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

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

Draft

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Re-discussion in MLWP	
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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
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BG (bulgarski): Африканска слива, кора	LT (lietuvių kalba): Afrikinių slyvų žievė
CS (čeština): kůra slivoně africké	LV (latviešu valoda): Pigejas miza
DA (dansk): rosenolie	MT (Malti): Qoxra tal-sigra tal-Pruna Afrikana
DE (Deutsch): Afrikanische Pflaumenbaumrinde	NL (Nederlands): Rood Stinkhout
EL (elliniká): Προύμνης αφρικανικής φλοιός	PL (polski): Kora śliwy afrykańskiej
EN (English): Pygeum africanum bark	PT (português): Ameixoeira Africana, casca
ES (español): Pígeum, corteza de	RO (română):
ET (eesti keel): aafrika ploomipuu koor	SK (slovenčina): Kôra slivky africkéj
FI (suomi): afrikankirsikkapu, kuori	SL (slovenščina): skorja afriške slive
FR (français): Prunier d'Afrique (écorce de)	SV (svenska): Afrikansk lagerhägg, bark
HR (hrvatski): kora afričke trešnje	IS (íslenska):
HU (magyar): afrikai szilvafa kéreg	NO (norsk): Pygeumbark
IT (italiano): Pruno africano (pigeo africano) corteccia	

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 as amended</p> <p><i>Prunus africana</i> (Hook f.) Kalkm., cortex</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</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
	<p>doctor.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.</p>

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: 25-50 mg</p> <p>Daily dose: up to 100 mg</p> <p>There is no relevant use in women, adolescents and children.</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
	<p>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.</p> <p>The use in children and adolescents under 18 years of age is not recommended because of lower urinary tract symptoms in these populations requires medical supervision.</p>

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. 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 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
	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. Tests on genotoxicity, reproductive toxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

24 November 2015