



12 November 2013
EMA/HMPC/321185/2012
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Pimpinella anisum* L., aetheroleum

Final

Initial assesement	
Discussion in Working Party on Community monographs and Community list (MLWP)	May 2006 September 2006
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	7 September 2006
End of consultation (deadline for comments).	2 January 2007
Rediscussion in MLWP	July 2007
Adoption by HMPC Monograph (EMA/HMPC/263273/2006) AR (EMA/HMPC/137421/2006) List of references (EMA/HMPC/359388/2006) Overview of comments received during the public consultation (EMA/HMPC/286756/2007) HMPC Opinion (EMA/HMPC/286986/2007)	5 July 2007
First systematic review	
Discussion in MLWP	May 2012 September 2012 November 2012 September 2013
Adoption by HMPC for release for consultation	N/A
End of consultation (deadline for comments)	N/A
Rediscussion in MLWP	N/A
Adoption by HMPC	12 November 2013

A search for the versions adopted in July 2007 can be made via the EMA document search function, using the documents' reference number, at:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/landing/document_library_search.jsp&mid=

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Pimpinella anisum</i> L., aetheroleum; Anisi aetheroleum; anise oil
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<p>BG (bългарski): Анасоново масло</p> <p>CS (čeština): anýzová silice</p> <p>DA (dansk): Anisolie</p> <p>DE (Deutsch): Anisöl</p> <p>EL (elliniká): έλαιο ανίσου του ασπεροειδούς-αιθέριο έλαιο ανίσου</p> <p>EN (English): Anise Oil</p> <p>ES (español): Anís, aceite esencial de</p> <p>ET (eesti keel): aniisiõli</p> <p>FI (suomi): anisöljy</p> <p>FR (français): Anis (huile essentielle d')</p> <p>HR (hrvatska): anišev plod</p> <p>HU (magyar): Ánizsolaj</p> <p>IT (italiano): Anice (Anice verde), essenza</p>	<p>LT (lietuvių kalba): Anyžių eterinis aliejus</p> <p>LV (latviešu valoda): Anīsa ēteriskā eļļa</p> <p>MT (malti): Żejt tal-Anisi</p> <p>NL (nederlands): Anijsolie</p> <p>PL (polski): Olejek eteryczny anyżowy</p> <p>PT (português): Óleo essencial de anis</p> <p>RO (română): ulei volatil de anason</p> <p>SK (slovenčina): Anízová silica</p> <p>SL (slovenščina): eterično olje janeža</p> <p>SV (svenska): Anisolja</p> <p><i>IS (íslenska):</i></p> <p><i>NO (norsk): Anisolje</i></p>
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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}

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

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastrointestinal complaints including bloating and flatulence. Indication 2)

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

² The material complies with the Ph. Eur. monograph (ref. 01/2008:0804 corrected 7.0)

Well-established use	Traditional use
	<p>Traditional herbal medicinal product used as an expectorant in cough associated with cold.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration

Well-established use	Traditional use
Posology	<p>Posology</p> <p>Indications 1) and 2)</p> <p><i>Adult and Elderly</i></p> <p>Single dose</p> <p>50-200 microliters of anise oil, three times daily.</p> <p>The use in children and adolescents under 18 years of age is contraindicated (see section 4.3 Contraindications).</p> <p>Duration of use</p> <p>Not to be taken for more than two weeks.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance and to other plants of the Apiaceae (Umbelliferae) family (fennel, caraway, celery, coriander and dill) or to anethole.</p> <p>Children and adolescents under 18 years of age because of the lack of data and the presence of estragole.</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

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

Well-established use	Traditional use
	None reported.

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. No fertility data available.

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	Traditional use
	Ingestion of 1 to 5 millilitres of anise oil has been associated with nausea, vomiting, seizures and

Well-established use	Traditional use
	pulmonary oedema.

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
	<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 at high concentrations demonstrated <i>in vitro</i> and in laboratory animals are not considered relevant to human exposure given the recommended posology and conditions of use (short term use in adults and elderly).</p> <p>Results from non-clinical studies showed a weak mutagenic potential of anethole. Anethole and its metabolites are unlikely to be genotoxic <i>in vivo</i>.</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. The content of estragole in anise oil is not of concern in adults and elderly, because the intake with traditional herbal medicinal products, given the specified condition of use (short term use), can be considered negligible compared to the background exposure via foods and beverages containing</p>

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

Well-established use	Traditional use
	anise.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

12 November 2013