►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
►M1	Commission Decision 2010/28/EC of 28 July 2009	L 11	12	16.1.2010
►M2	Commission Decision 2010/30/EU of 9 December 2009	L 12	14	19.1.2010
►M3	Commission Decision 2010/180/EU of 25 March 2010	L 80	52	26.3.2010
►M4	Commission Implementing Decision 2011/785/EU of 28 November 2011	L 319	102	2.12.2011
►M5	Commission Implementing Decision 2012/67/EU of 3 February 2012	L 34	5	7.2.2012
►M6	Commission Implementing Decision 2012/68/EU of 3 February 2012	L 34	8	7.2.2012

▼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)

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:

▼M3

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)

▼M4

Hamamelis virginiana L., *folium et cortex aut ramunculus destillatum*

▼M3

Mentha x piperita L.

▼M1

Pimpinella anisum L

▼M5

Thymus vulgaris L., *Thymus zygis* Loefl. ex L., aetheroleum

▼M6

Vitis vinifera L., folium

▼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 (bălgarski): Невен, цвят

CS (čeština): Měsíčkový květ

DA (dansk): Morgenfrueblomst

DE (Deutsch): Ringelblumenblüten

EL (elliniká): Άνθος καλέντουλας

EN (English): Calendula flower

ES (español): Flor de caléndula

ET (eesti keel): Saialilleõisik

FI (suomi): Tarhakehäkukan kukka

FR (français): Souci

HU (magyar): A körömvirág virága

IT (italiano): Calendula fiore

LT (lietuvių kalba): Medetkų žiedai

LV (latviešu valoda): Kliņģerītes ziedi

MT (malti): Fjura calendula

NL (nederlands): Goudsbloem

PL (polski): Kwiat nagietka

PT (português): Flor de calêndula

RO (română): Floare de gălbenele (calendula)

SK (slovenčina): Nechtíkový kvet

SL (slovenščina): Cvet vrtnega ognjiča

SV (svenska): Ringblomma, blomma

IS (íslenska): Morgunfrú, blóm

NO (norsk): Ringblomst

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 reference

Calendula 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:

▼M1

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)

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.

▼M1

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 (bălgarski): пурпурна ехинацея, пресен стрък

CS (čeština): čerstvá nať třapatky nachové

DA (dansk): Purpursolhat, frisk urt

DE (Deutsch): Purpursonnenhutkraut, frisch

EL (elliniká): Πόα Εχινάκεας της πορφυράς

EN (English): purple coneflower herb

ES (español): Equinácea purpúrea, partes aéreas incluidas sumidades floridas

ET (eesti keel): punane siilkübar

FI (suomi): kaunopunahattu, tuore verso

FR (français): parties aériennes fraîches d'échinacée pourpre

HU (magyar): bíbor kasvirág virágos hajtása

IT (italiano): Echinacea purpurea, pianta fresca

LT (lietuvių kalba): rausvažiedžių ežiuolių žolė

LV (latviešu valoda): purpursarkanās ehinacejas laksti

MT (malti): Echinacea Vjola

NL (nederlands): rood zonnehoedkruid

PL (polski): jeżówka purpurowa, świeże ziele

PT (português): Equinácea, partes aéreas floridas

RO (română): iarbă proaspătă de Echinacea, pălăria soarelui

SK (slovenčina): echinacea purpurová, čerstvá vňať

SL (slovenščina): sveža zel škrlatne ehinaceje

SV (svenska): röd solhatt, färsk ört

IS (íslenska): Sólhattur

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.

▼M2

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.

