

Saw Palmetto

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SAW PALMETTO - SERENOA REPENS Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 59 KB) 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 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 on the label. Date January 10, 2025 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Preparation(s) Serenoa repens Sabal Saw palmetto Saw-palmetto Scrub-palmetto Serenoa repens Fruit Dry Saw palmetto liposterolic extract Serenoa repens Fruit Dry References: Proper name: USDA 2024; Common names: USDA 2024, Gardner and McGuffin 2013; Source information: USP-NF 2024, 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. Use(s) or Purpose(s) All subpopulations Traditionally used in Herbal Medicine as a mild diuretic to help relieve symptoms associated with minor urinary tract infections, such as burning sensation and/or frequent urination (Bradley 2006; Blumenthal et al. 2000; Grieve 1971; Felter and Lloyd 1898). Adult males only Used in Herbal Medicine to help relieve the urologic symptoms associated with mild to moderate benign prostatic hyperplasia (BPH) (e.g., weak urine flow/incomplete voiding/frequent daytime/nighttime urination) (USP-NF 2024; Croom and Chan 2010; Bradley 2006; Wilt et al. 2002; Blumenthal et al. 2000). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) All uses Methods of preparation: Dry, Powdered, Non-Standardized or Standardized* Extracts (Dry extract 1,2 , Glycerite, Tincture, Fluid extract, Supercritical Fluid Extraction) 1 - 4 grams of dried fruit, per day (Bradley 2006; Blumenthal et al. 2000). *Note: Optional potency: 70 - 95% total fatty acids. Urologic symptoms associated with benign prostatic hyperplasia Methods of preparation: Standardized Extracts (Dry extract 1,2 , Supercritical Fluid Extraction) 100 - 400 milligrams of liposterolic extract of dried fruit standardized to 70 - 95% total fatty acids, per day (USP-NF 2024; Croom and Chan 2010; derMarderosian and Beutler 2009). Notes: 1 Dry extract means that any solvent was evaporated; however, it includes lipidic/liposterolic fractions that are liquid at room temperature. 2 Does not include water extracts as water would not be an appropriate solvent to extract the active constituents. Combination rule The two medicinal ingredients listed in Table 1 cannot be combined in Class I. However, they may be combined in Class II if the total combined amount of saw palmetto fruit (e.g., Quantity for powdered/dry and/or Quantity crude equivalent (QCE) for extracts) does not exceed 4 grams per day. In order to verify this, the QCE must be provided on the PLA form or cover letter for standardized Saw palmetto liposterolic extracts. Direction(s) for use Take with food to minimize gastric disturbance (USP NF-2024; derMarderosian and Beutler 2009). Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) All subpopulations Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Adult males only Ask a health care practitioner/health care provider/health care professional/doctor/physician before use to exclude a diagnosis of prostate cancer (USP-NF 2024; Mills and Bone 2005). Adult females only Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking oral contraceptives or hormone replacement therapy (UpToDate 2024). Contraindication(s) Adult females only Do not use if you are pregnant, breastfeeding, or attempting to conceive (UpToDate 2024). 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations . All products (information for industry; not for labelling) Preserve in tight containers, protected from light (USP-NF 2024; 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. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. 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. 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Available from : https://www.uptodate.com/contents/clinical-use-of-saw-palmetto?search=saw%20palmetto&source=search_result&selectedTitle=1%7E9&usage_type=default&display_rank=1 USDA 2024: United States Department of Agriculture, Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2024 November 14]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> USP-NF 2024: United States Pharmacopeia and the National Formulary. Rockville (MD): The United States Pharmacopeial Convention, Inc.; 2024. 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. 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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. 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MEDICINAL INGREDIENT(S)

Direction(s) for use Take with food to minimize gastric disturbance (USP NF-2024; derMarderosian and Beutler 2009).

DOSAGE FORM(S)

Acceptable dosage forms oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

RISK INFORMATION

Caution(s) and warning(s) All subpopulations Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Adult males only Ask a health care practitioner/health care provider/health care professional/doctor/physician before use to exclude a diagnosis of prostate cancer (USP-NF 2024; Mills and Bone 2005). Adult females only Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking oral contraceptives or hormone replacement therapy (UpToDate 2024). Contraindication(s) Adult females only Do not use if you are pregnant, breastfeeding, or attempting to conceive (UpToDate 2024). 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 CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations. All products (information for industry; not for labelling) Preserve in tight containers, protected from light (USP-NF 2024; 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.

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Serenoa repens	SabalSaw palmettoSaw-palmettoScrub-palmetto	Serenoa repens	Fruit	Dry
Saw palmetto liposterolic extract	Serenoa repens	Fruit	Dry	