

COMMISSION

COMMISSION DECISION

of 21 November 2008

establishing of a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products

(notified under document number C(2008) 6933)

(Text with EEA relevance)

(2008/911/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ⁽¹⁾, and in particular Article 16(f) thereof,

Having regard to the opinions of the European Medicines Agency, formulated on 7 September 2007 by the Committee for Herbal Medicinal Products,

Whereas:

- (1) *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung comply with the requirements set out in Directive 2001/83/EC. *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung can be considered as herbal substances, herbal preparations and/or combinations thereof.
- (2) It is therefore appropriate to establish a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products including the entry of *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and the entry of *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung.

- (3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

A list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products is established in Annex I including the entry of *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and the entry of *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung.

Article 2

The indications, the specified strengths and the posology, the route of administration and any other information necessary for the safe use as a traditional medicinal product relevant for *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung are set out in Annex II to this decision.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 21 November 2008.

For the Commission
Günter VERHEUGEN
Vice-President

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

ANNEX I

List of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products established in accordance with Article 16f of Directive 2001/83/EC as amended by Directive 2004/24/EC

Foeniculum vulgare Miller subsp. *vulgare* var. *vulgare* (bitter fennel fruit)

Foeniculum vulgare Miller subsp. *vulgare* var. *dulce* (Miller) Thellung (sweet fennel fruit)

ANNEX II

A.

COMMUNITY LIST ENTRY ON FOENICULUM VULGARE MILLER SUBSP. VULGARE VAR. VULGARE, FRUCTUS**Scientific name of the plant**

Foeniculum vulgare Miller subsp. *vulgare* var. *vulgare*

Botanical family

Apiaceae

Herbal substance

Fennel, bitter

Common name in all EU official languages of herbal substance

BG (bългарski): Горчиво резене, плод	LT (lietuvių kalba): Karčiųjų pankolių vaisiai
CS (čeština): Plod fenyklu obecného pravého	LV (latviešu valoda): Rūgtā fenheļa augļi
DA (dansk): Fennikel, bitter	MT (malti): Bużbież morr, frotta
DE (Deutsch): Bitterer Fenchel	NL (nederlands): Venkelvrucht, bitter
EL (elliniká): Μαραθόσπορος πικρός	PL (polski): Owoc kopru włoskiego (odmiana gorzka)
EN (English): Bitter fennel, fruit	PT (português): Fruto de funcho amargo
ES (español): Hinojo amargo, fruto de	RO (română): Fruct de fenicul amar
ET (eesti keel): Mõru apteegitill, vili	SK (slovenčina): Feniklový plod horký
FI (suomi): Karvasfenkoli, hedelmä	SL (slovenščina): Plod grenkega navadnega komarčka
FR (français): Fruit de fenouil amer	SV (svenska): Bitterfänkål, frukt
HU (magyar): Keserűédeskömény-termés	IS (íslenska): Bitur fennel aldin
IT (italiano): Finocchio amaro (o selvatico), frutto	NO (norsk): Fenikkel, bitter

Herbal preparation(s)

Fennel, bitter, dried comminuted ⁽¹⁾ fruit.

European Pharmacopoeia monograph reference

Foeniculi amari fructus (01/2005:0824).

Indication(s)

- Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.
- Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstrual periods.
- Traditional herbal medicinal product used as an expectorant in cough associated with cold.

The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

Type of tradition

European, Chinese.

Specified strength

Please see 'Specified posology'.

⁽¹⁾ 'Comminuted fruit' is intended to cover also 'crushed fruit'.

Specified posology*Adults*

Single dose

1,5 to 2,5 g of (freshly ⁽¹⁾) comminuted fennel fruits with 0,25 l of boiling water (brew for 15 minutes) three times daily as a herbal tea.

Adolescents over 12 years of age, indication (a)

Adult dose

Children between four and 12 years of age, indication (a)

Average daily dose

3-5 g of (freshly) comminuted fruits as a herbal tea, in three divided doses, for short-term use in mild transitory symptoms only (less than one week).

