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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

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BG (bălgarski): Сминдух, семе CS (čeština): semeno pískavice řeckého sena DA (dansk): Bukkehornsfrø DE (Deutsch): Bockshornsamen EL (elliniká): EN (English): Fenugreek ES (espanol): Alholva, semilla de ET (eesti keel): põld-lambaläätse seeme FI (suomi): FR (français): Fenugrec (graine de) HU (magyar): Görögszénamag IT (italiano):	LT (lietuvių kalba): Ožragių sėklos LV (latviešu valoda): Grieķu siena trigonellas sēklas MT (malti): Żerriegħa tal-Fenugriek NL (nederlands): Fenegriekzaad PL (polski): Nasienie kozieradki PT (português): RO (română): sămânţă de schinduf SK (slovenčina): Semeno senovky gréckej SL (slovenščina): SV (svenska): Bockhornsklöver, frö *IS (íslenska)*: Grikkjasmári *NO (norsk)*: Bukkehornfrø

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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[1, 2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Trigonella foenum-graecum* L., semen (fenugreek) i) Herbal substance As defined in the Ph. Eur. monograph. ii) Herbal preparations a) Dry extract (DER 4:1), extraction solvent: ethanol 20% v/v b) Soft extract (DER 5-6:1), extraction solvent: ethanol 60% v/v

1 The material complies with the Ph. Eur. monograph (ref.: 01/2008:1323 corrected 6.6).
2 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal substance as herbal tea for oral use. Herbal preparation in solid dosage form for oral use. Herbal substance for infusion preparation for cutaneous 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
	Indication 1) Traditional herbal medicinal product used for temporary loss of appetite. Indication 2) Traditional herbal medicinal product for the symptomatic treatment of minor inflammations of the skin. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults and elderly* Indication 1) i) Herbal substance Herbal substance as a tea preparation: 1 to 6 g daily in divided doses. ii) Herbal preparations a) Dry extract: 295 mg, 2 times daily. b) Soft extract: 500 mg, 2 times daily.

Well-established use	Traditional use
	Indication 2) Herbal substance as an infusion preparation for cutaneous use: 50 g/250 ml of water. The still warm infusion is used in cataplasm. The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1) 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. Indication 2) 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. **Method of administration** Indication 1) Oral use. Indication 2) Cutaneous use.

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
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. Oral use Due to a possible hypoglycaemic effect of fenugreek, close monitoring of glycaemic control should be considered in patients treated for diabetes mellitus. For extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

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

Well-established use	Traditional use
	None reported.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	There are no or limited data from use during pregnancy and lactation. Studies in animals have shown reproductive toxicity (see section 5.3 'Preclinical safety data'). The use is not recommended during pregnancy and lactation.

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
	Oral use Gastrointestinal disorders: flatulence, diarrhoea may occur. Nervous system disorders: dizziness may occur. The frequency is not known. Cutaneous use Allergic reactions have been reported after local application (facial angioedema, wheezing) or ingestion (asthma, allergic rhinitis). The frequency is not known. 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
	High doses (between 25 g and 100 g daily of debitterised 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**
	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 have not been performed. Decreased thyroid hormone levels (T3, triiodothyronine) were reported in rodents treated with hydro-ethanolic extracts at 110 mg/kg/day and above; a NOAEL was not determined. 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; a NOAEL was not determined. Conventional embryo-foetal and peri- and postnatal toxicity studies were not performed. Limited studies showed conflicting results regarding the occurrence of malformations in rats.

6. Pharmaceutical particulars

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

7. Date of compilation/last revision

27 January 2011