



London, 5 July 2007
Doc. Ref: EMEA/HMPC/263273/2006

This document was valid from July 2007 until November 2013. It is now superseded by a [new version](#) adopted by the HMPC on 12 November 2013 and published on the EMA website.

FINAL

COMMUNITY HERBAL MONOGRAPH ON *PIMPINELLA ANISUM* L., AETHEROLEUM

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	May 2006 September 2006
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	7 September 2006
END OF CONSULTATION (DEADLINE FOR COMMENTS)	2 January 2007
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	July 2007
ADOPTION BY HMPC	5 July 2007

KEYWORDS	Herbal medicinal products; HMPC; Community herbal monograph; traditional use; <i>Pimpinella anisum</i> L.; Anisi aetheroleum; anise oil
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COMMUNITY HERBAL MONOGRAPH ON *PIMPINELLA ANISUM* L., AETHEROLEUM

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) Herbal substance Not applicable</p> <p>ii) Herbal preparations <i>Pimpinella anisum</i> L., aetheroleum (anise oil)</p>

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Herbal preparation in solid or liquid dosage forms 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. 01/2005:0804 corrected 5.0)

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 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> <i>Adults, elderly</i> Indications a) and b) 50-200 microliters of anise oil, three times daily. The use in children and adolescents 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.
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4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u> Hypersensitivity to the active substance or to Apiaceae (Umbelliferae) (fennel, caraway, celery, coriander and dill) or to anethole. Children and adolescents because of the lack of data and because of the presence of estragole.
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4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u> Not applicable.
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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 anise oil in pregnant patients. It is unknown if anise oil 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 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> Ingestion of 1 to 5 milliliters of anise oil has been associated with nausea, vomiting, seizures and pulmonary oedema.
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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.

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.

5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u>
	<p>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.</p> <p>Data on estrogenic activity and 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.</p> <p>Results from non-clinical studies showed a weak mutagenic potential of anethole.</p> <p>Estragole is a constituent of anise oil. Several studies have shown the carcinogenic effects of estragole and some of its metabolites in mice (mainly malignant liver tumors)³.</p>

6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u>
	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' (EMA/HMPC/137212/2005).