

## SAW PALMETTO

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

### 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 are synonyms or that the statements are synonymous. Either term or statement may be selected by the applicant.

**Date:** December 23, 2010

**Proper name(s):** *Serenoa repens* (W. Bartram) Small (Arecaceae) (USDA 1997)

**Common name(s):** Saw palmetto (McGuffin et al. 2000; USDA 1997)

**Source material(s):** Fruit (USP 32; Blumenthal et al. 2000; Mills and Bone 2000)

**Route(s) of administration:** Oral

### Dosage form(s):

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to chewables (eg. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons.
- ▶ This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

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

**Dose(s):**

**Subpopulation:** Adult males

**Quantity:** Preparations equivalent to 1-4 g dried fruit, per day (Bradley 2006; Blumenthal et al. 2000)  
If potencies are declared, the only acceptable potencies are:  
70-90 % fatty acids (Bradley 2006; Blumenthal et al. 2000).

**Directions for use:** Take with food to minimize gastric disturbance (derMarderosian and Beutler 2009; USP 32).

See Appendix 1 for examples of dosage preparations and frequencies of use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

**Duration of use:** No statement required.

**Risk information:** Statement(s) to the effect of:

**Caution(s) and warning(s):**

- ▶ Consult a healthcare practitioner if symptoms persist or worsen.
- ▶ Consult a health care practitioner prior to use to exclude a diagnosis of prostate cancer (USP 32; 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* 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; WHO 2002)

**Specifications:**

- ▶ The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- ▶ The medicinal ingredient may comply with the specifications outlined in the pharmacopoeial monographs listed in Table 1

**Note:** Information detailed in this section is not to be submitted with the compendial PLA, although it may be requested at Health Canada's discretion.

Table 1 Saw palmetto monographs published in British, European and U.S. pharmacopoeias

Pharmacopoeia	Monograph
British Pharmacopoeia (BP)	Saw Palmetto Fruit
European Pharmacopoeia (P.Eur.)	Saw Palmetto Fruit
U.S. Pharmacopoeia (USP)	Saw Palmetto, Powdered Saw Palmetto

**References cited:**

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**Appendix 1:** Examples of dosage preparations and frequencies of use taken verbatim from the cited references.

Dried berry:

- ▶ 2-4 g, per day (Bradley 2006; Mills and Bone 2000)
- ▶ 1-2 g, per day (derMarderosian and Beutler 2010; Blumenthal et al. 2000)

Decoction:

Traditional Preparations:

Tea—1 to 2 grams per day.

As a decoction, bring to a boil 1 cup of water and one third the total daily dose of saw palmetto fruits and simmer gently for 5 minutes. Drink 1 cup three times daily. As this is a hydrophilic extract process, it contains few lipophilic components (USP Verified 2010).

Fluidextract:

- ▶ 2-4 g dried equivalent, per day  
BPC 1934 (1:1, 90% ethanol, 2-4 ml) (BHP 1983) (Bradley 2006)
- ▶ 1-2 g cut fruit  
1:1 (g/ml): 1-2 ml, twice daily (Blumenthal et al. 2000)
- ▶ (BPC 1934P), 1:1 herb to extract ratio, 0.6 to 1.5 mL three times daily (USP Verified 2010)

Tincture:

- ▶ 1-2 g cut fruit  
1:2 (g/ml): 2-4 ml twice daily (Blumenthal et al. 2000)
- ▶ 80% alcohol (fresh fruit, 1:2 [herb to extract ratio]; dried fruit, 1:5 [herb to extract ratio]), 1 to 2 mL three to four times daily (USP Verified 2010)