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

▼M2

Common name in all EU official languages of herbal substance

BG (bălgarski): елеутерокок, корен

CS (čeština): eleuterokokový kořen

DA (dansk): Russisk rod

DE (Deutsch): Taigawurzel

EL (elliniká): Ρίζα Ελευθεροκόκκου

EN (English): Eleutherococcus root

ES (español): Eleuterococo, raíz de

ET (eesti keel): eleuterokokijuur

FI (suomi): venäjänjuuren juuri

FR (français): racine d'éleuthérocoque (racine de ginseng sibérien)

HU (magyar): Szibériai ginszeng gyökér (tajga gyökér)

IT (italiano): Eleuterococco radice

LT (lietuvių kalba): Eleuterokokų šaknys

LV (latviešu valoda): Eleiterokoka sakne

MT (malti): Għerq ta' l-elewterokokku

NL (nederlands): Russische ginsengwortel

PL (polski): korzeń eleuterokoka

PT (português): Raiz de Ginseng Siberiano

RO (română): Rădăcină de ginseng siberian

SK (slovenčina): Všehojovcový koreň

SL (slovenščina): korenina elevterokoka

SV (svenska): Rysk rot

IS (íslenska): Síberíu ginseng, rót

NO (norsk): Russisk rot

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.

▼M2

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.

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

▼B

Common name in all EU official languages of herbal substance

BG (bălgarski): Горчиво резене, плод

CS (čeština): Plod fenyklu obecného pravého

DA (dansk): Fennikel, bitter

DE (Deutsch): Bitterer Fenchel

EL (elliniká): Μαραθόσπορος πικρός

EN (English): Bitter fennel, fruit

ES (español): Hinojo amargo, fruto de

ET (eesti keel): Mõru apteegitill, vili

FI (suomi): Karvasfenkoli, hedelmä

FR (français): Fruit de fenouil amer

HU (magyar): Keserűédeskömény-termés

IT (italiano): Finocchio amaro (o selvatico), frutto

LT (lietuvių kalba): Karčiųjų pankolių vaisiai

LV (latviešu valoda): Rūgtā fenheļa augļi

MT (malti): Bużbież morr, frotta

NL (nederlands): Venkelvrucht, bitter

PL (polski): Owoc kopru włoskiego (odmiana gorzka)

PT (português): Fruto de funcho amargo

RO (română): Fruct de fenicul amar

SK (slovenčina): Feniklový plod horký

SL (slovenščina): Plod grenkega navadnega komarčka

SV (svenska): Bitterfänkål, frukt

IS (íslenska): Bitur fennel aldin

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.

(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 ([2])) 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’).

([1]) ‘Comminuted fruit’ is intended to cover also ‘crushed fruit’.

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

▼B

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.

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

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 (bălgarski): Сладко резене, плод

CS (čeština): Plod fenyklu obecného sladkého

DA (dansk): Fennikel, sød

DE (Deutsch): Süßer Fenchel

EL (elliniká): Μαραθόσπορος γλυκύς

EN (English): Sweet fennel, fruit

ES (español): Hinojo dulce, fruto de

ET (eesti keel): Magus apteegitill, vili

FI (suomi): Makea fenkoli, hedelmä

FR (français): Fruit de fenouil doux

HU (magyar): Édesköménytermés

IT (italiano): Finocchio dolce (o romano), frutto

LT (lietuvių kalba): Saldžiųjų pankolių vaisiai

LV (latviešu valoda): Saldā fenheļa augļi

MT (malti): Bużbież ħelu, frotta

NL (nederlands): Venkelvrucht, zoet

PL (polski): Owoc kopru włoskiego (odmiana słodka)

PT (português): Fruto de funcho doce

RO (română): Fruct de fenicul dulce

SK (slovenčina): Feniklový plod sladký

SL (slovenščina): Plod sladkega navadnega komarčka

SV (svenska): Sötfänkål, frukt

IS (íslenska): Sæt fennel aldin

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.

(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]) ‘Comminuted fruit’ is intended to cover also ‘crushed fruit’.

▼B

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.

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.

([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

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.

▼M4

COMMUNITY LIST ENTRY ON *HAMAMELIS VIRGINIANA* L., *FOLIUM ET CORTEX AUT RAMUNCULUS DESTILLATUM*

Scientific name of the plant

Hamamelis virginiana L.

