



24 November 2014
EMA/HMPC/280079/2013
Committee on Herbal Medicinal Products (HMPC)

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

Draft

Discussion in Working Party on Community monographs and Community list (MLWP)	September 2013 November 2013 January 2014 March 2014 May 2014 July 2014 September 2014
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	24 November 2014
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 March 2015
Rediscussion in MLWP	
Adoption by HMPC	

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> serrulatae fructus, Saw palmetto fruit
----------	--

BG (bългарски): 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 (hrvatska) : Sabalov plod HU (magyar): Szabalpálma termés IT (italiano): Sabal (<i>Serenoa repens</i>) frutto	LT (lietuvių kalba): Šeivamedžių žiedai LV (latviešu valoda): Plūškoka augļi MT (malti): Frott tas-Sambuka NL (nederlands): Zaagpalmvrucht - Sabal PL (polski): Owoc palmy sabal PT (português): Palmeto, fruto RO (română): Palmier pitic SK (slovenčina): Sabalový plod SL (slovenščina): Plod palmeta SV (svenska): Sägpalmettofrukt <i>IS (islenska):</i> <i>NO (norsk):</i> Dvergpalmefrukt
---	---



Community 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 (extraction solvent hexane: DER 7-11:1) ³	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 form for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.	Herbal preparations in solid dosage form 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.:07/2012:1848).

³ Containing 97% of fatty acids (free or esterified) and 3% 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) 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
<p>Hypersensitivity to the active substance.</p> <p>Hepatic disease.</p>	<p>Hypersensitivity to the active substance.</p> <p>Hepatic disease.</p>

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 or a pharmacist should be consulted.</p> <p>Medical review is required for the diagnosis of BPH.</p>	<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 or a qualified healthcare practitioner should be consulted.</p>

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-values have been described.	A few cases of suspected interactions with warfarin have been reported. Increased INR-values have been described.

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
Not relevant. No fertility data available.	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
Gastro-intestinal disorders (nausea, abdominal pain) may occur. The frequency is not known. Cases of acute hepatitis have been reported very rarely. Skin rash and oedema have been reported very rarely. Reversible gynecomastia cases have been observed. The frequency is not known. Intra-operative floppy iris syndrome can occur during cataract extraction. The frequency is not known. If adverse reactions occur, a doctor or a pharmacist should be consulted.	Gastro-intestinal disorders (nausea, abdominal pain) may occur. The frequency is not known. Cases of acute hepatitis have been reported very rarely. Skin rash and oedema have been reported very rarely. Reversible gynecomastia cases have been observed. The frequency is not known. Intra-operative floppy iris syndrome can occur during cataract extraction. The frequency is not known. If 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.	No case of overdose has been reported.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
Pharmacotherapeutic group: benign prostatic hyperplasia. 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 genotoxicity, carcinogenicity and reproductive toxicity 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 genotoxicity, carcinogenicity and reproductive toxicity have not been performed.

6. Pharmaceutical particulars

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

7. Date of compilation/last revision

24 November 2014