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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

FINAL

COMMUNITY HERBAL MONOGRAPH ON *FOENICULUM VULGARE* MILLER SUBSP. *VULGARE* VAR. *DULCE* (MILLER) THELLUNG, FRUCTUS

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COMMUNITY HERBAL MONOGRAPH ON *FOENICULUM VULGARE* MILLER SUBSP. *VULGARE* VAR. *DULCE* (MILLER) THELLUNG, FRUCTUS

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 *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung, fructus (Fennel, Sweet) i) Herbal substance Dried fennel, sweet ii) Herbal preparations Dried fennel, sweet, comminuted

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Herbal substance or herbal preparation in solid dosage forms or as herbal tea for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

[1] The material complies with the Ph. Eur. monograph (ref. 01/2005:0825).

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	a) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating, and flatulence. b) Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstrual periods. c) Traditional herbal medicinal product used as an expectorant in cough associated with cold. 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* Single dose 1.5 to 2.5 g (freshly[3]) comminuted fennel fruits with 0.25 l of boiling water (brew for 15 minutes) three times daily as a herbal tea. Fennel powder: 400 mg 3 times a day (with a maximum of 2 g daily) *Adolescents over 12 years of age,* Indication a) Adult dose *Children between 4 and 12 years of age,* Indication a) Average daily dose 3-5 g of (freshly[3]) comminuted fruits as a herbal tea, in three divided doses, for short-term use in mild transitory symptoms only (less than one week) The use is not recommended in children under 4 years of age (see section 4.4 Special warnings and precautions for use).

[3] For commercial preparation of crushed fennel fruits the applicant must carry out appropriate stability testing related to the content of essential oil components.

Well-established use	Traditional use
	Duration of use *Adults* *Adolescents over 12 years of age,* Indication a) Not to be taken for more than 2 weeks. *Children between 4 and 12 years of age,* Indication a) For short-term use in mild transitory symptoms only (less than one week). If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to Apiaceae (Umbelliferae) (**aniseed, caraway, celery, coriander and dill)** or to anethole.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use is not recommended in children under 4 years of age due to the lack of adequate data and paediatrician advice should be sought.

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 data from the use of fennel fruit in pregnant patients. It is unknown if fennel constituents are excreted in human breast milk. In the absence of sufficient data, the use during pregnancy and lactation 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
	Allergic reactions to fennel, affecting the skin or the respiratory system, may occur. 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
	No case of overdose has been reported.

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. A fennel aqueous extract was tested in an Ames test on *Salmonella typhimurium* strains TA98, TA100 and turned out as negative. Results from studies carried out in laboratory animals showed a weak mutagenic activity of anethole. The genotoxic risk[4] related to estragole is not considered to be relevant in the specified conditions of use due to the small amount present in herbal infusions prepared from fennel.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

5 July 2007

[4] Please refer to the HMPC 'Public statement on the use of herbal medicinal products containing estragole' (EMEA/HMPC/137212/2005).