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EMA/HMPC/372839/2016
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Mill.) Batt. & Trab., fructus

Draft – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	25 October 2006
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	26 October 2006
End of consultation (deadline for comments).	28 February 2007
Rediscussion in MLWP	May 2007 July 2007
Adoption by HMPC Monograph (EMA/263293/2006) Assessment Report (EMA/HMPC/137426/2006) List of references (EMA/HMPC/456740/2006) Overview of comments received during the public consultation (EMA/HMPC/200856/2007) HMPC Opinion (EMA/HMPC/280074/2007)	5 July 2007
First systematic revision	
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End of consultation (deadline for comments). Comments should be provided using this [template](#) to hmpc.secretariat@ema.europa.eu.

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Keywords

Herbal medicinal products; HMP; European Union herbal monographs; traditional use; *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Mill.) Batt. & Trab.; *Foeniculi dulcis fructus*; Sweet fennel

BG (bulgarski): Сладко резене, плод
CS (čeština): plod fenyklu obecného sladkého
DA (dansk): Fennikel, sød
DE (Deutsch): Süßer Fenchel
EL (elliniká): μαραθου γλυκου καρπος
EN (English): Sweet fennel
ES (español): hinojo dulce, fruto de
ET (eesti keel): magusa apteegitilli vili
FI (suomi): makeafenkoli, siemen
FR (français): fenouil doux (fruit de)
HR (hrvatski): plod slatkog komorača
HU (magyar): édeskömény termés
IT (italiano): Finocchio dolce (o romano), frutto

LT (lietuvių kalba): Saldieji pankolių vaisiai
LV (latviešu valoda): Saldā fenheļa augļi
MT (Malti): frotta tal-busbies ħelu
NL (Nederlands): Zoete Venkel
PL (polski): Owoc kopru włoskiego (odmiany słodkiej)
PT (português): funcho doce, fruto
RO (română): fruct de fenicul dulce
SK (slovenčina): plod fenikla sladkého
SL (slovenščina): plod sladkega navadnega komarčka
SV (svenska): sötfänkål, frö
IS (íslenska): Sæt fennel aldin
NO (norsk): søt fennikel

European Union herbal monograph on *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Mill.) Batt. & Trab., 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 <i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>dulce</i> (Mill.) Batt. & Trab., fructus (Sweet fennel) i) Herbal substance Fresh or dry fruit ii) Herbal preparations Not applicable

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal substance 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.: 04/2011:0825).

Well-established use	Traditional use
	<p data-bbox="810 255 967 286">Indication 2)</p> <p data-bbox="810 311 1294 416">Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstrual periods.</p> <p data-bbox="810 441 967 472">Indication 3)</p> <p data-bbox="810 497 1390 562">Traditional herbal medicinal product used as an expectorant in cough associated with cold.</p> <p data-bbox="810 586 1422 694">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="810 882 935 913">Posology</p> <p data-bbox="810 938 1070 969">Indications 1) and 3)</p> <p data-bbox="810 994 1091 1025"><i>Adults and adolescents</i></p> <p data-bbox="810 1050 954 1081">Single dose</p> <p data-bbox="810 1106 1426 1211">Herbal tea: 1.5 g of herbal substance in 250 ml of boiling water (steep for 15 minutes) as a herbal infusion 3 times daily.</p> <p data-bbox="810 1236 1018 1267">Daily dose: 4.5 g</p> <p data-bbox="810 1292 1299 1323"><i>Children between 4 and 12 years of age</i></p> <p data-bbox="810 1348 954 1379">Single dose</p> <p data-bbox="810 1404 1401 1509">Herbal tea: 1.0 g of the herbal substance in 100 ml boiling water (steep for 15 minutes) as a herbal infusion, 3 times daily.</p> <p data-bbox="810 1534 1018 1565">Daily dose: 3.0 g</p> <p data-bbox="810 1590 1385 1695">For further information on the use in children between 4 and 12 years of age see section 4.4 'Special warnings and precautions for use'.</p> <p data-bbox="810 1720 1406 1825">The use is not recommended in children under 4 years of age (see section 4.4 'Special warnings and precautions for use').</p> <p data-bbox="810 1850 1278 1881">See section 6 for content of estragole.</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).

