



24 November 2015
EMA/HMPC/280079/2013
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Serenoa repens* (W. Bartram) Small, fructus

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	September 2013 November 2013 March 2014 May 2014 July 2014 November 2014
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; well-established medicinal use; traditional use; <i>Serenoa repens</i> (W. Bartram) Small, fructus; <i>Sabal</i> <i>serrulatae</i> fructus, Saw palmetto fruit
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BG (bulgarski): Сереноа репенс, плод CS (čeština): serenový plod DA (dansk): Savpalmefrugt DE (Deutsch): Sägepalmenfrüchte EL (elliniká): Σερενόας έρπουσας (πριονοφύλλου) καρπός EN (English): Saw palmetto fruit ES (español): Sabal, fruto de ET (eesti keel): serenoapalmivili FI (suomi): sahapalmu, hedelmä FR (français): Palmier de Floride (fruit de) HR (hrvatski): sabalov plod HU (magyar): szabalpálma termés IT (italiano): Sabal (<i>Serenoa repens</i>) frutto	LT (lietuvių kalba): Šliaužiančiųjų serenojų vaisiai LV (latviešu valoda): Smalki zāgzobainās sabalpalmas augļi MT (Malti): Frotta tas-Serenoa NL (Nederlands): Sabal PL (polski): Owoc palmy sabal PT (português): Palmeto, fruto RO (română): Fruct de palmier pitic, fruct de <i>Serenoa repens</i> . SK (slovenčina): Plod serenoy plazivej SL (slovenščina): plod palmeta SV (svenska): Sägpalmetto, frukt IS (íslenska): NO (norsk): Dvergpalmefrukt
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European Union herbal monograph on *Serenoa repens* (W. Bartam) Small, fructus

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
With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended <i>Serenoa repens</i> , fructus (saw palmetto, fruit) i) Herbal substance Not applicable. ii) Herbal preparation a) Soft extract (DER 7-11:1) ³ , extraction solvent: hexane	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended <i>Serenoa repens</i> , fructus (saw palmetto, fruit) i) Herbal substance Not applicable. ii) Herbal preparations a) Soft extract (DER 7.5-14.3:1), extraction solvent: ethanol 90% to 96% m/m

3. Pharmaceutical form

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

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
Herbal medicinal product for the symptomatic treatment of benign prostatic hyperplasia.	Traditional medicinal product for the relief of lower urinary tract symptoms related to benign prostatic hyperplasia, after serious conditions have been excluded by a doctor. The product is a traditional herbal medicinal

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.: 1848).

³ Containing 92% of fatty acids (free or esterified) and 2% of an unsaponifiable part.

Well-established use	Traditional use
	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>a) 320 mg once daily or 160 mg 2 times daily.</p> <p>There is no relevant indication for women, children and adolescents.</p> <p>Duration of use</p> <p>Long-term use is possible (see section 4.4 'Special warnings and precautions for use').</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a pharmacist should be consulted.</p> <p>Method of administration</p> <p>Oral use.</p>	<p>Posology</p> <p><i>Adults and elderly</i></p> <p>a) 320 mg once daily.</p> <p>There is no relevant indication for women, children and adolescents.</p> <p>Duration of use</p> <p>Long-term use is possible (see section 4.4 'Special warnings and precautions for use').</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use.</p>

4.3. Contraindications

Well-established use	Traditional use
Hypersensitivity to the active substance.	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 or a pharmacist should be consulted.	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 or a qualified healthcare practitioner should be consulted.

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

Well-established use	Traditional use
A few cases of suspected interactions with warfarin have been reported. Increased INR-	A few cases of suspected interactions with warfarin have been reported. Increased INR-

Well-established use	Traditional use
values have been described.	values have been described.

4.6. Fertility, pregnancy and lactation

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

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.	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
<p><i>Gastro-intestinal disorders</i> Common: abdominal pain Uncommon: nausea</p> <p><i>Hepatobiliary disorders</i> Uncommon: increase of transaminases or gamma-glutamyltransferases</p> <p><i>Skin and subcutaneous tissue disorders</i> Uncommon: skin rash</p> <p><i>Endocrine disorders</i> Uncommon: reversible gynecomastia</p> <p><i>Nervous system disorders</i> Common: headache</p> <p>If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.</p>	<p><i>Gastro-intestinal complaints</i> Uncommon: nausea, vomiting, diarrhoea, abdominal pain (especially when taken on an empty stomach).</p> <p><i>Immune system disorders</i> Allergic or hypersensitivity reactions may occur. The frequency is not known.</p> <p><i>Nervous system disorders</i> Headache may occur. The frequency is not known.</p> <p>If other adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

4.9. Overdose

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

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
Pharmacotherapeutic group: benign prostatic hyperplasia. The mechanism of action is not known. Proposed ATC code: G04CX02	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
No data available.	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
Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.	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 reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
Not applicable.	Not applicable.

7. Date of compilation/last revision

24 November 2015