



## NATURAL HEALTH PRODUCT

### PYGEUM – *PRUNUS AFRICANA*

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

August 5, 2019

#### 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>Prunus africana</i>	<ul style="list-style-type: none"> <li>▶ Pygeum</li> <li>▶ Red stinkwood</li> </ul>	<i>Prunus africana</i>	<ul style="list-style-type: none"> <li>▶ Stem bark</li> <li>▶ Trunk bark</li> </ul>	Dried

References: Proper name: USDA 2019; Common names: USDA 2019, Godfrey et al. 2010; Source materials: Godfrey et al. 2010, Mills and Bone 2005.

#### 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)

### *Standardized extracts*

Helps reduce the urologic symptoms (such as weak urine flow, incomplete voiding, frequent daytime and nighttime urination) associated with benign prostatic hyperplasia (Wilt et al. 2002; Ishani et al. 2000; Chatelain et al. 1999; Breza et al. 1998; Carani et al. 1991; Barlet et al. 1990).

### *Non-standardized preparations*

No claim (safety only)

## Dose(s)

### Subpopulation(s)

*Standardized extracts making a claim for symptoms of benign prostatic hyperplasia*

Adult Males 18 years and older

*Non-standardized preparations*

Adults 18 years and older

## Quantity(ies)

*Symptoms of benign prostatic hyperplasia*

Methods of preparation: Standardized extracts

75 - 200 milligrams of extract per day, standardized to 12-14% of phytosterols (Wilt et al. 2002; Ishani et al. 2000; Chatelain et al. 1999; Breza et al. 1998; Carani et al. 1991; Barlet et al. 1990).

*No claim (safety only)*

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

Not to exceed 4 grams of dried stem bark and/or trunk bark, per day.<sup>1</sup>

### <sup>1</sup>Note

Maximum daily dose of the crude material is based on a conservative extrapolation of the dose supported in the available evidence.



### **Direction(s) for use**

No statement required.

### **Duration(s) of use**

No statement required.

### **Risk information**

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

*Standardized extracts making a claim for symptoms of benign prostatic hyperplasia (adult males)*

- ▶ Consult a health care 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 the diagnosis of prostate cancer (Goldman and Ausiello 2004).

*Non-standardized preparations for adults (i.e. including women) (safety only)*

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.

#### **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**

No statement required.



## 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.
- ▶ Please note that this organism, one of its parts, or the organism or part from which this ingredient is derived, is considered at risk and is listed in Appendix II of CITES. Details are available from the following reference(s): [http://www.ec.gc.ca/cites/default.asp?lang=En&n=C5F64D6F-1#\\_004](http://www.ec.gc.ca/cites/default.asp?lang=En&n=C5F64D6F-1#_004).

## References cited

Barlet A, Albrecht J, Aubert A, Fischer M, Grof F, Grothuesmann HG, Masson JC, Mazeman E, Mermon R, Reichelt H. Efficacy of Pygeum africanum extract in the medical therapy of urination disorders due to benign prostatic hyperplasia: evaluation of objective and subjective parameters. A placebo-controlled double-blind multicenter study. *Wiener Klinische Wochenschrift* 1990;102(22):667-73.

Breza J, Dzurny O, Borowka A, Hanus T, Petrik R, Blane G, Chadha-Boreham H. Efficacy and acceptability of tadenan (Pygeum africanum extract) in the treatment of benign prostatic hyperplasia (BPH): a multicentre trial in central Europe. *Current Medical Research and Opinion* 1998;14(3):127-39.

Carani C, Salvioli V, Scuteri A, Borelli A, Baldini A, Granata AR, Marrama P. Urological and sexual evaluation of treatment of benign prostatic disease using Pygeum africanum at high doses. *Archivio italiano di urologia, nefrologia, andrologia* 1991 Sep;63(3):341-5

Chatelain C, Autet W, Brackman F. Comparison of once and twice daily dosage forms of Pygeum africanum extract in patients with benign prostatic hyperplasia: a randomized, double-blind study, with long-term open label extension. *Urology* 1999 Sep;54(3):473-8.

Godfrey A, Saunders PR, with Barlow K, Gilbert C, Gowan M, Smith F. Principles and Practices of Naturopathic Botanical Medicine. Volume 1: Botanical Medicine Monographs. Toronto (ON): CCNM Press; 2010.

Goldman L, Ausiello D. Cecil Textbook of Medicine. 22<sup>nd</sup> edition. Philadelphia (PA): Saunders; 2004.

Ishani A, MacDonald R, Nelson D, Rutks I, Wilt TJ. Pygeum africanum for the treatment of patients with benign prostatic hyperplasia: a systematic review and quantitative meta-analysis. *American Journal of Medicine* 2000;109: 654-66

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



USDA 2019: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [Internet]. *Prunus africana* (Hook.f.). National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2019 June 7]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx>

Wilt T, Ishani A, MacDonald R, Rutks I, Stark G. Pygeum africanum for benign prostatic hyperplasia (review). Cochrane Database of Systematic Reviews 2002;(1):CD001044

### References reviewed

Brinker, F. 2009. Updates and Additions for Herb Contradictions and Drug Interactions, 3<sup>rd</sup> ed. With extensive appendices addressing influences on phase i, ii & iii metabolism [Accessed 2013 August 14]. Available from: <http://www.eclecticherb.com/emp/updatesHCDI.html>

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

Kadu C, Parich A, Schueler S, Konrad H, Muluvi G, Eyog-Matig O, Muchugi A, Williams V, Ramamonjisoa L, Kapinga C, Foahom B, Katsvanga C, Hafashimana D, Obama C, Vinceti B, Schumacher R, Geburek T. Bioactive constituents in *Prunus africana*: Geographical variation throughout Africa and associations with environmental and genetic parameters. *Phytochemistry* 2012;83:70-78