

## NATURAL HEALTH PRODUCT

### SAW PALMETTO – *SERENOA REPENS*

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

#### Notes

- ▶ Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- ▶ The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

**Date** September 25, 2018

#### Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
<i>Serenoa repens</i>	<ul style="list-style-type: none"> <li>▶ Sabal</li> <li>▶ Saw palmetto</li> <li>▶ Saw-palmetto</li> <li>▶ Scrub-palmetto</li> </ul>	<i>Serenoa repens</i>	Fruit	Dried

References: Proper name: USDA 2018; Common names: USDA 2018, McGuffin et al. 2000; Source material: USP 32 2009, Blumenthal et al. 2000, Mills and Bone 2000.

#### Route of administration

Oral

#### Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.



## Use(s) or Purpose(s)

Used in Herbal Medicine to help relieve the urologic symptoms (e.g. weak urine flow/ incomplete voiding/frequent daytime /night time urination) associated with mild to moderate benign prostatic hyperplasia (BPH) (Croom and Chan 2010; USP 32 2009; Bradley 2006; Wilt et al. 2002; Blumenthal et al. 2000).

## Dose(s)

### Subpopulation(s)

Adult males 18 years and older

### Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

1-4 grams of dried fruit, per day (Bradley 2006; Blumenthal et al. 2000)

### Directions for use

Take with food to minimize gastric disturbance (derMarderosian and Beutler 2009; USP 32 2009).

## Duration of use

No statement required.

## Risk information

### Caution(s) and warning(s)

- ▶ Consult a healthcare practitioner/health care provider/health care professional/doctor/ physician if symptoms persist or worsen.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/ physician prior to use to exclude a diagnosis of prostate cancer (USP 32 2009; Mills and Bone 2005).

### **Contraindication(s)**

No statement required.

### **Known adverse reaction(s)**

No statement required.

### **Non-medicinal ingredients**

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

### **Storage conditions**

Store in a tightly closed, light-resistant container in a cool, dry place (USP 32 2009; WHO 2002)

### **Specifications**

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

### **References cited**

Blumenthal M, Goldberg A, Brinkmann J, editors. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications; 2000.

Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (GB): British Herbal Medicine Association; 2006.

Croom EM, Chan M. Saw palmetto. In: Coates PM, Betz JM, Blackman MR, Cragg GM, Levine M, Moss J, White JD, editors. Encyclopedia of Dietary Supplements. Second Edition. New York (NY): Informa Healthcare; 2010. p. 700-710.



derMarderosian A, Beutler JA, editors. The Review of Natural Products. [Saw Palmetto: Issue date June 2009; Updated July 2009]. St Louis (MO): Facts and Comparisons, Wolters Kluwer Health; Printed in 2008 and Updated to November 2010.

McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. Herbs of Commerce. 2<sup>nd</sup> edition. Silver Spring (MD): American Herbal Products Association; 2000.

Mills S, Bone K. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone; 2000.

Mills S, Bone K. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone; 2005.

USDA 2018: ARS, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). “*Serenoa repens* (W. Bartram) Small”. Last updated May 1997. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2018 July 12]. Available from: [http://www.ars-grin.gov/cgi-bin/npgs/html/tax\\_search.pl](http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl)

USP 32 2009: United States Pharmacopeial Convention. United States Pharmacopeia and the National Formulary (USP 32 - NF 27). Rockville (MD): The United States Pharmacopeial Convention; 2009.

Print

WHO 2002: World Health Organization. WHO Monographs on Selected Medicinal Plants. Volume 2. “Fructus *Serenoae Repentis*”. Geneva (CH): World Health Organization; 2002.

Wilt T, Ishani A, Stark G, MacDonald R, Mulrow C, and Lau J. *Serenoa repens* for benign prostatic hyperplasia. The Cochrane Library 2002;1:1-14.

### References reviewed

Beckert BW, Concannon MJ, Henry SL, Smith DS, Puckett CL. The effect of herbal medicines on platelet function: an in vivo experiment and review of the literature. *Plastic and Reconstructive Surgery* 2007;120(7):2044-2050.

Bent S, Kane C, Shinohara K, Neuhaus J, Hudes ES, Goldberg H, Avins AL. Saw palmetto for benign prostatic hyperplasia. *The New England Journal of Medicine* 2006;354(6):557-565.

Bone K. Saw Palmetto: a critical review. *The European Journal of Herbal Medicine* 1994(1):1524.



Boyle P, Robertson C, Lowe F, Roehrborn C. Meta-analysis of clinical trials of permixon in the treatment of symptomatic benign prostatic hyperplasia. *Urology* 2000;55(4):533-539.

Braeckman J. The extract of *Serenoa repens* in the treatment of benign prostatic hyperplasia: a multicenter open study. *Current Therapeutic Research* 1994;55(7):776-785.

