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► **B**

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)

(OJ L 328, 6.12.2008, p. 42)

Amended by:

Official Journal

		No	page	date
► <u>M1</u>	Commission Decision 2010/28/EC of 28 July 2009	L 11	12	16.1.2010
► <u>M2</u>	Commission Decision 2010/30/EU of 9 December 2009	L 12	14	19.1.2010
► <u>M3</u>	Commission Decision 2010/180/EU of 25 March 2010	L 80	52	26.3.2010



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.

Article 2

The indications, the specified strengths and the posology, the route of administration and any other information necessary for the safe use of the herbal substance as a traditional medicinal product relevant for the herbal substances listed in Annex I are set out in Annex II.

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

▼B

Article 3

This Decision is addressed to the Member States.

▼ B*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

▼ M1

Calendula officinalis L

▼ M2

Echinacea purpurea (L.) Moench

Eleutherococcus senticosus (Rupr. et Maxim.) Maxim

▼ B

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

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

▼ M3

Mentha x piperita L.

▼ M1

Pimpinella anisum L

▼B*ANNEX II***▼M1****COMMUNITY LIST ENTRY ON *CALENDULA OFFICINALIS* L****Scientific name of the plant***Calendula officinalis* L.**Botanical family**

Asteraceae

Herbal substance

Calendula flower

Common name in all EU official languages of herbal substance

BG (bългарski): Невен, цвят	LV (latviešu valoda): Kliņģerītes ziedi
CS (čeština): Měsíčkový květ	MT (malti): Fjura calendula
DA (dansk): Morgenfrueblomst	NL (nederlands): Goudsbloem
DE (Deutsch): Ringelblumenblüten	PL (polski): Kwiat nagietka
EL (elliniká): Άνθος καλέντουλας	PT (português): Flor de calêndula
EN (English): Calendula flower	RO (română): Floare de gălbenele (calendula)
ES (español): Flor de caléndula	SK (slovenčina): Nechtíkový kvet
ET (eesti keel): Saialilleõisik	SL (slovenščina): Cvet vrtnega ognjiča
FI (suomi): Tarhakehäkukan kukka	SV (svenska): Ringblomma, blomma
FR (français): Souci	IS (íslenska): Morgunfrú, blóm
HU (magyar): A körömvirág virága	NO (norsk): Ringblomst
IT (italiano): Calendula fiore	
LT (lietuvių kalba): Medetkų žiedai	

Herbal preparation(s)

- A. Liquid extract (DER 1:1), extraction solvent ethanol 40-50 % (v/v).
- B. Liquid extract (DER 1:1,8-2,2), extraction solvent ethanol 40-50 % (v/v).
- C. Tincture (DER 1:5), extraction solvent ethanol 70-90 % (v/v).

European Pharmacopoeia monograph referenceCalendula flower – *Calendulae flos* (01/2005:1297)**Indication(s)**

- (a) Traditional herbal medicinal product for the symptomatic treatment of minor inflammations of the skin (such as sunburn) and as an aid in healing of minor wounds.
- (b) Traditional herbal medicinal product for the symptomatic treatment of minor inflammations in the mouth or the throat.

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

Type of tradition

European

Specified strength

Please see 'Specified posology'.

Specified posology

Herbal preparations:

- A. Liquid extract (DER 1:1)

In semi-solid dosage forms: amount equivalent to 2-10 % herbal substance.

- B. Liquid extract (DER 1:1,8-2,2)

▼M1

In semi-solid dosage forms: amount equivalent to 2-5 % herbal substance.

C. Tincture (DER 1:5)

In compresses diluted at least 1:3 with freshly boiled water.

In semi-solid dosage forms: amount equivalent to 2-10 % herbal substance.

As a gargle or mouth rinse in a 2 % solution.

2 to 4 times daily

Indication (a)

The use is not recommended in children under 6 years of age (see below 'Special warnings and precautions for use').

Indication (b)

The use in children under 12 years of age is not recommended because there is no experience available (see below 'Special warnings and precautions for use').

Route of administration

Cutaneous and oromucosal use.

Duration of use or any restrictions on the duration of use

Compresses: remove after 30-60 minutes

All herbal preparations: If the symptoms persist after 1 week 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 members of the *Asteraceae* (*Compositae*) family.

