbal Medicine for the symptomatic relief of mild prostate complaints.

120 capsules \$0.51 per capsule

One-off purchase

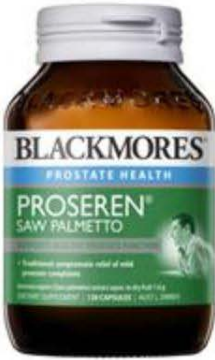
This medicine may not be right for you. Read the [warnings](#) below before purchase. Follow directions for use. If symptoms persist, worsen or change talk to your health professional.

Add to cart **\$60.99**

<https://www.blackmores.com.au/products/proseren-saw-palmetto#Comments>

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[Home](#) / [Health](#) / [Vitamins](#) / [Blackmores](#) / [Blackmores Men's Health](#)



1/2 PRICE OFF RRP

Blackmores Proseren Prostate Support 120 Capsules


Product ID: 2517670


★★★★☆ 4.5 (13) [Write a review](#)

\$30.99

\$30.00 Off RRP
Don't Pay RRP: \$60.99

QTY

 **ADD TO CART**

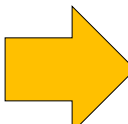
 **Click & Collect** ⓘ
Chemist Warehouse Koornang Rd VIC
[CHECK AVAILABILITY](#)

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.

General Information

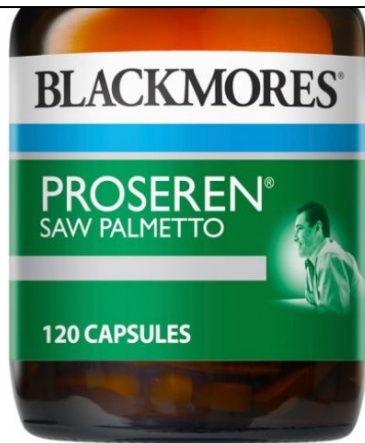
Traditionally used in western herbal medicine for the symptomatic relief of mild prostate complaints.

Blackmores Proseren® Saw Palmetto with Serenoa repens is traditionally used in western herbal medicine for the symptomatic relief of mild prostate complaints such as frequent urination, weak or interrupted urinary flow, or the feeling of not being able to empty the bladder completely. Helping you to support healthy prostate function, in an easy-to-swallow capsule. Contains a standardised extract of saw palmetto.



<https://www.chemistaustralia.com.au/blackmores-proseren-saw-palmetto-capsules-120>

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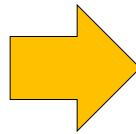
SKU: 73480

\$49.99

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ADD TO CART 

ADD TO WISHLIST 



Blackmores Proseren® Saw Palmetto supports healthy prostate function. Contains the herb saw palmetto which has been used traditionally in Western Herbal Medicine for symptomatic relief of mild prostate complaints.

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

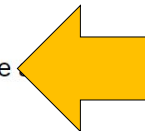
Vitamins and supplements may be of assistance if dietary intake is inadequate.

▼ More Product Information

Easy-to-swallow capsule. Helps support healthy prostate function, healthy flow of urine healthy urine frequency.

Saw palmetto is thought to improve bladder emptying and urinary tract flow.

Product	Blackmores Proseren Saw Palmetto 120 Capsules
Brand	Blackmores
Category	Men's Health
Dosage Form	Capsule, soft



<https://www.priceline.com.au/blackmores-proseren-saw-palmetto-120-capsules>