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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

FINAL

**COMMUNITY HERBAL MONOGRAPH ON *FOENICULUM VULGARE* MILLER SUBSP.
VULGARE VAR. *VULGARE*, FRUCTUS**

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	May 2006 September 2006 October 2006
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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monograph; traditional use; <i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>vulgare</i> ; Foeniculi amari fructus; bitter fennel fruit
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**COMMUNITY HERBAL MONOGRAPH ON *FOENICULUM VULGARE* MILLER SUBSP.
VULGARE VAR. *VULGARE*, FRUCTUS**

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION^{1,2}

<u>Well-established use</u>	<u>Traditional use</u>
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended.</p> <p><i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>vulgare</i>), fructus (Fennel, Bitter)</p> <p>i) Herbal substance Dried fennel, bitter</p> <p>ii) Herbal preparations Dried fennel, bitter, comminuted</p>

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Herbal substance or herbal preparation as herbal tea for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

¹ The material complies with the Ph. Eur. monograph (ref. 01/2005:0824).

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

<u>Well-established use</u>	<u>Traditional use</u> 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.
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4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u> Posology <i>Adults</i> Single dose 1.5 to 2.5 g of (freshly ³) comminuted fennel fruits with 0.25 l of boiling water (brew for 15 minutes) three times daily as a herbal tea. <i>Adolescents over 12 years of age, Indication a)</i> Adult dose <i>Children between 4 and 12 years of age, Indication a)</i> 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).
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³ For commercial preparation of crushed fennel fruits the applicant must carry out appropriate stability testing related to the content of essential oil components.

<u>Well-established use</u>	<u>Traditional use</u> Duration of use <i>Adults</i> <i>Adolescents over 12 years of age, Indication a)</i> Not to be taken for more than 2 weeks. <i>Children between 4 and 12 years of age, Indication a)</i> 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.
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4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u> Hypersensitivity to the active substance and its preparations or to Apiaceae (Umbelliferae) (aniseed, caraway, celery, coriander and dill) or to anethole.
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4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u> 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.
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4.5. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u> None reported.
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4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u> 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.
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4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u> No studies on the effect on the ability to drive and use machines have been performed.
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4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u> 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.
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4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u> No case of overdose has been reported.
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5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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5.2. Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u> 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 <i>Salmonella typhimurium</i> 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.
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6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u> Not applicable.
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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).