



27 January 2011  
EMA/HMPC/729635/2010  
Committee on Herbal Medicinal Products (HMPC)

## Overview of comments received on Community herbal monograph on *Trigonella foenum-graecum* L., semen

**This document was valid from 27 January 2011 until 24 November 2021.**

Table 1: Organisations and/or individuals that commented on the draft Community herbal monograph on *Trigonella foenum-graecum* L., semen as released for public consultation on 6 May 2010 until 15 September 2010

	<b>Organisations and/or individuals</b>
1	ESCOP



Table 2: Discussion of comments

### General comments to draft document

Interested party	Comment and Rationale	Outcome
ESCOP	<p>We suggest, to add a third indication (“Adjuvant use for mild forms of non-insulin dependent diabetes mellitus, NIDDM”) to section 4.1, with an associated posology adaptation in section 4.2, for internal and traditional use of fenugreek.</p> <p><b>General comment:</b></p> <p>As glucose-lowering effects of constituents of fenugreek seeds were already investigated as early as 1967 (4), the diabetes-associated indication or metabolic abnormalities associated with undiagnosed diabetes, appear to relate to an existing traditional use of fenugreek for this indication. In our opinion, the use as an adjuvant in patients already treated with other hypoglycaemic/antidiabetic drugs (not Insulin), is plausible on the basis of human experience and long-standing use and may therefore be considered as traditional (1, 2, 3 and 5). It is clear that a doctor or a qualified health care practitioner should monitor glycaemic control in these patients, as is already mentioned in §4.4 of the community herbal monograph (precautions for use).</p>	See below.

### SPECIFIC COMMENTS ON TEXT

Section number and heading	Interested party	Comment and Rationale	Outcome
4.1 Therapeutic indications Traditional use	ESCOP	<p>We suggest adding a third indication (shown below), because several clinical studies in humans (references 1, 2, 3, reviewed in reference 5) as well as pharmacological studies in animals were conducted to support this third indication. This is not a “regular” traditional-use indication. However, because these</p>	<p>We do not agree with the ESCOP proposal to add an indication as "an adjuvant for mild forms of non-insulin dependent diabetes mellitus, NIDDM" for the two main reasons:</p> <ul style="list-style-type: none"> <li>- the studies submitted are insufficient and not relevant</li> </ul>

		<p>clinical studies were done with small patient numbers and partly lacked information concerning the design, they appeared not to qualify fully for an established-use indication, according to the HMPC assessment report. The studies did provide safety information and clearly documented the use in humans. Moreover the fenugreek preparations were administered together with established anti-diabetic drugs.</p> <p><b>Proposed change, addition:</b> Indication 3) Traditional herbal medicinal product used as an adjuvant in the treatment of mild forms of non-insulin-dependent diabetes mellitus (NIDDM).</p>	<p>as no adequate demonstration of an effect on glycaemic control has been shown with fenugreek, - no product containing fenugreek is currently indicated as adjuvant for mild forms of non-insulin dependent diabetes mellitus, NIDDM although this is a mandatory condition (traditional use in one European country since 30 years in this indication) to grant this indication.</p> <p>Moreover, diabetes mellitus is not suitable for self-treatment with a Traditional Herbal Medicinal Product.</p>
<p>4.2 Posology and method of administration Traditional use</p>	<p>ESCOMP</p>	<p><b>Comments to posology for Indication 3):</b> The dose of 25 g daily of powdered herbal substance, together with an antidiabetic drug, was documented in a small clinical trial (2). The dose of 1 g daily of a hydroalcoholic extract of fenugreek (approx. 80% of patients received an antidiabetic drug) was documented in a small controlled randomised double-blind trial (3) and is already integrated in § 4.2. ii) b) of this monograph.</p> <p><b>Proposed change, addition:</b> Herbal substance ..... Herbal substance in food: up to 25g daily in divided doses.</p> <p><b>Proposed change, addition:</b> <b>Duration of use</b> <i>Indication 3)</i> During treatment, a doctor or a qualified health care practitioner should monitor glycaemic control.</p>	<p>As a consequence of our above mentioned comment for the 4.1 section, we then do not agree with the ESCOP proposal to add to a specific posology for the requested indication "adjuvant for mild forms of non-insulin dependent diabetes mellitus, NIDDM".</p>

#### REFERENCES:

1. Sharma RD, Raghuram TC. Hypoglycaemic effect of fenugreek seeds in non-insulin dependent diabetic subjects. *Nutr Res* 1990;10:731-39.
2. Raghuram TC, Sharma RD, Sivakumar B, Sahay BK. Effect of fenugreek seeds on intravenous glucose disposition in non-insulin dependent diabetic patients. *Phytotherapy Res* 1994;8:83-6.
3. Gupta A, Gupta R, Lal B. Effect of *Trigonella foenum-graecum* (Fenugreek) seeds on glycaemic control and insulin resistance in type 2 diabetes mellitus: a double blind placebo controlled study. *J Assoc Physicians India* 2001;49:1057-61.
4. Mishkinsky J, Joseph B, Sulman FG, Goldschmied A. Hypoglycaemic effect of trigonelline. *Lancet* 1967;2:1311-2.
5. Basch E, Ulbricht C, Kuo G, Szapary P, Smith M. Therapeutic applications of fenugreek (review). *Alternative Med Review* 2003;8:20-7.