

SAW PALMETTO, LIPOSTEROLIC EXTRACT

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 (e.g. 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: 100 - 400 mg liposterolic extract of dried fruit standardized to 70 - 95 % fatty acids, per day (Croom and Chan 2010; derMarderosian and Beutler 2009; USP 32).

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 below.

- ▶ Acceptable lipophilic extraction methods of the dried saw palmetto fruit (Croom and Chan 2010; USP Verified 2010; derMarderosian and Beutler 2009) are as follows:
 - N-hexane
 - Supercritical carbon dioxide
 - 90 % ethanol.

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, Saw Palmetto Extract

References cited:

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

Fluidextract:

- ▶ 2-4 g dried equivalent, per day
BPC 1934 (1:1, 90% ethanol, 2-4 ml) (BHP 1983) (Bradley 2006).

Soft native extract (lipophilic extract):

- ▶ 10:1-14:1 (w/w) (contains ~85-95% fatty acids): 160 mg, twice daily (Blumenthal et al. 2000)
- ▶ extracts standardized to 85% to 95% fatty acids (derMarderosian and Beutler 2009)

Dry normalized extract:

- ▶ 4:1 (w/w) (contains ~ 25% fatty acids): 400 mg, twice daily (Blumenthal et al. 2000)
- ▶ extracts standardized to 25% (derMarderosian and Beutler 2009)

Standardized extract:

- ▶ Clinical Trial Preparations: Liposterolic Extract (LESP)— 320 mg orally once daily or 160 mg twice daily (liquid or solid), with an approximate 10:1 herb to extract ratio (HER), standardized to 70 to 95% free fatty acids which corresponds to about 3 grams of dried fruits daily. All doses should be taken with food to minimize gastric disturbances (USP Verified 2010).
- ▶ Saw Palmetto Extract: Saw Palmetto extract is obtained from comminuted Saw Palmetto by extraction with hydroalcoholic mixtures or solvent hexane, or by supercritical extraction with carbon dioxide. The ratio of starting crude plant material to Extract is between 8.0:1 and 14.3:1. The Extract contains not less than 70.0 percent and not more than 95.0 percent of fatty acids and not less than 0.2 percent and not more than 0.5 percent of sterols, calculated on an anhydrous basis (USP 32).
- ▶ Typical dosages of standardized extracts range from 100 to 400 mg given twice daily (derMarderosian and Beutler 2009).
- ▶ 320 mg saw palmetto fruit liposterolic extract, per day (Bradley 2006)
- ▶ 320 mg lipophilic ingredients (extracted with lipophilic solvents such as hexane or ethanol 90% v/v), per day (Blumenthal et al. 2000).