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Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Trigonella foenum-graecum* L., semen

Draft

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BG (bългарски): CS (čeština): semeno pískavice řeckého sena DA (dansk): DE (Deutsch): EL (ελληνικά): EN (English): Fenugreek ES (español): ET (eesti keel): FI (suomi): FR (français): Fenugrec HU (magyar): Görögszéna IT (italiano):	LT (lietuvių kalba): LV (latviešu valoda): MT (malti): NL (nederlands): PL (polski): PT (português): RO (română): SK (slovenčina): SL (slovenščina): SV (svenska): <i>IS (íslenska):</i> <i>NO (norsk):</i>
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# Community herbal monograph on *Trigonella foenum-graecum* 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>Trigonella foenum-graecum</i> L., semen (fenugreek)</p> <p>i) Herbal substance</p> <p>Dried seed</p> <p>ii) Herbal preparations</p> <p>a) Dry extract (DER 4 : 1), extraction solvent ethanol 20 % V/V</p> <p>b) Soft extract (DER 5-6 : 1), extraction solvent ethanol 60 %V/V</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal substance or herbal preparation in solid dosage forms or as herbal tea for oral use.</p> <p>Herbal substance for infusion for cutaneous 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>Indication 1)</p> <p>Traditional herbal medicinal product used in temporary loss of appetite.</p>

<sup>1</sup> The material complies with the Ph. Eur. monograph (ref.: 01/2008:1323 corrected 6.6).

<sup>2</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

Well-established use	Traditional use
	<p data-bbox="810 255 970 286"><b>Indication 2)</b></p> <p data-bbox="810 311 1423 412">Traditional herbal medicinal product for the symptomatic treatment of minor inflammations of the skin.</p> <p data-bbox="810 441 1423 542">The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

#### 4.2. Posology and method of administration

Well-established use	Traditional use
	<p data-bbox="810 732 938 763"><b>Posology</b></p> <p data-bbox="810 788 893 819"><i>Adults</i></p> <p data-bbox="810 844 928 875"><b>Oral use</b></p> <p data-bbox="810 900 1050 931">i) Herbal substance</p> <p data-bbox="810 956 1385 1023">Herbal substance for tea preparation : 1 to 6 g daily in divided doses</p> <p data-bbox="810 1048 1088 1079">ii) Herbal preparations</p> <p data-bbox="810 1104 1417 1171">a) Dry extract (4 : 1 ethanol 20 %V/V) : 295 mg 2 times daily</p> <p data-bbox="810 1196 1407 1263">b) Soft extract (5-6 : 1 ethanol 60 % V/V) : 500 mg 2 times daily</p> <p data-bbox="810 1288 1015 1319"><b>Cutaneous use</b></p> <p data-bbox="810 1344 1050 1375">i) Herbal substance</p> <p data-bbox="810 1400 1359 1500">Infusion for cutaneous use: 50 g / 250 ml of water. The still warm infusion is used in cataplasm.</p> <p data-bbox="810 1588 1423 1688">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 data-bbox="810 1713 1018 1744"><b>Duration of use</b></p> <p data-bbox="810 1769 963 1800"><b>Indication 1)</b></p> <p data-bbox="810 1825 1423 1971">If the symptoms persist more than two weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 1995 963 2027"><b>Indication 2)</b></p>

Well-established use	Traditional use
	<p>If the symptoms persist more than one week 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> <p>Cutaneous use.</p>

#### 4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s).

#### 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 is not recommended because of incomplete data on safety.</p> <p><b>Oral use</b></p> <p>Due to a possible hypoglycaemic effect of fenugreek, close monitoring of glycaemic control should be considered in patients treated for diabetes mellitus.</p>

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

Well-established use	Traditional use
	No reported interactions of clinical relevance.

#### 4.6. Pregnancy and lactation

Well-established use	Traditional use
	<p>There are no or limited data from use during pregnancy and lactation.</p> <p>Studies in animals have shown reproductive toxicity (see section 5.3 'Preclinical safety data').</p> <p>The use should be avoided during pregnancy and lactation.</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
	<p><b>Oral use</b></p> <p>Gastrointestinal disorders: flatulence, diarrhoea</p> <p>Nervous system disorders: dizziness</p> <p>The frequency is not known.</p> <p><b>Cutaneous use</b></p> <p>Allergic reactions have been observed after local application (facial angioedema, wheezing) or ingestion (asthma, allergic rhinitis). The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

#### 4.9. Overdose

Well-established use	Traditional use
	High doses (between 25 g and 100 g daily of debitterized powder of fenugreek seeds divided into two equal doses) have been reported to cause minor gastrointestinal symptoms such as diarrhoea and flatulence in 4 out of 10 cases.

## 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
	<p>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.</p> <p>Tests on genotoxicity have not been performed with preparations of fenugreek covered by this monograph.</p> <p>Decreased thyroid hormone levels (T3, tri iodothyronine) were reported in rodents treated with hydro-ethanolic extracts at 110 mg/kg/day and above; a NOAEL was not determined.</p> <p>Testicular toxicity (altered sperm parameters, decreased testis weight, lowered / arrest of spermatogenesis, and degenerating seminiferous tubules) was reported in rats treated for 2 to 3 months with either fenugreek seed powder or the steroidal fraction of seeds. These effects are attributed to the treatment-related decrease in testosterone, and a NOAEL was not determined.</p> <p>Conventional embryo-fetal and peri-post-natal toxicity studies were not performed. Limited studies showed conflicting results regarding the occurrence of malformations in rats.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

## 7. Date of compilation/last revision

6 May 2010