Special warnings and precautions for use

Indication (a)

The use in children under 6 years of age is not recommended because there is no experience available.

Indication (b)

The use in children under 12 years of age is not recommended because there is no experience available.

If signs of skin infection are observed, a doctor or a qualified health care practitioner should be consulted.

Interactions with other medicinal products and other forms of interaction

None reported.

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.

Effects on ability to drive and use machines

Not relevant.

Undesirable effects

Skin sensitisation. 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

None reported.

▼M2

**COMMUNITY LIST ENTRY ON *ECHINACEA PURPUREA* (L.)
MOENCH, HERBA RECENS****Scientific name of the plant***Echinacea purpurea* (L.) Moench**Botanical family**

Asteraceae

Herbal substance

Purple coneflower herb

Common name in all EU official languages of herbal substance

BG (bългарski): пурпурна ехинацея, пресен стрък	LT (lietuvių kalba): rausvažiedžių ežiulių žolė
CS (čeština): čerstvá nat' třapatky nachové	LV (latviešu valoda): purpursarkanās ehinacejas laksti
DA (dansk): Purpursolhat, frisk urt	MT (malti): Echinacea Vjola
DE (Deutsch): Purpursonnenhutkraut, frisch	NL (nederlands): rood zonnehoeedkruid
EL (elliniká): Πόα Εχινάκεας της πορφύρας	PL (polski): jeżówka purpurowa, świeże ziele
EN (English): purple coneflower herb	PT (português): Equinácea, partes aéreas floridas
ES (español): Equinácea purpúrea, partes aéreas incluidas sumidades floridas	RO (română): iarbă proaspătă de Echinacea, pâlăria soarelui
ET (eesti keel): punane siilkübar	SK (slovenčina): echinacea purpurová, čerstvá vňat'
FI (suomi): kaunopunahattu, tuore verso	SL (slovenščina): sveža zel škrlatne ehinaceje
FR (français): parties aériennes fraîches d'échinacée pourpre	SV (svenska): röd solhatt, färsk ört
HU (magyar): bíbor kasvirág virágos hajtása	IS (íslenska): Sólhattur
IT (italiano): Echinacea purpurea, pianta fresca	NO (norsk): Rød solhatt

Herbal preparation(s)

Expressed juice and dried expressed juice from fresh flowering aerial parts.

European Pharmacopoeia monograph reference

N/A

Indication(s)

Traditional herbal medicinal product for treatment of small superficial wounds.

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

Type of tradition

European.

Specified strength

10 to 20 g/100 g of expressed juice or equivalent amount of dried expressed juice in liquid or semi-solid dosage forms.

Specified posology*Adolescents over the age of 12 years, adults, elderly*

Small amount of ointment is applied on the affected area 2-3 times a day.

The use in children under 12 years of age is not recommended (see below 'Special warnings and precautions for use').

Route of administration

Cutaneous use.

Duration of use or any restrictions on the duration of use

Do not use the medicinal product for more than 1 week.

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

▼ **M2****Any other information necessary for the safe use***Contra-indications*

Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family.

Special warnings and precautions for use

If signs of skin infection are observed, medical advice should be sought.

The use in children below 12 years of age is not recommended because a safe use has not been sufficiently documented.

Interactions with other medicinal products and other forms of interaction

None reported.

Pregnancy and lactation

There are no data on cutaneous use during pregnancy or lactation.

Products containing Echinacea should not be applied to the breast of breast-feeding women.

Effects on ability to drive and use machines

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

Undesirable effects

Hypersensitive reactions (local rash, contact dermatitis, eczema and angioedema of the lips) may occur.

The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

Overdose

No case of overdose has been reported.

**COMMUNITY LIST ENTRY ON *ELEUTHEROCOCCUS SENTICOSUS*
(RUPR. ET MAXIM.) MAXIM., RADIX**

Scientific name of the plant

Eleutherococcus senticosus (Rupr. et Maxim.) Maxim.

