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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. *VULGARE*, AETHEROLEUM

AGREED BY WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	25 October 2006
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COMMUNITY HERBAL MONOGRAPH ON *FOENICULUM VULGARE* MILLER SUBSP. *VULGARE* VAR. *VULGARE*, AETHEROLEUM

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 i) Herbal substance Not applicable ii) ii) Herbal preparations *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, aetheroleum (Bitter fennel fruit, oil)

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Herbal preparation in solid or liquid dosage forms for oral 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
	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 indication exclusively based upon long-standing use.

[1] The material complies with the Ph. Eur. monograph (.ref. 01/2005:1826)

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

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults, elderly* 200 microliters of essential oil, as a single dose per day or in multiple divided doses. The use in children and adolescents under 18 years of age is contraindicated (see section 4.3 Contraindications). **Duration of use** Not to be taken for more than two weeks. 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, dill)** or to anethole. Children and adolescents under 18 years of age because of the lack of data and because of the presence of estragole.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Because of its oestrogenic activity, excessive doses of fennel oil may affect hormone therapy, oral contraceptive pill and hormone replacement therapy (see sections 4.5 Interactions with other medicinal products and other forms of interaction and 5.3 Preclinical safety data).

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

Well-established use	Traditional use
	Excessive doses of preparations containing fennel oil may affect hormone therapy or oral contraception (see section 4.4 Special warnings and precautions for use). If the patient is on other medications he/she should seek medical advice (see section 4.4 Special warnings and precautions for use).

4.6. Pregnancy and lactation

Well-established use	Traditional use
	There are no data from the use of fennel oil in pregnant patients. It is unknown if fennel oil 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 oil, 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. Data on estrogenic activity of trans-anethole and an acetonic extract of fennel and of antifertility activity of trans-anethole demonstrated in vitro and in laboratory animals at high concentrations are not considered relevant to human exposure given the recommended posology and conditions of use. Fennel oil was found to be mutagenic. Results from studies carried out in laboratory animals showed a weak mutagenic activity of anethole. Estragole is a constituent of fennel oil. Several studies have shown the carcinogenic effects of estragole and some of its metabolites in mice (mainly malignant liver tumors)[3].

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

5 July 2007

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