



31 January 2024  
EMA/HMPC/372841/2016  
Committee on Herbal Medicinal Products (HMPC)

## European Union herbal monograph on *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, fructus

Final – Revision 1

<b>Initial assessment</b>	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	May 2006 September 2006 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/HMPC/137428/2006) 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/280039/2007)	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
Adoption of first draft Revision 1 by HMPC for release for consultation	20 July 2022

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



End of consultation (deadline for comments)	30 November 2022
Discussion in HMPC	September 2022 November 2022
Adoption of second draft Revision 1 by HMPC for release for consultation	23 November 2022
End of consultation (deadline for comments)	15 March 2023
Re-discussion in HMPC	May 2023 July 2023 September 2023 November 2023 January 2024
Adoption by HMPC	31 January 2024

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>vulgare</i> , fructus; <i>Foeniculi amari fructus</i> ; Bitter fennel
----------	--

BG (bulgarski): Горчиво резене, плод	LT (lietuvių kalba): Kartieji pankolių vaisiai
CS (čeština): plod fenyklu obecného pravého	LV (latviešu valoda): Rūgtā fenheļa augļi
DA (dansk): Fennikel, bitter	MT (Malti): frotta tal-Busbies morr
DE (Deutsch): Bitterer Fenchel	NL (Nederlands): Bittere Venkel
EL (elliniká): μάρραθου πικρού καρπός	PL (polski): Owoc kopru włoskiego (odmiany gorzkiej)
EN (English): Bitter fennel	PT (português): funcho amargo, fruto
ES (español): hinojo amargo, fruto de	RO (română): fruct de fenicul amar
ET (eesti keel): mõru apteegitilli vili	SK (slovenčina): plod fenikla horkého
FI (suomi): karvasfenkoli, hedelmä	SL (slovenščina): plod grenkega navadnega komarčka
FR (français): fenouil amer (fruit de)	SV (svenska): bitterfänkål, frukt
HR (hrvatski): plod gorkog komorača	IS (íslenska): Bitur fennel aldin
HU (magyar): keserű édeskömény termés	NO (norsk): bitter fennikel
IT (italiano): Finocchio amaro (o selvatico), frutto	

# European Union herbal monograph on *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, 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>vulgare</i> , fructus (bitter 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
	<b>Indication 1)</b> Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastrointestinal complaints including bloating and flatulence.

<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.: 04/2013:0824).

Well-established use	Traditional use
	<p data-bbox="810 253 970 286"><b>Indication 2)</b></p> <p data-bbox="810 309 1295 421">Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstrual periods.</p> <p data-bbox="810 443 970 477"><b>Indication 3)</b></p> <p data-bbox="810 499 1391 566">Traditional herbal medicinal product used as an expectorant in cough associated with cold.</p> <p data-bbox="810 589 1423 701">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 data-bbox="810 878 938 911"><b>Posology</b></p> <p data-bbox="810 934 1072 967"><b>Indications 1) and 3)</b></p> <p data-bbox="810 990 1098 1023"><i>Adults and adolescents</i></p> <p data-bbox="810 1046 954 1079">Single dose</p> <p data-bbox="810 1102 1423 1214">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 1024 1270">Daily dose: 4.5 g</p> <p data-bbox="810 1292 1295 1326"><i>Children between 4 and 12 years of age</i></p> <p data-bbox="810 1348 954 1382">Single dose</p> <p data-bbox="810 1404 1401 1516">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 1538 1024 1572">Daily dose: 3.0 g</p> <p data-bbox="810 1594 1391 1706">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 1729 1407 1841">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 1863 1359 1897">See section 6 'Pharmaceutical particulars' for</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>content of estragole.</p> <p><b>Indication 2)</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>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>See section 6 'Pharmaceutical particulars' for the content of estragole.</p> <p><b>Duration of use</b></p> <p><b>Indications 1), 2) and 3)</b></p> <p><i>Adults and adolescents</i></p> <p>Not to be taken for more than 2 weeks.</p> <p><b>Indications 1) and 3)</b></p> <p><i>Children between 4 and 12 years of age</i></p> <p>For short-term use in mild transitory symptoms only (less than one week).</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><b>Method of administration</b></p> <p>Oral use.</p>

### 4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance or to Apiaceae (Umbelliferae) family (aniseed, caraway, celery, coriander and dill) or to anethole.</p> <p>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 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 amari 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/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