Botanical family

Araliaceae

Herbal substance

Eleutherococcus root

Common name in all EU official languages of herbal substance

BG (bългарски): елеутерокок, корен	LT (lietuvių kalba): Eleuterokokų šaknys
CS (čeština): eleuterokokový kořen	LV (latviešu valoda): Eleiterokoka sakne
DA (dansk): Russisk rod	MT (malti): Gherq ta' l-eleuterokokku
DE (Deutsch): Taigawurzel	NL (nederlands): Russische ginsengwortel
EL (elliniká): Πίζα Ελευθεροκόκκου	PL (polski): korzeń eleuterokoka
EN (English): Eleutherococcus root	PT (português): Raiz de Ginseng Siberiano
ES (español): Eleuterococo, raíz de	RO (română): Rădăcină de ginseng siberian
ET (eesti keel): eleuterokokijuur	SK (slovenčina): Všeňojovcový koreň
FI (suomi): venäjänjuuren juuri	SL (slovenščina): korenina elevterokoka
FR (français): racine d'éleuthérocoque (racine de ginseng sibérien)	SV (svenska): Rysk rot
HU (magyar): Szibériai ginszeng gyökér (tajga gyökér)	IS (íslenska): Síberíu ginseng, rót
IT (italiano): Eleuterococco radice	NO (norsk): Russisk rot

▼M2**Herbal preparation(s)**

Comminuted herbal substance for preparation of a herbal tea

Liquid extract (1:1, ethanol 30-40 % v/v)

Dry extract (13-25: 1, ethanol 28-40 % v/v)

Dry extract (17-30: 1, ethanol 70 % v/v)

Dry aqueous extract (15-17:1)

Tincture (1:5, ethanol 40 % v/v)

European Pharmacopoeia monograph reference

Eleutherococcus — Eleutherococci radix (ref.: 01/2008: 1419 corrected 6.0)

Indication(s)

Traditional herbal medicinal product for symptoms of asthenia such as fatigue and weakness.

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

Type of tradition

Chinese, European.

Specified strength

Not applicable.

Specified posology

Adolescents over 12 years of age, adults, elderly

Herbal preparations.

Daily dose.

Comminuted herbal substance as herbal tea: 0,5-4 g.

Tea preparation: 0,5 to 4 g of comminuted herbal substance for infusion in 150 ml of boiling water.

Dosage frequency: 150 ml of tea infusion should be divided in one to three doses taken during the day.

Liquid extract: 2-3 ml.

Dry extracts (ethanol 28-70 % v/v) corresponding to 0,5-4 g dried root.

Dry aqueous extract (15-17:1): 90-180 mg.

Tincture: 10-15 ml.

The daily dose can be taken in one to three doses.

The use is not recommended in children under 12 years of age (see below 'Special warnings and precautions for use').

Route of administration

Oral use.

Duration of use or any restrictions on the duration of use

Not to be taken for more than 2 months.

If the symptoms persist for more than 2 weeks during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

Any other information necessary for the safe use*Contra-indications*

Hypersensitivity to the active substance.

Arterial hypertension.

Special warnings and precautions for use

The use in children under 12 years of age is not recommended because sufficient experience is not available.

▼M2

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

Interactions with other medicinal products and other forms of interaction

None reported.

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.

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

Insomnia, irritability, tachycardia and headaches may occur. The frequency is not known.

Overdose

No case of overdose has been reported.

▼B

**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): Karčiujų 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 (islenska): 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)

- (a) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.
- (b) Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstrual periods.

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

▼B

- (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.

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.

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

▼B*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.

**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 (bългарски): 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 helu, frota
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.
- (b) Traditional herbal medicinal product for symptomatic treatment of minor spasm associated with menstrual periods.

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

▼B

- (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.

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.

⁽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.

▼B*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.

▼M3

**COMMUNITY LIST ENTRY ON *MENTHA* x *PIPERITA* L.,
AETHEROLEUM**

Scientific name of the plant

Mentha x piperita L.

Botanical family

Lamiaceae (Labiatae)

Herbal preparation(s)

Peppermint oil: essential oil obtained by steam distillation from the fresh aerial parts of the flowering plant

European Pharmacopoeia monograph reference

Peppermint oil — *Menthae piperitae aetheroleum* (01/2008:0405)

Indication(s)

Herbal medicinal product traditionally used:

1. for the relief of symptoms in coughs and colds;
2. for the symptomatic relief of localised muscle pain;
3. for the symptomatic relief of localised pruritic conditions in intact skin.

