



## NATURAL HEALTH PRODUCT

### SAW PALMETTO – LIPOSTEROLIC EXTRACT

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>	Saw palmetto liposterolic extract	<i>Serenoa repens</i>	Fruit	Dried

References: Proper name: USDA 2018; Common name: 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: Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

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

### Direction(s) 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.

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