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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
► <u>M4</u>	Commission Implementing Decision 2011/785/EU of 28 November 2011	L 319	102	2.12.2011
► <u>M5</u>	Commission Implementing Decision 2012/67/EU of 3 February 2012	L 34	5	7.2.2012
► <u>M6</u>	Commission Implementing Decision 2012/68/EU of 3 February 2012	L 34	8	7.2.2012
► <u>M7</u>	Commission Implementing Decision (EU) 2016/1658 of 13 September 2016	L 247	19	15.9.2016
► <u>M8</u>	Commission Implementing Decision (EU) 2016/1659 of 13 September 2016	L 247	22	15.9.2016

▼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)

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▼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.

▼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*

▼ M8

Melaleuca alternifolia (Maiden and Betch) Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and/or other species of *Melaleuca*, aetheroleum

▼ M3

Mentha x piperita L.

▼ M1

Pimpinella anisum L

▼ M5

Thymus vulgaris L., *Thymus zygis* Loebl. 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 (bългарски): 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:

▼ 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 (bългарски): 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 zonnehoeckruid
EL (elliniká): Πόα Εχινάκας 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 incluídas 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): bibor 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.

▼ 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 (bългарski): елеутерокок, корен	IT (italiano): Eleuterococco radice
CS (čeština): eleuterokokový kořen	LT (lietuvių kalba): Eleuterokokų šaknys
DA (dansk): Russisk rod	LV (latviešu valoda): Eleiterokoka sakne
DE (Deutsch): Taigawurzel	MT (malti): Għerq ta' l-eleuterokokku
EL (elliniká): Ρίζα Ελευθεροκόκκου	NL (nederlands): Russische ginsengwortel
EN (English): Eleutherococcus root	PL (polski): korzeń eleuterokoka
ES (español): Eleuterococo, raíz de	PT (português): Raiz de Ginseng Siberiano
ET (eesti keel): eleuterokokijuur	RO (română): Rădăcină de ginseng siberian
FI (suomi): venäjänjuuren juuri	SK (slovenčina): ► M7 Koreň eleuterokoka ◀
FR (français): racine d'éléuthérocoque (racine de ginseng sibérien)	SL (slovenščina): korenina elevterokoka
► M7 HR (hrvatska): Korijen sibirskog ginsenga ◀	SV (svenska): Rysk rot
HU (magyar): Szibériai ginszeng gyökér (tajga gyökér)	IS (íslenska): Síberíu ginseng, rót
	NO (norsk): Russisk rot

Herbal preparation(s)▼ **M7**

Comminuted herbal substance

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

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

▼ **M2**

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

▼ **M7**

Dry aqueous extract (DER 15-17:1)

Tincture (ratio of herbal substance to extraction solvent 1:5, extraction solvent ethanol 40 % v/v)

▼ **M2****European Pharmacopoeia monograph reference**Eleutherococcus — Eleutherococci radix (ref.: 01/2008: 1419 corrected ► **M7** 7.0 ◀)**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▼ **M7**

European, Chinese.

▼ **M2****Specified strength**▼ **M7**

Please see 'Specified posology'.

▼ **M2****Specified posology**Adolescents ► **M7** ————— ◀, adults, elderly

Herbal preparations.

▼ **M7**

Average daily dose.

▼ M2

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.

► **M7** The use in children under 12 years of age is not recommended ◀ (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**▼ M7**

Contraindication

▼ M2

Hypersensitivity to the active substance.

▼ M7

▼ M2

Special warnings and precautions for use

▼ M7

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

▼ M2

If the symptoms worsen during the use of the medicinal product, a doctor or a qualified healthcare practitioner should be consulted. ► **M7** For tinctures and 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.

▼ M7

Fertility, pregnancy and lactation

▼ M2

Safety during pregnancy and lactation has not been established.

In the absence of sufficient data, the use during pregnancy and lactation is not recommended. ► **M7** No fertility data available. ◀

Effects on ability to drive and use machines

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

▼ M2*Undesirable effects*

Insomnia, irritability, tachycardia and headaches may occur. The frequency is not known. ► **M7** 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.

▼ M7*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

**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

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 aldín
IT (italiano): Finocchio amaro (o selvatico), frutto	NO (norsk): Fenikkel, bitter
LT (lietuvių kalba): Karčiąjų pankolių vaisiai	

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.

⁽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*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. 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, 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 (islenska): Sæt fennel aldin
IT (italiano): Finocchio dolce (o romano), frutto	NO (norsk): Fenikkel, søt

▼B**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

1,5 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.

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.

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

⁽²⁾ 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**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.

▼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⁾

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

▼ M4**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').

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.

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

▼ M4**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.

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.

