

DECISIONS

COMMISSION IMPLEMENTING DECISION

of 3 February 2012

amending Decision 2008/911/EC establishing a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products*(notified under document C(2012) 514)***(Text with EEA relevance)**

(2012/67/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on European Union and the Treaty on the Functioning of the European Union,

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 16f thereof,

Having regard to the opinion of the European Medicines Agency, formulated on 15 July 2010 by the Committee for Herbal Medicinal Products,

Whereas:

- (1) *Thymus vulgaris* L., *Thymus zygis* Loebl. ex L. can be considered as a herbal substance, a herbal preparation or a combination thereof within the meaning of Directive 2001/83/EC and it complies with the requirements set out in that Directive.
- (2) It is therefore appropriate to include *Thymus vulgaris* L., *Thymus zygis* Loebl. ex L. in the list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products established by Commission Decision 2008/911/EC ⁽²⁾.

- (3) Decision 2008/911/EC should therefore be amended accordingly.

- (4) 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

Annexes I and II to Decision 2008/911/EC are amended in accordance with the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 3 February 2012.

For the Commission

John DALLI

Member of the Commission⁽¹⁾ OJ L 311, 28.11.2001, p. 67.⁽²⁾ OJ L 328, 6.12.2008, p. 42.

ANNEX

Decision 2008/911/EC is amended as follows:

(1) in Annex I, the following substance is inserted after *Pimpinella anisum* L.:

Thymus vulgaris L., *Thymus zygis* Loebl. ex L., aetheroleum;

(2) in Annex II, the following is inserted after the entry on *Pimpinella anisum* L.:

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

Scientific name of the plant

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

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.

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.
