



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 November 2022
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Committee for Herbal Medicinal Products (HMPC)

European Union list entry on *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, fructus

Draft – Revision 1

Initial assessment	
Discussed 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	05 July 2007
First systematic review	
Discussion in HMPC	September 2022
Adoption by HMPC for release for consultation	23 November 2022
Start of public consultation	15 December 2022
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 March 2023

Keywords	Herbal medicinal products; HMPC; European Union list of herbal substance(s), preparation(s) and combinations thereof for use in traditional herbal medicinal products; traditional use; <i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>vulgare</i> ; Foeniculi amari fructus; bitter fennel fruit
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Entry to list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products on *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare*, fructus

Scientific name of the plant	
<i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>vulgare</i>	
Botanical family	
Apiaceae	
Herbal substance	
Foeniculi amari fructus	
Common name of herbal substance in all EU official languages	
BG (bulgarski): Горчиво резене, плод CS (čeština): plod fenyklu obecného pravého DA (dansk): Fennikel, bitter DE (deutsch): Bitterer Fenchel EL (elliniká): μαραθου πικρου καρπος EN (English): Bitter fennel ES (español): hinojo amargo, fruto de ET (eesti keel): mõru apteegitilli vili FI (suomi): karvasfenkoli, hedelmä FR (français): fenouil amer (fruit de) HR (hrvatski): plod gorkog komorača HU (magyar): keserű édeskömény termés IT (italiano): Finocchio amaro (o selvatico), frutto	LT (lietuvių kalba): Kartieji pankolių vaisiai LV (latviešu valoda): Rūgtā fenheļa augļi MT (Malti): frotta tal-busbies morr NL (Nederlands): Bittere Venkel PL (polski): Owoc kopru włoskiego (odmiany gorzkiej) PT (português): funcho amargo, fruto RO (română): fruct de fenicul amar SK (slovenčina): plod fenikla horkého SL (slovenščina): plod grenkega navadnega komarčka SV (svenska): bitterfänkål, frukt IS (íslenska): Bitur fennel aldin NO (norsk): bitter fennikel
Herbal preparation(s)	
Not applicable	
European Pharmacopoeia monograph reference	
Fennel, bitter - Foeniculi amari fructus (04/2013: 0824)	
Indication(s)	
Indication 1) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.	
Indication 2) Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstrual periods.	
Indication 3)	

<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>
Type of tradition
European
Specified strength
Please see 'Specified posology'.
Specified posology
<p>Indications 1) and 3)</p> <p><i>Adults and adolescents</i></p> <p>Single dose</p> <p>Herbal tea: 1.5 g of the 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 herbal substance in 100 ml of 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 'Special warnings and precautions for use').</p> <p>Indication 2)</p> <p><i>Adults and adolescents</i></p> <p>Single dose</p> <p>Herbal tea: 1.5 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>
Route of administration
Oral use.
Duration of use or any restrictions on the duration of use

Indications 1), 2) and 3)

Adults and adolescents

Not to be taken for more than 2 weeks.

Indications 1) and 3)

Children between 4 and 12 years of age

For short-term use in mild transitory symptoms only (less than one week). If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Any other information necessary for the safe use

Contraindications

Hypersensitivity to the active substance or to Apiaceae (Umbelliferae) family (aniseed, caraway, celery, coriander and dill) or to anethole.

Hypersensitivity to mugwort pollen, due to cross-reactivity with fennel.

Special warnings and precautions for use

Indications 1) and 3)

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.

The use in children under 4 years of age without the advice of a paediatrician is not recommended.

Indication 2)

The use in children under 12 years of age has not been established due to lack of adequate data.

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

Interactions with other medicinal products and other forms of interaction

None reported.

Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

There is evidence that *trans*-anethole is excreted in human breast milk.

No fertility data available.

Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

Undesirable effects

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.

Overdose

No case of overdose has been reported.

Pharmaceutical particulars

In the general population exposure to estragole should be kept as low as practically achievable.

In pregnant and breast-feeding women, the daily intake of estragole has to be below 0.05 mg/person per day.

In children below 12 years of age, the daily intake of estragole has to be below 1.0 µg/kg bw.

For further details see "Public statement on the use of herbal medicinal products containing estragole" (EMA/HMPC/137212/2005 Rev 1).

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience

Not applicable.

Date of compilation/Last revision

23 November 2022