



31 January 2024  
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

Final – Revision 1

<b>Initial assessment</b>	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	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
Re-discussion 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)	05 July 2007
<b>First revision</b>	
Discussion in MLWP/HMPC	April 2016 May 2016 June 2016 January 2021 March 2021 July 2021 September 2021 January 2022 March 2022 May 2022 July 2022

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Adoption of first draft Revision 1 by HMPC for release for consultation	20 July 2022
End of consultation (deadline for comments)	30 November 2022
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>dulce</i> (Mill.) Batt. & Trab.; <i>Foeniculi dulcis fructus</i> ; Sweet fennel
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BG (bulgarski): Сладко резене, плод	LT (lietuvių kalba): Saldieji pankolių vaisiai
CS (čeština): plod fenyklu obecného sladkého	LV (latviešu valoda): Saldā fenheļa augļi
DA (dansk): Fennikel, sød	MT (Malti): frotta tal-busbies ħelu
DE (Deutsch): Süßer Fenchel	NL (Nederlands): Zoete Venkel
EL (elliniká): μαραθου γλυκου καρπος	PL (polski): Owoc kopru włoskiego (odmiany słodkiej)
EN (English): Sweet fennel	PT (português): funcho doce, fruto
ES (español): hinojo dulce, fruto de	RO (română): fruct de fenicul dulce
ET (eesti keel): magusa apteegitilli vili	SK (slovenčina): plod fenikla sladkého
FI (suomi): makeafenkoli, siemen	SL (slovenščina): plod sladkega navadnega komarčka
FR (français): fenouil doux (fruit de)	SV (svenska): sötfänkål, frö
HR (hrvatski): plod slatkog komorača	IS (íslenska): Sæt fennel aldin
HU (magyar): édeskömény termés	NO (norsk): søt fennikel
IT (italiano): Finocchio dolce (o romano), frutto	

# 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<sup>1, 2</sup>

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 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 gastro-intestinal complaints including bloating and flatulence. Indication 2)

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

<sup>2</sup> The material complies with the Ph. Eur. monograph (ref.: 04/2011:0825).

Well-established use	Traditional use
	<p>Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstrual periods.</p> <p><b>Indication 3)</b></p> <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<sup>3</sup>

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><b>Indications 1) and 3)</b></p> <p><i>Adults and adolescents</i></p> <p>Single dose</p> <p>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>Daily dose: 4.5 g</p> <p><i>Children between 4 and 12 years of age</i></p> <p>Single dose</p> <p>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>Daily dose: 3.0 g</p> <p>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>The use is not recommended in children under 4 years of age (see section 4.4 'Special warnings and precautions for use').</p> <p>See section 6 'Pharmaceutical particulars' for content of estragole.</p>

<sup>3</sup> 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="810 257 970 286">Indication 2)</p> <p data-bbox="810 313 1093 342"><i>Adults and adolescents</i></p> <p data-bbox="810 369 954 398">Single dose</p> <p data-bbox="810 425 1396 526">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 1021 582">Daily dose: 4.5 g</p> <p data-bbox="810 609 1412 710">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="810 736 1364 806">See section 6 'Pharmaceutical particulars' for content of estragole.</p> <p data-bbox="810 833 1018 862"><b>Duration of use</b></p> <p data-bbox="810 889 1114 918">Indications 1), 2) and 3)</p> <p data-bbox="810 945 1093 974"><i>Adults and adolescents</i></p> <p data-bbox="810 1001 1292 1030">Not to be taken for more than 2 weeks.</p> <p data-bbox="810 1057 1066 1086">Indications 1) and 3)</p> <p data-bbox="810 1113 1300 1142"><i>Children between 4 and 12 years of age</i></p> <p data-bbox="810 1169 1396 1238">For short-term use in mild transitory symptoms only (less than one week).</p> <p data-bbox="810 1265 1396 1366">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 1393 1145 1422"><b>Method of administration</b></p> <p data-bbox="810 1449 922 1478">Oral use.</p>

### 4.3. Contraindications

Well-established use	Traditional use
	<p data-bbox="810 1666 1356 1803">Hypersensitivity to the active substance or to Apiaceae (Umbelliferae) family (aniseed, caraway, celery, coriander and dill) or to anethole.</p> <p data-bbox="810 1830 1404 1899">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 due to the lack of adequate data.</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 sections 5.3 'Preclinical safety data' and 6 'Pharmaceutical particulars' 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 data<sup>4</sup>

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

<sup>4</sup> 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>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 'Pharmaceutical particulars' 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.</p> <p>Adequate tests on reproductive toxicity have not been performed.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	<p>In the general population 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

31 January 2024

