



12 July 2016
EMA/HMPC/680626/2013
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Prunus africana* (Hook f.) Kalkm., cortex

Final

Discussion in Working Party on European Union monographs and list (MLWP)	September 2013 January 2014 May 2014 July 2015 September 2015
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	24 November 2015
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Prunus africana</i> (Hook f.) Kalkm., cortex; Pruni africanae cortex; pygeum africanum bark
BG (bulgarski): Африканска слива, кора CS (čeština): kůra slivoně africké DA (dansk): Rosenolie DE (Deutsch): Afrikanische Pflaumenbaumrinde EL (elliniká): Προύμνης αφρικανικής φλοιός EN (English): pygeum africanum bark ES (español): pígeum, corteza de ET (eesti keel): aafrika ploomipuu koor FI (suomi): afrikankirsikkapuu, kuori FR (français): prunier d'Afrique (écorce de) HR (hrvatski): kora afričke trešnje HU (magyar): afrikai szilvafa kéreg IT (italiano): Pruno africano (pigeo africano) corteccia	LT (lietuvių kalba): Afrikinių slyvų žievė LV (latviešu valoda): Pigejas miza MT (Malti): qoxra tal-sigra tal-pruna afrikana NL (Nederlands): rood stinkhout PL (polski): Kora śliwy afrykańskiej PT (português): ameixoeira Africana, casca RO (română): scoarță de Prunus africana/prun african SK (slovenčina): kôra slivky africkéj SL (slovenščina): skorja afriške slive SV (svenska): afrikansk lagerhägg, bark IS (íslenska): NO (norsk): pygeumbark



European Union herbal monograph on *Prunus africana* (Hook f.) Kalkm., cortex

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{1, 2}

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC .</p> <p><i>Prunus africana</i> (Hook f.) Kalkm., cortex (pygeum africanum bark)</p> <p>i) Herbal substance</p> <p>Not applicable</p> <p>ii) Herbal preparations</p> <p>Soft extract (DER 114-222: 1), extraction solvent: chloroform; (stabilised by 1.2% of ethanol >99.9%)</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparations in solid dosage forms for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Traditional herbal medicinal product for the relief of lower urinary tract symptoms related to benign prostatic hyperplasia after serious conditions have been excluded by a medical doctor.</p>

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

² The material complies with the Ph. Eur. monograph (ref.: 1886)

Well-established use	Traditional use
	The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and elderly</i></p> <p>Single dose: 50 mg</p> <p>Daily dose: 100 mg</p> <p>There is no relevant use in children and adolescents under 18 years of age and women.</p> <p>Duration of use</p> <p>Long-term use is possible (see section 4.4 'Special warnings and precautions for use').</p> <p>Method of administration</p> <p>Oral use</p>

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	If complaints worsen or if symptoms such as fever, spasms or blood in the urine, painful urination or urinary retention occur during the use of the medicinal product, a doctor should be consulted.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	No fertility data available. Pregnancy and lactation not relevant.

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	Rarely: digestive disorders (nausea, constipation or diarrhoea). If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

Well-established use	Traditional use
	<p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product.</p> <p>Tests on carcinogenicity have not been performed.</p> <p>Adequate tests on genotoxicity and reproductive toxicity have not been performed.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation/last revision

12 July 2016