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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      |
| ► <b><u>M1</u></b> | Commission Decision 2010/28/EC of 28 July 2009                   | L 11             | 12   | 16.1.2010 |
| ► <b><u>M2</u></b> | Commission Decision 2010/30/EU of 9 December 2009                | L 12             | 14   | 19.1.2010 |
| ► <b><u>M3</u></b> | Commission Decision 2010/180/EU of 25 March 2010                 | L 80             | 52   | 26.3.2010 |
| ► <b><u>M4</u></b> | Commission Implementing Decision 2011/785/EU of 28 November 2011 | L 319            | 102  | 2.12.2011 |



## 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 <sup>(1)</sup>, and in particular Article 16(f) thereof,

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

Whereas:

- (1) *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung comply with the requirements set out in Directive 2001/83/EC. *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung can be considered as herbal substances, herbal preparations and/or combinations thereof.
- (2) It is therefore appropriate to establish a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products including the entry of *Foeniculum vulgare* Miller subsp. *vulgare* var. *vulgare* and the entry of *Foeniculum vulgare* Miller subsp. *vulgare* var. *dulce* (Miller) Thellung.
- (3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:



### Article 1

A list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products is established in Annex I.

### Article 2

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

<sup>(1)</sup> OJ L 311, 28.11.2001, p. 67.

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*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

▼ **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 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 (bългарски): пурпурна ехинацея,<br>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 Εχινάκεας της πορφύρας                                       | PL (polski): jeżówka purpurowa, świeże ziele                   |
| EN (English): purple coneflower herb  | PT (português): Equinácea, partes aéreas floridas              |
| ES (español): Equinácea purpúrea,<br>partes aéreas incluídas sumidades floridas | RO (română): iarbă proaspătă de Echinacea, pâlăria<br>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<br>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                                     | LT (lietuvių kalba): Eleuterokokų šaknys  |
| CS (čeština): eleuterokokový kořen                                     | LV (latviešu valoda): Eleiterokoka sakne  |
| DA (dansk): Russisk rod  | MT (malti): Għerq ta' l-eleuterokokku     |
| DE (Deutsch): Taigawurzel  | NL (nederlands): Russische ginsengwortel  |
| EL (elliniká): Πίζα Ελευθεροκόκκου                                     | PL (polski): korzeń eleuterokoka          |
| EN (English): Eleutherococcus root                                     | PT (português): Raiz de Ginseng Siberiano |
| ES (español): Eleuterococo, raíz de                                    | RO (română): Rădăcină de ginseng siberian |
| ET (eesti keel): eleuterokokijuur                                      | SK (slovenčina): Všehojovcový koreň       |
| FI (suomi): venäjänjuuren juuri  | SL (slovenščina): korenina elevterokoka   |
| FR (français): racine d'éléuthérocoque<br>(racine de ginseng sibérien) | SV (svenska): Rysk rot                    |
| HU (magyar): Szibériai ginszeng gyökér (tajga gyökér)                  | IS (íslenska): Síberíu ginseng, rót       |
| IT (italiano): Eleuterococco radice                                    | NO (norsk): Russisk rot                   |

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

**Herbal preparation(s)**

Fennel, bitter, dried comminuted <sup>(1)</sup> 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 <sup>(2)</sup>) 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').

<sup>(1)</sup> 'Comminuted fruit' is intended to cover also 'crushed fruit'.

<sup>(2)</sup> 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 (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 ħelu, frotta                   |
| DE (Deutsch): Süßer Fenchel                       | NL (nederlands): Venkelvrucht, zoet                |
| EL (elliniká): Μαραθόσπορος γλυκός                | PL (polski): Owoc kopru włoskiego (odmiana słodka) |
| EN (English): Sweet fennel, fruit                 | PT (português): Fruto de funcho doce               |
| ES (español): Hinojo dulce, fruto de              | RO (română): Fruct de fenicul dulce                |
| ET (eesti keel): Magus apteegitill, vili          | SK (slovenčina): Feniklový plod sladký             |
| FI (suomi): Makea fenkoli, hedelmä                | SL (slovenščina): Plod sladkega navadnega komarčka |
| FR (français): Fruit de fenouil doux              | SV (svenska): Sötfränkål, frukt                    |
| HU (magyar): Édesköménytermés                     | IS (islenska): Sæt fennel aldin                    |
| IT (italiano): Finocchio dolce (o romano), frutto | NO (norsk): Fenikkel, søt                          |

**Herbal preparation(s)**Fennel, sweet, dried comminuted <sup>(1)</sup> 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

<sup>(1)</sup> 'Comminuted fruit' is intended to cover also 'crushed fruit'.

**▼B**

1,5 to 2,5 g of (freshly <sup>(1)</sup>) 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.

<sup>(1)</sup> 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 %) <sup>(1)</sup>

**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').

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

**▼M4***Adolescents, adults and elderly***Indication (b)**

Eye drops <sup>(1)</sup> 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.

<sup>(1)</sup> 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 (bългарski): Анасон, плод               | LT (lietuvių kalba): Anyžių sėklos    |
| CS (čeština): Anýzový plod                 | LV (latviešu valoda): Anīsa sēklas    |
| DA (dansk): Anisfrø                        | MT (malti): Frotta tal-Anisi          |
| DE (Deutsch): Anis                         | NL (nederlands): Anijsvrucht          |
| EL (elliniká): Γλυκάνισο                   | PL (polski): Owoc anyżu               |
| EN (English): Aniseed                      | PT (português): Anis                  |
| ES (español): Fruto de anís                | RO (română): Fruct de anason          |
| ET (eesti keel): Aniis                     | SK (slovenčina): Anízový plod         |
| FI (suomi): Anis                           | SL (slovenščina): Plod vrtnega janeža |
| FR (français): Anis (fruit d)              | SV (svenska): Anis                    |
| HU (magyar): Ánizsmag                      | IS (íslenska): Anís                   |
| IT (italiano): Anice (Anice verde), frutto | NO (norsk): Anis                      |

**Herbal preparation(s)**

Dried aniseed, comminuted or crushed

**European Pharmacopoeia monograph reference**

*Anisi fructus* (01/2005:0262)

**Indication(s)**

- (a) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence.
- (b) Traditional herbal medicinal product used as an expectorant in cough associated with cold.

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

**Type of tradition**

European

**Specified strength**

Please see 'Specified posology'

**▼ M1****Specified posology**

*Adolescents over 12 years of age, adults, elderly:*

Indications (a) and (b)

1 to 3,5 g of whole or (freshly <sup>(1)</sup>) 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.

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