



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 November 2021
EMA/HMPC/179591/2018
Committee on Herbal Medicinal Products (HMPC)

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

Final – Revision 1

Initial assessment	
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	06 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) Assessment Report (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
Revision	
Discussion in HMPC	July 2019 September 2020 November 2020 January 2021 March 2021
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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): Гръцки сминдух, семе	LT (lietuvių kalba): Vaistinių ožragių sėklos
CS (čeština): semeno pískavice řeckého sena	LV (latviešu valoda): Grieku siena trigonellas sēklas
DA (dansk): Bukkehornsfrø	MT (Malti): żerriegħa tal-fenugriek
DE (Deutsch): Bockshornsamen	NL (Nederlands): Fenegriek
EL (elliniká): σπέρμα τριγωνίσκου	PL (polski): Nasienie kozieradki
EN (English): Fenugreek	PT (português): alforvas
ES (español): alholva, semilla de	RO (română): sămânță de schinduf
ET (eesti keel): põld-lambaläätse seeme	SK (slovenčina): semeno senovky gréckej
FI (suomi): sarviapila, siemen	SL (slovenščina): seme mnogosemenskega triplata
FR (français): fenugrec (graine de)	SV (svenska): bockhornsklöver, frö
HR (hrvatski): sjeme grčke piskavice	IS (íslenska): Grikkjasmári
HU (magyar): Görögszénamag	NO (norsk): bukkehornfrø
IT (italiano): Fieno greco seme	

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^{1, 2}

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC</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>

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 Ph. Eur. monograph (ref.: 1323).

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p data-bbox="810 405 967 432">Indication 1)</p> <p data-bbox="810 461 1358 524">Traditional herbal medicinal product used for temporary loss of appetite.</p> <p data-bbox="810 553 967 580">Indication 2)</p> <p data-bbox="810 609 1406 710">Traditional herbal medicinal product used for the symptomatic treatment of minor inflammations of the skin.</p> <p data-bbox="810 739 1350 840">The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p data-bbox="810 1030 935 1057">Posology</p> <p data-bbox="810 1086 1031 1113"><i>Adults and elderly</i></p> <p data-bbox="810 1142 967 1169">Indication 1)</p> <p data-bbox="810 1198 1046 1225">i) Herbal substance</p> <p data-bbox="810 1254 1382 1317">Herbal tea: 1-6 g daily of the herbal substance in 250 ml of boiling water, before meals</p> <p data-bbox="810 1346 1086 1373">ii) Herbal preparations</p> <p data-bbox="810 1402 1214 1429">a) Comminuted herbal substance</p> <p data-bbox="810 1458 1326 1520">Comminuted herbal substance: 1-2 g with liquid, 3 times daily, before meals</p> <p data-bbox="810 1550 1382 1657">Macerate: 0.5 g comminuted herbal substance macerated in 150 ml cold water for 3 hours; strain. Drink 3 times daily</p> <p data-bbox="810 1686 1177 1713">b) Powdered herbal substance</p> <p data-bbox="810 1742 1310 1769">Single dose: 380-1100 mg, 3 times daily</p> <p data-bbox="810 1798 1134 1825">Daily dose: 1140-3300 mg</p> <p data-bbox="810 1854 983 1881">c) Dry extract</p>

³ 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>Indication 2)</p> <p>Herbal substance or powdered herbal substance for infusion for cutaneous use: 50 g 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>Indication 1) and 2)</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>Indication 1)</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>Indication 2)</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>Method of administration</p> <p>Indication 1)</p> <p>Oral use.</p> <p>Indication 2)</p> <p>Cutaneous use.</p>

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance, peanut, soya, and to other plants of the Fabaceae (legume) family ⁴ .

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><i>Oral use</i></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> <p>For extracts containing ethanol, the appropriate warning for ethanol, taken from the 'Annex to the European Commission guideline on excipients in the labelling 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
	<p>There are no or limited data from use during pregnancy and lactation.</p> <p>Studies in animals have shown reproductive toxicity including male and female fertility (see section 5.3 'Preclinical safety data').</p> <p>The use during pregnancy and lactation and in women of childbearing potential not using</p>

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

Well-established use	Traditional use
	contraception is not recommended.

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><i>Oral use</i> Gastrointestinal disorders: flatulence, diarrhoea may occur. Nervous system disorders: dizziness may occur. The frequency is not known.</p> <p><i>Oral use and cutaneous use</i> 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 of powder of fenugreek seeds divided into two equal daily 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.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

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, 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 no-observed-adverse-effect-level (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

24 November 2021