Botanical family

Hamamelidaceae

Herbal preparation(s)

1. Distillate prepared from fresh leaves and bark (1:1.12 – 2.08; extraction solvent ethanol 6 % m/m)

2. Distillate prepared from dried twigs (1:2; extraction solvent ethanol 14-15 %) ([1])

European pharmacopoeia monograph reference

Not applicable

Indication(s)

Indication (a)

Traditional herbal medicinal product for relief of minor skin inflammation and dryness of the skin.

Indication (b)

Traditional herbal medicinal product to be used for the temporary relief of eye discomfort due to dryness of the eye or to exposure to wind or sun.

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

Children over six years of age, adolescents, adults and elderly

Indication (a)

Distillate in a strength corresponding to 5-30 % in semi-solid preparations, several times daily.

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

([1]) According to USP (USP-31- NF 26, 2008 Vol 3:3526).

▼M4

Adolescents, adults and elderly

Indication (b)

Eye drops [1] Distillate (2) diluted (1:10), 2 drops/each eye, 3-6 times daily.

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

Route of administration

Cutaneous use.

Ocular use.

Duration of use or any restrictions on the duration of use

Children over six years of age, adolescents, adults and elderly

Indication (a)

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

Adolescents, adults and elderly

Indication (b)

The recommended duration of use is four days. If the symptoms persist longer than two days 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

Contraindications

Hypersensitivity to the active substance.

Special warnings and precautions for use

Indication (a)

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

Indication (b)

If eye pain, changes in vision, continued redness, or irritation of the eye is experienced, or if the condition worsens or persists for more than 48 hours during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted.

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

For extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

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.

[1] The medicinal product complies with the Ph. Eur. monograph on eye preparations (01/2008:1163).

▼M4

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

Indication (a)

Allergic contact dermatitis may occur in sensitive patients. The frequency is not known.

Indication (b)

Conjunctivitis cases have been reported. 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.

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 %

▼M3

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 %

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.

▼M3

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.

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 (bălgarski): Анасон, плод

CS (čeština): Anýzový plod

DA (dansk): Anisfrø

DE (Deutsch): Anis

EL (elliniká): Γλυκάνισο

EN (English): Aniseed

ES (español): Fruto de anís

ET (eesti keel): Aniis

FI (suomi): Anis

FR (français): Anis (fruit d)

HU (magyar): Ánizsmag

IT (italiano): Anice (Anice verde), frutto

LT (lietuvių kalba): Anyžių sėklos

LV (latviešu valoda): Anīsa sēklas

MT (malti): Frotta tal-Anisi

NL (nederlands): Anijsvrucht

PL (polski): Owoc anyżu

PT (português): Anis

RO (română): Fruct de anason

SK (slovenčina): Anízový plod

SL (slovenščina): Plod vrtnega janeža

SV (svenska): Anis

IS (íslenska): Anís

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’

▼M1

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

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 practitionerf should be consulted.

Overdose

No case of overdose has been reported.

▼M5

COMMUNITY LIST ENTRY ON *THYMUS VULGARIS* L., *THYMUS ZYGIS* LOEFL. EX L., AETHEROLEUM

Scientific name of the plant

Thymus vulgaris L., *Thymus zygis* Loefl. ex L.

([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.

▼M5

Botanical family

Lamiaceae

Herbal preparation(s)

Essential oil obtained by steam distillation from the fresh flowering aerial parts of *Thymus vulgaris* L., *Thymus zygis* Loefl. ex L. or a mixture of both species

European Pharmacopoeia monograph reference

01/2008:1374

Indication(s)

Traditional herbal medicinal product for the relief of symptoms in coughs and colds.

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

Type of tradition

European

Specified strength

Please see 'Specified posology'

Specified posology

Adults and elderly

Cutaneous use: in liquid and semi-solid dosage forms in concentrations up to 10 %; apply up to 3 times daily.

Use as bath additive: 0,007-0,025 g per litre.

Adolescents

Use as bath additive: 0,007-0,025 g per litre

Children 6-12 years

Use as bath additive: 0,0035-0,017 g per litre

Children 3-6 years

Use as bath additive: 0,0017-0,0082 g per litre

One bath every day or every second day.

