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This document was valid from July 2007 until November 2013. It is now superseded by a <u>new version</u> 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
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ADOPTION BY HMPC	5 July 2007

KEYWORDS		Herbal medicinal products; HMPC; Community herbal monograph; traditional
	\neg	use: Pimpinella anisum L.: Anisi aetheroleum: anise oil

COMMUNITY HERBAL MONOGRAPH ON PIMPINELLA ANISUM L., AETHEROLEUM

1. NAME OF THE MEDICINAL PRODUCT

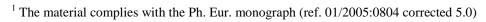
To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION 1,2

Well-established use	<u>Traditional use</u>
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended
	i) Herbal substance Not applicable
	ii) Herbal preparations *Pimpinella anisum L., aetheroleum (anise 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.



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

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4. CLINICAL PARTICULARS

4.1. Therapeutic indications

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.

4.2. Posology and method of administration

Well-established use	<u>Traditional use</u>
	Adults, elderly
	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.

4.3. Contraindications

Well-established use	<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

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

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

Well-established use	<u>Traditional use</u>	
	None reported.	

4.6. Pregnancy and lactation

Well-established use	Traditional use
	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.

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 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	<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

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

5.2. Pharmacokinetic properties

Well-established use	<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

Well-established use	<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.
	Determine the second section of the
	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.
	of use.
	Results from non-clinical studies showed a weak
	mutagenic potential of anethole.
	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 .

6. PHARMACEUTICAL PARTICULARS

Well-established use	<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' (EMEA/HMPC/137212/2005).

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