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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Thymus vulgaris* L., *Thymus zygis* Loefl. ex L., aetheroleum

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BG (bългарски): Неприложимо. CS (čeština): Neuplatňuje se. DA (dansk): Ikke relevant. DE (Deutsch): Nicht zutreffend. EL (ελληνικά): Άνευ αντικειμένου. EN (English): Not applicable. ES (español): No procede. ET (eesti keel): Ei ole asjakohane. FI (suomi): Ei sovelleta. FR (français): Sans objet. HU (magyar): Nem értelmezhető. IT (italiano): Non applicabile.	LT (lietuvių kalba): Duomenys nebūtini. LV (latviešu valoda): Nav piemērojams. MT (malti): Ma jghoddx. NL (nederlands): Niet van toepassing. PL (polski): Nie dotyczy. PT (português): Não aplicável. RO (română): Nu este cazul. SK (slovenčina): Neuplatňuje sa. SL (slovenščina): Navedba smiselno ni potrebna. SV (svenska): Erfodras ej. <i>IS (íslenska):</i> A ekki vid. <i>NO (norsk):</i> Ikke relevant.
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Community herbal monograph on *Thymus vulgaris* L., *Thymus zygis* Loefl. ex L., aetheroleum

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{1,2}

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Thymus vulgaris</i> L. or <i>Thymus zygis</i> Loefl. ex L. or a mixture of both species, aetheroleum (thyme oil)</p> <p>i) Herbal substance Not applicable.</p> <p>ii) Herbal preparations Essential oil.</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>In liquid dosage forms for oral use (indication 1) and in liquid or semi-solid dosage forms for cutaneous use and use as a bath additive (indication 2).</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

¹ The material complies with the Ph. Eur. monograph (ref.: 01/2008:1374).

² The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product used as an expectorant in cough associated with cold.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for the relief of symptoms in coughs and colds.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration

Well-established use	Traditional use
	<p>Posology</p> <p>Indication 1)</p> <p><i>Adults and elderly</i></p> <p>Oral use: 4-5 drops (single dose), 3-5 times daily.</p> <p>The oral use in children and adolescents under 18 years of age is not recommended (see 4.4 Special warnings and precaution for use).</p> <p>Indication 2)</p> <p><i>Adults and elderly</i></p> <p>Cutaneous use: in liquid and semi-solid dosage forms in concentrations up to 10%; apply up to 3 times daily.</p> <p>Use as bath additive: 0.007 – 0.025 g per litre.</p> <p><i>Adolescents</i></p> <p>Use as bath additive: 0.007 – 0.025 g per litre.</p> <p><i>Children 6-12 years</i></p> <p>Use as bath additive: 0.0035 – 0.017 g per litre.</p> <p><i>Children 3-6 years</i></p> <p>Use as bath additive: 0.0017 – 0.0082 g per litre.</p> <p>One bath every day or every second day.</p> <p>The cutaneous use in children and adolescents</p>

	<p>under 18 years of age is not recommended (see 4.4 Special warnings and precaution for use).</p> <p>The use as bath additive in children under 3 years of age is not recommended (see 4.4 Special warnings and precaution for use).</p> <p>Duration of use</p> <p>Indication 2)</p> <p>Duration of a bath: 10-20 minutes.</p> <p>Indications 1) and 2)</p> <p>If the symptoms persist longer than 1 week, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Indication 1)</p> <p>Oral use.</p> <p>Indication 2)</p> <p>Cutaneous use: apply on the chest and the back. Use as bath additive: recommended temperature of bath: 35 – 38 °C.</p>
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4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance.</p> <p>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.</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>Indication 1)</p> <p>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 two years because of the risk of a laryngospasm.</p> <p>When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner</p>

	<p>should be consulted.</p> <p>The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data.</p> <p>Indication 2)</p> <p>Use as bath additive: When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted.</p> <p>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.</p> <p>In cases of hypertension, a full bath should be used with caution.</p> <p>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 two 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.</p> <p>The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data.</p>
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4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	<p>Safety during pregnancy and lactation has not been established.</p> <p>In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p>

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	Indication 1) Hypersensitivity reactions have been observed. The frequency is not known. Indication 2) 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.

4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless

	<p>necessary for the safe use of the product.</p> <p>Thyme essential oil had no mutagenic or DNA-damaging activity in either the Ames test (strains TA1535, TA1537, TA98, TA100, with and without metabolic activation) or Bacillus subtilis rec-Assay.</p> <p>Adequate tests on reproductive toxicity and carcinogenicity have not been performed.</p>
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6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

16 September 2010

Superseded