

# Pygeum - Prunus africana

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PYGEUM - PRUNUS AFRICANA 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 - 53 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 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 Prunus africana Pygeum Red stinkwood Prunus africana Stem bark Trunk bark 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 any age category listed in this monograph for the specified route of administration are listed 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. 1 1 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 nd 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 rd ed. With extensive appendices addressing influences on phase i, ii & iii metabolism [Accessed 2013 August 14]. Available from: <http://www.eclecticherb.com/emp/updatesHC DI.html> Brinker F. Herb Contraindications and Drug Interactions, 3 rd 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 Report a problem on this page Date modified: 2019-03-01

## MEDICINAL INGREDIENT(S)

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.

## DOSAGE FORM(S)

Acceptable dosage forms for any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document.

## DOSE(S)

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. 22nd 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

## 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.

## STORAGE CONDITION(S)

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

Route of Administration Oral

Proper name(s)	Common name(s)	Source material(s)		
Proper name(s)	Part(s)	Preparation		

Prunus africana	PygeumRed stinkwood	Prunus africana	Stem barkTrunk bark	Dried
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