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

Type of tradition

European

Specified strength

Indications 1, 2 and 3

Single dose

Children between 4 to 10 years of age

Semi-solid preparations 2-10 %

Hydroethanolic preparations 2-4 %

Children between 10 to 12 years of age, adolescents between 12 to 16 years of age

Semi-solid preparations 5-15 %

Hydroethanolic preparations 3-6 %

▼M3

Adolescents over 16 years of age, adults

Semi-solid and oily preparations 5-20 %

In aqueous-ethanol preparations 5-10 %

In nasal ointments 1-5 % essential oil.

Specified posology

Up to three times daily

The use in children under 2 years of age is contraindicated (see 'Contraindications').

The use is not recommended in children between 2 to 4 years of age (see 'Special warnings and precautions for use').

Route of administration

Cutaneous and transdermal.

Duration of use or any restrictions on the duration of use

Indication 1

Not to be used for more than 2 weeks.

Indications 2 and 3

It is not recommended to use the medicinal product continuously for more than 3 months.

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

Children under 2 years of age, because menthol can induce reflex apnoea and laryngospasm.

Children with history of seizures (febrile or not).

Hypersensitivity to peppermint oil or menthol.

Special warnings and precautions for use

Eye contact with unwashed hands after the application of peppermint oil may potentially cause irritation.

Peppermint oil should not be applied on broken or irritated skin.

The use is not recommended in children between 2 to 4 years of age, as there is no sufficient experience available.

Interactions with other medicinal products and other forms of interaction

None reported.

Pregnancy and lactation

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

Hypersensitivity reactions such as skin rash, contact dermatitis, and eye irritation have been reported. These reactions are most of the time mild and transient. The frequency is not known.

Irritation of the skin and mucosa of the nose is possible, after local application. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

▼ M3*Overdose*

No case of overdose has been reported.

▼ M1**COMMUNITY LIST ENTRY ON *PIMPINELLA ANISUM* L****Scientific name of the plant**

Pimpinella anisum L.

Botanical family

Apiaceae

Herbal substance

Aniseed

Common name in all EU official languages of herbal substance

BG (bългарski): Анасон, плод	LT (lietuvių kalba): Anyžių sėklos
CS (čeština): Anýzový plod	LV (latviešu valoda): Anīsa sēklas
DA (dansk): Anisfrø	MT (malti): Frotta tal-Anisi
DE (Deutsch): Anis	NL (nederlands): Anijsvrucht
EL (elliniká): Γλυκάνισο	PL (polski): Owoc anyżu
EN (English): Aniseed	PT (português): Anis
ES (español): Fruto de anís	RO (română): Fruct de anason
ET (eesti keel): Aniis	SK (slovenčina): Anízový plod
FI (suomi): Anis	SL (slovenščina): Plod vrtnega janeža
FR (français): Anis (fruit d)	SV (svenska): Anis
HU (magyar): Ánizsmag	IS (íslenska): Anís
IT (italiano): Anice (Anice verde), frutto	NO (norsk): Anis

Herbal preparation(s)

Dried aniseed, comminuted or crushed

European Pharmacopoeia monograph reference

Anisi fructus (01/2005:0262)

Indication(s)

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

Specified strength

Please see 'Specified posology'

Specified posology

Adolescents over 12 years of age, adults, elderly:

Indications (a) and (b)

1 to 3,5 g of whole or (freshly ⁽¹⁾) comminuted or crushed aniseed in 150 ml of boiling water as a herbal tea

3 times daily

⁽¹⁾ For commercial preparations of comminuted or crushed aniseed the applicant must carry out appropriate stability testing related to the content of essential oil components.

▼M1

The use in children under 12 years is not recommended of age (see below 'Special warnings and precautions for use').

Route of administration

Oral use

Duration of use or any restrictions on the duration of use

Not to be taken for more than 2 weeks.

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

Special warnings and precautions for use

The use is not recommended in children under 12 years of age due to the lack of adequate data for safety assessment.

Interactions with other medicinal products and other forms of interaction

None reported.

Pregnancy and lactation

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

It is unknown if aniseed 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 aniseed 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.