▼ M8

UNION LIST ENTRY ON *MELALEUCA ALTERNIFOLIA* (MAIDEN AND BETCH) CHEEL, *M. LINARIIFOLIA* SMITH, *M. DISSITIFLORA* F. MUELLER AND/OR OTHER SPECIES OF *MELALEUCA*, AETHEROLEUM

Scientific name of the plant

Melaleuca alternifolia (Maiden and Betch) Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and other species of *Melaleuca*

Botanical family

Myrtaceae

▼M8**Common name in all EU official languages of herbal preparation**

BG (bългарски): Чаено дърво, масло	IT (italiano): Melaleuca essenza
CS (čeština): silice kajeputu střídavolistého	LT (lietuvių kalba): Arbatmedžių eterinis aliejus
DA (dansk): Tetræolie	LV (latviešu valoda): Tējaskoka ēteriskā eļļa
DE (Deutsch): Teebaumöl	MT (Malti): Żejt tal-Melaleuca
EL (elliniká): Μελαλεύκης αιθέριο έλαιο	NL (Nederlands): Theeboomolie
EN (English): Tea tree oil	PL (polski): Olejek eteryczny drzewa herbacianego
ES (español): Melaleuca alternifolia, aceite esencial de	PT (português): Óleo essencial de melaleuca
ET (eesti keel): teepuuõli	RO (română): Melaleuca (arbore de ceai) (ulei esențial)
FI (suomi): teepuuöljy	SK (slovenčina): Silica melaleuky
FR (français): Mèlaleuca (arbre à thé) (huile essentielle de)	SL (slovenščina): eterično olje melalevke
HR (hrvatska): eteričnog ulje australijskog čajevca	SV (svenska): Teträdsolja
HU (magyar): Teafa-olaj	NO (norsk): Tetreolje

Herbal preparation

Essential oil

European Pharmacopoeia monograph reference

01/2008:1837

Indications**Indication (a)**

Traditional herbal medicinal product for treatment of small superficial wounds and insect bites.

Indication (b)

Traditional herbal medicinal product for treatment of small boils (furuncles and mild acne).

Indication (c)

Traditional herbal medicinal product for the relief of itching and irritation in cases of mild athlete's foot.

Indication (d)

Traditional herbal medicinal product for symptomatic treatment of minor inflammation of the oral mucosa.

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**Indication (a)**

Adolescents, adults and elderly

Single dose

0,03-0,07 ml of undiluted essential oil to be applied to the affected area using a cotton bud 1-3 times daily.

▼M8

Liquid preparations containing 0,5 % to 10 % of essential oil to be applied to the affected area 1-3 times daily.

Indication (b)

Adolescents, adults and elderly

Single dose

Oily liquid or semi-solid preparations containing 10 % of essential oil to be applied to the affected area 1-3 times daily, or

0,7-1 ml of essential oil stirred into 100 ml of lukewarm water to be applied as an impregnated dressing to the affected areas of skin. Undiluted essential oil to be applied to the boil using a cotton bud 2-3 times daily.

Indication (c)

Adolescents, adults and elderly

Single dose

Oily liquid or semi-solid preparations containing 10 % of essential oil to be applied on the affected area 1-3 times daily. 0,17-0,33 ml of essential oil in an appropriate volume of warm water to cover the feet. Soak feet for 5-10 minutes daily.

Undiluted essential oil to be applied to the affected area using a cotton bud 2-3 times daily.

Indication (d)

Adolescents, adults and elderly

0,17-0,33 ml of essential oil to be mixed in 100 ml of water for rinse or gargle several 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**Indications (a), (b) and (c)**

Cutaneous use

Indication (d)

Oromucosal use.

Duration of use or any restrictions on the duration of use**Indication (a)**

If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Indications (b) and (c)

Not to be used for more than 1 month.

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

Indication (d)

If the symptoms persist longer than 5 days 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 colophony.

▼M8*Special warnings and precautions for use*

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

If a rash develops, discontinue use.

Not to be used orally or as inhalation.

Not to be used in eyes or ears.

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

Indication (a)

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

Indication (b)

In cases of severe acne a doctor or a qualified health care practitioner shall be consulted.

Indication (c)

For the eradication of fungal infection a doctor or a qualified health care practitioner shall be consulted.

Indication (d)

Not to be swallowed.

Interactions with other medicinal products and other forms of interaction

None reported.

Fertility, pregnancy and lactation

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

No fertility data available.

Effects on ability to drive and use machines

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

Undesirable effects

Adverse skin reactions including smarting pain, mild pruritus, burning sensation, irritation, itching, stinging, erythema, oedema (contact dermatitis) or other allergic reactions have been reported. The frequency is not known.

Burn-like skin reactions have been reported. The frequency is rare (< 1/1 000).

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

Overdose

Cutaneous use:

None reported.

Oromucosal use:

Accidental overdose may cause central nervous system depression and muscle weakness. However, in adults these symptoms generally resolve within 36 hours.

▼ M8

If ingestion occurs, the patient should be monitored and standard supportive treatment applied as required.

In children, ingestion of tea tree oil is a medical emergency requiring immediate hospital treatment and respiratory support.

Pharmaceutical particulars (if necessary)

Store in air-tight containers, protected from light and heat.

Proper storage and handling are needed to avoid the formation of oxidation products which have greater potential for skin sensitisation.

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 (bългарски): 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'

▼ 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 practitioner 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* Loebl. 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 substanceGrapevine leaf ⁽¹⁾**Common name of herbal substance in all EU official languages**

BG (bългарski): лоза, лист	LT (lietuvių kalba): Tikrųjų vynuogių 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.