



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Draft – Revision 1

<b>Initial assessment</b>	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	March 2010 May 2010
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	6 May 2010
End of consultation (deadline for comments).	15 September 2010
Re-discussion in MLWP	November 2010 January 2011
Adoption by HMPC Monograph (EMA/HMPC/146221/2010) AR (EMA/HMPC/146220/2010) List of references (EMA/HMPC/146222/2010) Overview of comments received during the public consultation (EMA/HMPC/729635/2021) HMPC Opinion (EMA/HMPC/M/H/0088)	27 January 2011
<b>Revision</b>	
Discussion in HMPC	Jul 2019 Sep 2020 Nov 2020 Jan 2021 Mar 2021
Adopted by HMPC for release for consultation	3 March 2021
Start of public consultation	15 April 2021
End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a> .	15 July 2021

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Trigonella foenum-graecum</i> L., semen; Trigonellae foenugraeci semen; Fenugreek
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BG (bulgarski): Сминдух, семе CS (čeština): semeno pískavice řeckého sena DA (dansk): Bukkehornsfrø DE (Deutsch): Bockshornsamen EL (elliniká): EN (English): Fenugreek ES (español): Alholva, semilla de ET (eesti keel): põld-lambaläätse seeme FI (suomi): FR (français): Fenugrec (graine de) HR (hrvatski): 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): Fenogrego, sementes RO (română): sămânță de schinduf SK (slovenčina): Semeno senovky gréckej SL (slovenščina): SV (svenska): Bockhornsklöver, frö IS (íslenska): Grikkjasmári NO (norsk): Bukkehornfrø
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# European Union 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>As defined in the Ph. Eur. monograph.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Powdered herbal substance</p> <p>c) Dry extract (DER 4:1), extraction solvent: ethanol 20% V/V</p> <p>d) 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 comminuted herbal substance as herbal tea for oral use.</p> <p>Herbal preparations in solid dosage forms for oral use.</p> <p>Herbal substance or powdered herbal substance for infusion for cutaneous use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</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 Ph. Eur. monograph (ref.: 01/2008:1323 corrected 6.6).*

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product used for temporary loss of appetite.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for the symptomatic treatment of minor inflammations of the skin.</p> <p>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<sup>3</sup>

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><i>Adults and elderly</i></p> <p>Indication 1)</p> <p>i) Herbal substance</p> <p><u>Herbal tea</u>: 1-6 g daily of the herbal substance in 250 ml of boiling water before meals</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p><u>Comminuted herbal substance</u>: 2 g with liquid 3 times daily, before meals</p> <p><u>Macerate</u>: 0.5 g comminuted herbal substance macerated in 150 ml cold water for 3 h; strain. Drink 3 times daily</p> <p>b) Powdered herbal substance</p> <p>Single dose: 380-1100 mg, 3 times daily</p> <p>Daily dose: 1140-3300 mg</p> <p>c) Dry extract</p>

<sup>3</sup> For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).>

Well-established use	Traditional use
	<p>Single dose: 295 mg, 2 times daily.</p> <p>Daily dose: 590 mg</p> <p>d) Soft extract</p> <p>Single dose: 500 mg, 2 times daily.</p> <p>Daily dose: 1 g</p> <p><b>Indication 2)</b></p> <p>Herbal substance or powdered herbal substance for infusion for cutaneous use: 50 g of in 250 ml of water, 2-3 times daily.</p> <p>The still warm infusion is used in cataplasm over the affected areas.</p> <p><b>Indication 1) and 2)</b></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><b>Duration of use</b></p> <p><b>Indication 1)</b></p> <p>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><b>Indication 2)</b></p> <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><b>Indication 1)</b></p> <p>Oral use.</p> <p><b>Indication 2)</b></p> <p>Cutaneous use.</p>

### 4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance, peanut,

Well-established use	Traditional use
	soya, and to other plants of the Fabaceae (legume) family. <sup>4</sup>

#### **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 has not been established due to lack of adequate safety data.</p> <p>Oral use Due to a possible hypoglycaemic effect of fenugreek, close monitoring of glycaemic control should be considered in patients treated for diabetes mellitus.</p> <p>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.</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
	There are no or limited data from use during pregnancy and lactation. Studies in animals have shown reproductive toxicity including male and female fertility (see section 5.3 'Preclinical safety data'). The use during pregnancy and lactation and in women of childbearing potential not using contraception is not recommended.

<sup>4</sup> In accordance with the 'Public statement on the allergenic potency of herbal medicinal products containing soya or peanut protein' (EMA/HMPC/138139/2005)

#### 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>Oral use</p> <p>Gastrointestinal disorders: flatulence, diarrhoea may occur.</p> <p>Nervous system disorders: dizziness may occur. The frequency is not known.</p> <p>Oral use and cutaneous use</p> <p>Allergic reactions have been reported 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 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>Decreased thyroid hormone levels (T3, triiodothyronine) were reported in rodents treated with hydro-ethanolic extracts at 110 mg/kg per day and above; a NOAEL was not determined.</p> <p>Adequate studies on reproductive toxicity have not been performed. However, testicular toxicity and decreased fertility have been reported in studies with high doses of fenugreek seed in mice, rats, and rabbits. In studies in rats and mice with high doses of fenugreek seed, embryo resorption, foetal death, growth retardation, malformations, and altered neurobehavioral performance have been reported.</p> <p>Tests on genotoxicity and carcinogenicity have not been performed.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

## 7. Date of compilation/last revision

3 March 2021