



London, 26 October 2006
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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

DRAFT

**COMMUNITY LIST ENTRY ON
FOENICULUM VULGARE MILLER SUBSP. *VULGARE* VAR. *DULCE* (MILLER)
THELLUNG, FRUCTUS**

AGREED BY WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST	25 October 2006
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	26 October 2006
END OF CONSULTATION (DEADLINE FOR COMMENTS)	28 February 2007

Comments should be provided using this [template](#) to hmpc.secretariat@emea.europa.eu
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KEYWORDS	Herbal medicinal products; HMPC; Community list of herbal substances, preparations and combinations thereof; traditional use; sweet fennel, fruit; <i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>dulce</i> (Miller) Thellung
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Scientific name of the plant	
<i>Foeniculum vulgare</i> Miller subsp. <i>vulgare</i> var. <i>dulce</i> (Miller) Thellung	
Botanical family	
Apiaceae	
Common name in all EU official languages	
ES (español): Hinojo dulce, fruto de CS (čeština): Plod fenyklu obecného sladkého DA (dansk): Fennikel, sød DE (Deutsch): Süßer Fenchel ET (eesti keel): magusa apteegitilli vili EL (elliniká): EN (English): Sweet fennel, fruit FR (français): fruit de fenouil doux IT (italiano): Finocchio dolce, frutto LV (latviešu valoda): Saldā fenheļa augļi LT (lietuvių kalba): Saldieji pankolių vaisiai HU (magyar): Édeskömény termés MT (Malti):	NL (Nederlands): PL (polski): PT (português): Fruto de funcho doce SK (slovenčina): Feniklový plod sladký SL (slovenščina): plod sladkega navadnega komarčka FI (suomi): SV (svenska): sötfänkål, frukt <i>BG (bălgarski): sladko rezene, plod</i> <i>RO (română): Fruct de fenicul dulce</i> <i>HR (hrvatski): plod slatkoga komorača</i> <i>TR (türkçe):</i> <i>IS (íslenska): Sæt fennel aldin</i> <i>NO (norsk): Fenikkel, søt</i>
Herbal preparation(s)	
Dried fennel, sweet, comminuted	
European Pharmacopoeia monograph reference	
Foeniculi dulcis fructus (01/2005:0825)	
Indications	
<p>a) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.</p> <p>b) Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstruation period.</p> <p>c) Traditional herbal medicinal product used as an expectorant in cough and cold.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based on long-standing use.</p>	
Type of tradition	
European	
Specified strength	
Please see “Specified posology”.	

Specified posology*Adults*

1.5 to 2.5 g of (freshly¹) comminuted fennel fruits with 0.25 l of boiling water (brew for 15 minutes) three times daily as a herbal tea.

Children, Indication a)

Average daily dose:

3 months-1 year of age: 1-2 g of crushed fruits as an infusion

1-4 years of age: 1.5-3 g of crushed fruits as an infusion

4-12 years of age: 3-5 g of crushed fruits as an infusion

Adolescents over 12 years of age, Indication a)

Adult dose

Route of administration

Oral use.

Duration of use or any restrictions on the duration of use*Adults*

Sweet fennel dried fruit (herbal substance) and sweet fennel preparations should not to be taken for more than 2 weeks.

Children, Indication a)

The use in children may be considered in case of acute symptoms. Administration for more than 1 week is not recommended because of the lack of adequate safety data on long-term use.

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

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

The traditional medicinal use of fennel is largely due to antispasmodic, secretolytic and antibacterial effects of its essential oil.

Secretolytic and expectorant effects may be due to the content of anethole and fenchone.

Any other information necessary for the safe use**Contraindications**

Known hypersensitivity to the active substance or to Apiaceae (Umbelliferae) (aniseed, caraway, celery, coriander, dill and fennel) or to anethole.

Special warnings and precautions for use

Patients with known hypersensitivity to Asteraceae (Compositae) should avoid the use of fennel and its preparations, because of cross-reactivity risk.

Interactions with other medicinal products and other forms of interaction

Not known.

¹ For commercial preparation of crushed fennel fruits the applicant must carry out appropriate stability testing related to the content of essential oil components.

Pregnancy and lactation

There are no data from the use of fennel fruit in pregnant patients.

It is unknown if fennel constituents are excreted in human breast milk.

In absence of sufficient data the use during pregnancy and lactation is not recommended.

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, the respiratory and gastro-intestinal system may occur.

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 [if necessary]

Not applicable.