



20 November 2012
EMA/HMPC/136024/2010
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Cucurbita pepo* L., semen

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	September 2010 November 2010 January 2011 May 2011
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	September 2011
End of consultation (deadline for comments)	15 February 2012
Rediscussion in Working Party on Community monographs and Community list (MLWP)	March 2012 September 2012
Adoption by Committee on Herbal Medicinal Products (HMPC)	20 November 2012

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Cucurbita pepo</i> L., semen; Cucurbitae semen; pumpkin seed
----------	--

BG (bългарski): Обикновена тиква, семе CS (čeština): tykvové semeno DA (dansk): Græskarfrø DE (Deutsch): Kürbissamen EL (elliniká): EN (English): pumpkin seed ES (español): Calabaza, semillas de ET (eesti keel): kõrvitsaseeme FI (suomi): kurpitsa, siemen FR (français): Courge citrouille (graine de) HU (magyar): Közönséges tökmag IT (italiano): Zucca seme	LT (lietuvių kalba): Moliūgų sėklos LV (latviešu valoda): Ķirbja sēklas MT (malti): Żerriegħa tal-Qargħa Ħamra NL (nederlands): Pompoenzaad PL (polski): Nasienie dyni PT (português): Abóbora, semente RO (română): semințe de dovleac SK (slovenčina): Tekvicové semeno SL (slovenščina): seme navadne buče SV (svenska): Pumpafrö IS (islenska): NO (norsk): Gresskarfrø
---	--



Community herbal monograph on *Cucurbita pepo* L., semen

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>Cucurbita pepo</i> L., semen (pumpkin seed)</p> <p>i) Herbal substance</p> <p>Whole, ripe and dried seeds</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Soft extract (DER 15-25:1), extraction solvent ethanol 92% m/m</p> <p>c) Dry extract (15-30:1), extraction solvent ethanol 60% v/v</p> <p>d) Fatty oil</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal substance or 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</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 German monograph (DAB 10, 1999).

Well-established use	Traditional use
	<p>prostatic hyperplasia or related to an overactive bladder, after serious conditions have been excluded by a medical 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><u>Herbal substance</u> Single dose: 2.5 – 7.5 g, 2 times daily.</p> <p><u>Herbal preparations</u></p> <p>a) Comminuted herbal substance Single dose: 2.5 – 7.5 g, 2 times daily.</p> <p>b) Soft extract Single dose: 500 mg, 2 times daily.</p> <p>c) Dry extract Single dose: 105 mg, 3 times daily or 152 mg, 2 times daily</p> <p>d) Fatty oil Single dose: 1 – 1.2 g, 3 times daily Daily dose: 3 - 4 g</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</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>The use in children and adolescents under 18 years of age and the use in pregnant women (see also section 4.6.) are not recommended because lower urinary tract symptoms in these populations require medical supervision.</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 health care professional should be consulted.</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
	<p>Safety during pregnancy and lactation has not been established for pumpkin extracts. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No concern has arisen about any malformation in humans, following the consumption of pumpkin seeds and fatty oil. Can be used during pregnancy and lactation if clinically needed.</p> <p>No fertility data available.</p>

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
	Mild gastrointestinal complaints have been reported. The frequency is common (4%). 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
	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.

7. Date of compilation/last revision

20 November 2012