Brinker F. Online Updates and Additions to Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications; 2008. [Accessed 2008 April 15]. Available from: <http://www.eclecticherb.com/emp/updatesHCDI.html>

Brinker F. Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications; 2001.

Cheema P, El-Mefty O, Jazieh AR. Intraoperative haemorrhage associated with the use of extract of Saw Palmetto herb: a case report and review of literature. *Journal of Internal Medicine* 2001;250(2):167-169.

Chitturi S, Farrell GC. Herbal hepatotoxicity: an expanding but poorly defined problem. *Journal of Gastroenterology and Hepatology* 2000;15(10):1093-1099.

De Bernardi di Valserra M, Tripodi AS, Contos S, Germogli R. *Serenoa repens* capsules: a bioequivalence study. *Acta Toxicologia Therapeutica* 1994;15(1):21-39.

Debruyne F, Koch G, Boyle P, Da Silva FC, Gillenwater JG, Hamdy FC, Perrin P, Teillac P, Vela-Navarrete R, Raynaud JP. Comparison of a phytotherapeutic agent (Permixon) with an alpha-blocker (Tamsulosin) in the treatment of benign prostatic hyperplasia: a 1-year randomized international study. *European Urology* 2002;41(5):497-507.

Di Silverio F, D'Eramo G, Lubrano C, Flammia GP, Sciarra A, Palma E, Caponera M, Sciarra F. Evidence that *Serenoa repens* extract displays an antiestrogenic activity in prostatic tissue of benign prostatic hypertrophy patients. *European Urology* 1992;21(4):309-314.

Di Silverio F, Monti S, Sciarra A, Varasano PA, Martini C, Lanzara S, D'Eramo G, Di Nicola S, Toscano V. Effects of long-term treatment with *Serenoa repens* (Permixon) on the concentrations and regional distribution of androgens and epidermal growth factor in benign prostatic hyperplasia. *Prostate* 1998;37(2):77-83.

Ernst E. Herbal medications for common ailments in the elderly. *Drugs & Aging* 1999;15(6):423-428.

Ernst E. The risk-benefit profile of commonly used herbal therapies: Ginkgo, St. John's Wort, Ginseng, Echinacea, Saw Palmetto, and Kava. *Annals of Internal Medicine* 2002;136(1):42-53.



Gerber GS. Saw palmetto for the treatment of men with lower urinary tract symptoms. *The Journal of Urology* 2000;163(5):1408-1412.

Gerber GS, Fitzpatrick JM. The role of a lipido-sterolic extract of *Serenoa repens* in the management of lower urinary tract symptoms associated with benign prostatic hyperplasia. *British Journal of Urology International* 2004;94(3):338-344.

Goepel M, Hecker U, Kregel S, Rübgen H, Michel MC. Saw palmetto extracts potently and noncompetitively inhibit human alpha1-adrenoceptors in vitro. *Prostate* 1999;38(3):208-215.

Grasso M, Montesano A, Buonaguidi A, Castelli M, Lania C, Rigatti P, Rocco F, Cesana BM, Borghi C. Comparative effects of alfuzosin versus *Serenoa repens* in the treatment of symptomatic benign prostatic hyperplasia. *Archivos españoles de urología* 1995;48(1):97-103.  
Hoffmann D. *Medical Herbalism: The Science and Practice of Herbal Medicine*. Rochester (VT): Healing Arts Press; 2003.

Khwaja TA, Friedman EP. Pharmaceutical grade saw palmetto. United States Patent 6039950. Los Angeles (CA): University of Southern California and Irvine (CA): Pharmaprint Inc. 2000. [Accessed 2010 October 19]. Available at: <http://www.freepatentsonline.com/6039950.html>

Marks LS, Hess DL, Dorey FJ, Luz Macairan M, Cruz Santos PB, Tyler VE. Tissue effects of saw palmetto and finasteride: use of biopsy cores for in situ quantification of prostatic androgens. *Urology* 2001;57(5):999-1005.

Sorenson WR, Sullivan D. 2007. Determination of campesterol, stigmasterol, and beta sitosterol in saw palmetto raw materials and dietary supplements by gas chromatography: collaborative study. *Journal of the Association of Official Analytical Chemists [AOAC] International* 90(3):670-678

Tacklind J, MacDonald R, Rutks I, Wilt TJ. *Serenoa repens* for benign prostatic hyperplasia. *Cochrane Database of Systematic Reviews* 2009, Issue 2. Art. No.: CD001423. DOI: 10.1002/14651858.CD001423.pub2

Yue QY. Herbal drug curbicin and anticoagulant effect with and without warfarin: possibly related to the vitamin E component. *Journal of the American Geriatric Society* 2001;49(6)838.