The cutaneous use in children and adolescents under 18 years of age is not recommended (see section 'Special warnings and precaution for use').

The use as bath additive in children under 3 years of age is not recommended (see section 'Special warnings and precaution for use').

Route of administration

Cutaneous use: apply to the chest and the back.

Use as a bath additive: recommended temperature of bath: 35-38 °C.

Duration of use or any restrictions on the duration of use

Duration of a bath: 10-20 minutes.

If the symptoms persist longer than 1 week, 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.

▼M5

Use as bath additive:

Full baths are contraindicated in cases of open wounds, large skin injuries, acute skin diseases, high fever, severe infections, severe circulatory disturbances and cardiac insufficiency.

Special warnings and precautions for use

Cutaneous use:

Like other essential oils Thyme oil should not be applied to the face particularly in the nasal area of babies and infants under the age of 2 years because of the risk of a laryngospasm.

When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted.

The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data.

Use as bath additive:

When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted.

The use in children under 3 years of age is not recommended because medical advice should be sought and due to lack of adequate data.

In cases of hypertension, a full bath should be used with caution.

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

Hypersensitivity reactions and skin irritation have been observed. 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.

▼M6

COMMUNITY LIST ENTRY ON *VITIS VINIFERA* L., FOLIUM

Scientific name of the plant

Vitis vinifera L.

Botanical family

Vitaceae

Herbal substance

Grapevine leaf ([1])

Common name of herbal substance in all EU official languages

BG (bălgarski): лоза, лист	LT (lietuvių kalba): Tikrųjų vynmedžių lapai
CS (čeština): Červený list vinné révy	LV (latviešu valoda): Īstā vīnkoka lapas
DA (dansk): Vinblad	MT (malti): Werqa tad-dielja
DE (Deutsch): Rote Weinrebenblätter	NL (nederlands): Wijnstokblad
EL (elliniká): Φύλλο Αμπέλου	PL (polski): Liść winorośli właściwej
EN (English): Grapevine leaf	PT (português): Folha de videira
ES (español): Vid, hoja de	RO (română): Frunze de viță-de-vie
ET (eesti keel): Viinapuu lehed	SK (slovenčina): List viniča
FI (suomi): Aitoviiniköynnös, lehti	SL (slovenščina): List vinske trte
FR (français): Feuille de vigne rouge	SV (svenska): Blad från vinranka
HU (magyar): Bortermő szőlő levél	IS (íslenska): Vínviðarlauf
IT (italiano): Vite, foglia	NO (norsk): Rød vinranke, blad

Herbal preparation(s)

Soft extract (2.5-4:1; extraction solvent water)

European Pharmacopoeia monograph reference

Not applicable

Indication(s)

Traditional herbal medicinal product to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances.

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

Type of tradition

European

Specified strength

Please see ‘Specified posology’.

Specified posology

Adults and elderly

Soft extract (2.5-4:1; extraction solvent water) in a cream base (10 g contain 282 mg soft extract).

Apply a thin layer on the affected area 1-3 times daily.

([1]) The material complies with the monograph of the Pharmacopée Française X., 1996.

▼M6

The use in children and adolescents under 18 years of age is not recommended (see section 'Special warnings and precautions for use').

Route of administration

Cutaneous use.

Duration of use or any restrictions on the duration of use

Adults and elderly

The recommended duration of use is 4 weeks.

If the symptoms persist longer than 2 weeks 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.

Special warnings and precautions for use

If there is inflammation of the skin, thrombophlebitis or subcutaneous induration, severe pain, ulcers, sudden swelling of one or both legs, cardiac or renal insufficiency, a doctor should be consulted.

The product should not be used on broken skin, around the eyes or on mucous membranes.

In the absence of sufficient safety data, the use in children and adolescents below 18 years of age is not recommended.

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

Contact allergy and/or hypersensitivity reactions of the skin (itching and erythema, urticaria) have been reported. 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.