

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

Date

December 8, 2015

Proper name(s)

Prunus africana (Hook.f.) Kalkman (*Rosaceae*) (USDA 2009)

Common name(s)

- ▶ Pygeum (USDA 2009)
- ▶ Red stinkwood (Godfrey *et al.* 2010)

Source material(s)

- ▶ Stem bark (Godfrey *et al.* 2010; Mills and Bone 2005)
- ▶ Trunk bark (Godfrey *et al.* 2010; Mills and Bone 2005)

Route(s) of administration

Oral

Dosage form(s)

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to, capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.



- ▶ 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) Statement(s) to the effect of

Helps reduce the urologic symptoms (e.g. 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).

Dose(s)

Subpopulation

Adult Males (≥ 18 years)

Quantities

Products making a claim for symptoms of benign prostatic hyperplasia

All standardized extracts

75 – 200 mg of extract per day standardized to 12-14% 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).

All other products (safety only):

Valid only for Class II and III applications for supporting safety in adults

Dry, powder, tincture, fluid extract, decoction

Up to 4 g dried pygeum bark per day¹

Potency (optional): Up to 14% phytosterols; not to exceed 28 mg phytosterols per day (Wilt *et al.* 2002; Ishani *et al.* 2000; Chatelain *et al.* 1999; Breza *et al.* 1998; Carani *et al.* 1991; Barlet *et al.* 1990)

¹Note

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

Duration of use

No statement required.

Risk information Statement(s) to the effect of:



Caution(s) and warning(s)

Products making a claim for symptoms of benign prostatic hyperplasia

- ▶ If symptoms persist or worsen, consult a health care practitioner.
- ▶ To exclude the diagnosis of prostate cancer, consult a health care practitioner prior to use (Goldman and Ausiello 2004).

Products for adults (i.e. including women): Valid only for Class II and III applications

If pregnant or breastfeeding, consult a health care practitioner prior to use.

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 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

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