Well-established use	Traditional use
	<p data-bbox="810 255 970 286">Indication 2)</p> <p data-bbox="810 311 1093 342"><i>Adults and adolescents</i></p> <p data-bbox="810 367 954 398">Single dose</p> <p data-bbox="810 423 1426 528">Herbal tea: 1.5 g of herbal substance in 250 ml of boiling water (steep for 15 minutes) as a herbal infusion 3 times daily.</p> <p data-bbox="810 553 1023 584">Daily dose: 4.5 g</p> <p data-bbox="810 609 1410 714">The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p data-bbox="810 739 1278 770">See section 6 for content of estragole.</p> <p data-bbox="810 795 1018 826">Duration of use</p> <p data-bbox="810 851 1114 882">Indications 1), 2) and 3)</p> <p data-bbox="810 907 1093 938"><i>Adults and adolescents</i></p> <p data-bbox="810 963 1294 994">Not to be taken for more than 2 weeks.</p> <p data-bbox="810 1019 1066 1050">Indications 1) and 3)</p> <p data-bbox="810 1075 1299 1106"><i>Children between 4 and 12 years of age</i></p> <p data-bbox="810 1131 1394 1200">For short-term use in mild transitory symptoms only (less than one week).</p> <p data-bbox="810 1225 1401 1330">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 1355 1145 1386">Method of administration</p> <p data-bbox="810 1411 922 1442">Oral use.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p data-bbox="810 1630 1362 1771">Hypersensitivity to the active substance or to Apiaceae (Umbelliferae) family (aniseed, caraway, celery, coriander and dill) or to anethole.</p> <p data-bbox="810 1796 1331 1865">Hypersensitivity to mugwort pollen, due to cross-reactivity with fennel.</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>Indications 1) and 3)</p> <p>The use in children between 4 and 12 years of age is not recommended if the daily intake of estragole exceeds the guidance value of 1.0 µg/kg bw, unless justified by a risk assessment based on adequate safety data (see section 5.3 'Preclinical safety data').</p> <p>The use is not recommended in children under 4 years of age without the advice of a paediatrician.</p> <p>Indication 2)</p> <p>The use in children under 12 years of age has not been established due to lack of adequate 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 (see section 5.3 and 6 regarding preclinical safety data related to the content of estragole).</p> <p>In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>There is evidence that <i>trans</i>-anethole is excreted in human breast milk.</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
	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.

4.9. Overdose

Well-established use	Traditional use
	No cases of overdose have 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.

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data⁴

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the

⁴ Where herbal preparations from *Foeniculi dulci* fructus are used, the total exposure to estragole should be considered from a safety standpoint.

Well-established use	Traditional use
	<p>safe use of the product.</p> <p>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.</p> <p>Several studies have shown the carcinogenic effects of estragole and some of its metabolites in mice (liver tumours) and displayed suggestive but indirect evidence of carcinogenicity in rats. Estragole is considered a genotoxic carcinogen in rodents (see section 6 for further details).</p> <p>An aqueous extract of fennel seeds given daily to 24 female BALB/c mice from day 6 to day 15 of pregnancy showed a dose-dependent teratogenic effect. The embryotoxic effect resulted in morphological changes, skeletal disorders, and cellular alterations. The relevance of the observed effects is limited by the small number of animals tested.</p> <p>Adequate tests on reproductive toxicity have not been performed.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	<p>The amount of estragole has to be specified in herbal preparation for oral use.</p> <p>Because of the generally accepted evidence of genotoxic carcinogenicity, exposure to estragole should be kept as low as practically achievable.</p> <p>In pregnant and breast-feeding women, the daily intake of estragole has to be below 0.05 mg per person per day.</p> <p>In children below 12 years of age, the daily intake of estragole has to be below 1.0 µg/kg bw.</p> <p>For further details see "Public statement on the use of herbal medicinal products containing estragole" (EMA/HMPC/137212/2005 Rev 1).</p>

7. Date of compilation/last revision

20 July 2022