



12 November 2013
EMA/HMPC/321184/2012
Committee on Herbal Medicinal Products (HMPC)

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

Final

| Initial assessment | |
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| 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/137423/2006) AR (EMA/HMPC/137421/2006) List of references (EMA/HMPC/359388/2006) Overview of comments received during the public consultation (EMA/HMPC/286755/2007) HMPC Opinion (EMA/HMPC/286974/2007) | 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=

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| Keywords | Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Pimpinella anisum</i> L, fructus; Anisi fructus; aniseed |
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| BG (bългарski): Анасон, плод | LT (lietuvių kalba): Anyžių sėklos |
| CS (čeština): Anýzový plod | LV (latviešu valoda): Anīsa auglis |
| DA (dansk): Anisfrø | MT (malti): Frotta tal-Anisi |
| DE (Deutsch): Anis | NL (nederlands): Anijszaad |
| EL (elliniká): Γλυκάνισο - καρπός ανίσου | PL (polski): Owoc anyżu |
| EN (English): Aniseed | PT (português): Anis verde, fruto |
| ES (español): Anís, fruto de | RO (română): Fruct de anason |
| ET (eesti keel): Aniis | SK (slovenčina): Anízový plod |
| FI (suomi): Anis | SL (slovenščina): Plod vrtnega janeža |
| FR (français): Anis (fruit d') | SV (svenska): Anisfrö |
| HR (hrvatska) : anišev plod | IS (íslenska): Anís |
| HU (magyar): Ánizsmag | NO (norsk): Anis |
| IT (italiano): Anice (Anice verde), frutto | |

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

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 Dried aniseed ii) Herbal preparations Dried aniseed, comminuted or crushed |

3. Pharmaceutical form

| Well-established use | Traditional use |
|----------------------|---|
| | Herbal substance or herbal preparation as herbal tea 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. |

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. 01/2012:0262).

| Well-established use | Traditional use |
|----------------------|--|
| | <p data-bbox="810 255 967 286">Indication 2)</p> <p data-bbox="810 315 1390 383">Traditional herbal medicinal product used as an expectorant in cough associated with cold</p> <p data-bbox="810 412 1422 510">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 administration³

| Well-established use | Traditional use |
|----------------------|---|
| | <p data-bbox="810 696 938 728">Posology</p> <p data-bbox="810 757 1066 788">Indications 1) and 2)</p> <p data-bbox="810 817 1417 848"><i>Adolescents over 12 years of age, adults, elderly:</i></p> <p data-bbox="810 878 954 909">Single dose</p> <p data-bbox="810 938 1382 1037">Herbal tea: 1 to 3.5 g of the whole or (freshly) comminuted or crushed aniseed in 150 ml of boiling water as a herbal infusion 3 times daily</p> <p data-bbox="810 1066 1426 1196">The use in children under 12 years of age is not recommended (see section 4.4 Special warnings and precautions for use and section 5.3 Preclinical safety data).</p> <p data-bbox="810 1225 1018 1256">Duration of use</p> <p data-bbox="810 1285 1302 1317">Not to be taken for more than two weeks.</p> <p data-bbox="810 1346 1398 1444">If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 1473 1145 1505">Method of administration</p> <p data-bbox="810 1534 919 1565">Oral use.</p> |

4.3. Contraindications

| Well-established use | Traditional use |
|----------------------|--|
| | <p data-bbox="810 1736 1362 1839">Hypersensitivity to the active substance or to Apiaceae (Umbelliferae) (caraway, celery, coriander, dill and fennel) or to anethole.</p> |

³ For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

4.4. Special warnings and precautions for use

| Well-established use | Traditional use |
|-----------------------------|--|
| | <p>The use in children under 12 years of age has not been established due to lack of adequate data for safety assessment (see section 5.3 Preclinical safety data).</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> |

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 |
|-----------------------------|--|
| | <p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p> |

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 |
|-----------------------------|---|
| | <p>Allergic reactions to aniseed affecting the skin or the respiratory system may occur. The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p> |

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 |
|----------------------|--|
| | <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>An aniseed extract prepared with water was tested in an Ames test on <i>Salmonella typhimurium</i> strains TA98, TA100, TA102 and turned out as negative.</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>The genotoxic risk⁴ related to estragole is not considered to be relevant in the specified conditions of use (short term use in adolescents, adults and elderly) due to the small amount present in herbal infusions prepared from aniseed.</p> |

⁴ Please refer to the HMPC 'Public statement on the use of herbal medicinal products containing estragole' (EMA/HMPC/137212/2005).

6. Pharmaceutical particulars

| Well-established use | Traditional use |
|----------------------|-----------------|
| | Not applicable. |

7. Date of compilation/last revision

12 November 2013