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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Draft

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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): FR (français): Courge citrouille (graine de) HU (magyar): Közönséges tökmag IT (italiano): Zucca seme	LT (lietuvių kalba): LV (latviešu valoda): Ķirbja sēklas MT (malti): 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 (íslenska): NO (norsk): Gresskarfrø
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# 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<sup>1,2</sup>

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>

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

<sup>2</sup> The material complies with the German Monograph (DAB 10, 1991-1996).

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><b>Posology</b></p> <p><i>Adults and elderly</i></p> <p>Daily dose</p> <p><u>Herbal substance</u> 10–20 g to be taken in one single dose or divided into 2 - 3 doses.</p> <p><u>Herbal preparations</u></p> <p>a) Comminuted herbal substance 10–20 g divided into 2-3 doses.</p> <p>b) Soft extract 1000 mg divided into 2 single doses.</p> <p>c) Dry extract 300-320 mg, divided into 2-3 single doses.</p> <p>d) Fatty oil 1–4 g daily divided into several single doses.</p> <p>The use in children and adolescents under 18 years of the age is not recommended (see section 4.4. 'Special warnings and precautions for use').</p> <p><b>Duration of use</b></p> <p>If the symptoms persist longer than 4 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Method of administration</b></p> <p>Oral use.</p>

#### 4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to other plants of the <i>Cucurbitaceae</i> family.

#### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.  If complaints or symptoms such as fever, spasms or blood in the urine occur during the use of medicinal product, a doctor or a qualified health care professional 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
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.  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.

#### 4.8. Undesirable effects

Well-established use	Traditional use
	None known.  If adverse reactions occur, a doctor or a qualified

Well-established use	Traditional use
	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

13 September 2011