The use in children under four years of age is not recommended (see section 'Special warnings and precautions for use').

Route of administration

Oral use.

Duration of use or any restrictions on the duration of use*Adults**Adolescents over 12 years of age, indication (a)*

Not to be taken for more than two weeks.

Children between four and 12 years of age, indication (a)

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) (aniseed, caraway, celery, coriander and dill) or to anethole.

Special warnings and precautions for use

The use in children under four years of age is not recommended due to the lack of adequate data and a paediatrician's advice should be sought.

Interactions with other medicinal products and other forms of interaction

None reported.

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 the 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.

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

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 (if necessary)

Not applicable.

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience (if necessary for the safe use of the product)

Not applicable.

B.

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

Scientific name of the plant

Foeniculum vulgare Miller subsp. *vulgare* var. *dulce* (Miller) Thellung

Botanical family

Apiaceae

Herbal substance

Fennel, sweet

Common name in all EU official languages of herbal substance

BG (bългарski): Сладко резене, плод	LT (lietuvių kalba): Saldžiųjų pankolių vaisiai
CS (čeština): Plod fenyklu obecného sladkého	LV (latviešu valoda): Saldā fenheļa augļi
DA (dansk): Fennikel, sød	MT (malti): Bużbież ħelu, frotta
DE (Deutsch): Süßer Fenchel	NL (nederlands): Venkelvrucht, zoet
EL (elliniká): Μαραθόσπορος γλυκός	PL (polski): Owoc kopru włoskiego (odmiana słodka)
EN (English): Sweet fennel, fruit	PT (português): Fruto de funcho doce
ES (español): Hinojo dulce, fruto de	RO (română): Fruct de fenicul dulce
ET (eesti keel): Magus apteegitill, vili	SK (slovenčina): Feniklový plod sladký
FI (suomi): Makea fenkoli, hedelmä	SL (slovenščina): Plod sladkega navadnega komarčka
FR (français): Fruit de fenouil doux	SV (svenska): Sötfänkål, frukt
HU (magyar): Édesköménytermés	IS (íslenska): Sæt fennel aldin
IT (italiano): Finocchio dolce (o romano), frutto	NO (norsk): Fenikkel, søt

Herbal preparation(s)

Fennel, sweet, dried comminuted⁽¹⁾ or powdered fruit.

European Pharmacopoeia monograph reference

Foeniculi dulcis fructus (01/2005:0825).

Indication(s)

(a) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.

⁽¹⁾ 'Comminuted fruit' is intended to cover also 'crushed fruit'.

(b) Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstrual periods.

(c) Traditional herbal medicinal product used as an expectorant in cough associated with cold.

The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

Type of tradition

European, Chinese.

Specified strength

Please see 'Specified posology'.

Specified posology

Adults

Single dose

1,5 to 2,5 g of (freshly ⁽¹⁾) comminuted fennel fruits with 0,25 l of boiling water (brew for 15 minutes) three times daily as a herbal tea.

Fennel powder: 400 mg three times a day (with a maximum of 2 g daily).

Adolescents over 12 years of age, indication (a)

Adult dose

Children between four and 12 years of age, indication (a)

Average daily dose

3-5 g of (freshly) comminuted fruits as a herbal tea, in three divided doses, for short-term use in mild transitory symptoms only (less than one week).

The use in children under four years of age is not recommended (see section 'Special warnings and precautions for use').

Route of administration

Oral use.

Duration of use or any restrictions on the duration of use

Adults

Adolescents over 12 years of age, indication (a)

Not to be taken for more than two weeks.

Children between four and 12 years of age, indication (a)

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) (aniseed, caraway, celery, coriander and dill) or to anethole.

Special warnings and precautions for use

The use in children under four years of age is not recommended due to the lack of adequate data and a paediatrician's advice should be sought.

Interactions with other medicinal products and other forms of interaction

None reported.

⁽¹⁾ For commercial preparation of comminuted or powdered 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 the 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 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 (if necessary)

Not applicable.

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience (if necessary for the safe use of the product)

Not applicable.
