



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Eucalyptus globulus* Labill., *Eucalyptus polybractea* R.T. Baker and/or *Eucalyptus smithii* R.T. Baker, aetheroleum

Draft

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<p>BG (bългарski): Евкалипново масло CS (čeština): blahovičnicková silice DA (dansk): Eucalyptusolie DE (Deutsch): Eukalyptusöl EL (elliniká): έλαιο ευκαλύπτου- αιθέριο έλαιο ευκαλύπτου EN (English): Eucalyptus oil ES (español): Eucalipto, aceite esencial de ET (eesti keel): eukalüptiõli FI (suomi): eukalyptusöljy FR (français): Eucalyptus (huile essentielle d') HU (magyar): Eukalyptuszolaj IT (italiano): Eucalipto essenza</p>	<p>LT (lietuvių kalba): Eukaliptų eterinis aliejus LV (latviešu valoda): Eikalipta ēteriskā eļļa MT (malti): Żejt tal-Ewkaliptus NL (nederlands): Eucalyptusolie PL (polski): Olejek eteryczny eukaliptusowy PT (português): Óleo essencial de eucalipto RO (română): ueli volatil de eucalipt SK (slovenčina): Eukalyptová silica SL (slovenščina): eterično olje evkalipta SV (svenska): Eukalyptusolja IS (islenska): NO (norsk): Eukalyptusolje</p>
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Community herbal monograph on *Eucalyptus globulus* Labill., *Eucalyptus polybractea* R.T. Baker and *Eucalyptus smithii* R.T. Baker, 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>Eucalyptus globulus</i> Labill., <i>Eucalyptus polybractea</i> R.T. Baker and <i>Eucalyptus smithii</i> R.T. Baker, aetheroleum (Eucalyptus 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>Herbal preparation in solid or liquid dosage forms for oral use.</p> <p>Herbal preparations in liquid dosage forms for inhalation or as bath additives.</p> <p>Herbal preparations in liquid or semi-solid dosage forms for cutaneous use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

² The material complies with the Ph. Eur. monograph (ref.: 07/2012:0390).

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product used for relief of cough associated with cold.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for the symptomatic relief of localised muscle pain.</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><u>Oral use</u></p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 100-200 mg, 2 to 5 times a day</p> <p>The use in children under 30 months of age is contraindicated (see section 4.3 'Contraindications').</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><u>Cutaneous use</u></p> <p><i>Children between 4 and 12 years of age, adolescents, adults and elderly</i></p> <p>Single dose for liquid dosage forms: a few drops on chest or back, 2 to 3 times a day</p> <p>Single dose for semi-solid dosage forms (10% Eucalyptus oil): apply a thin layer on chest and back, 2 to 3 times a day</p> <p>The use in children under 30 months of age is contraindicated (see section 4.3</p>

Well-established use	Traditional use
	<p>'Contraindications').</p> <p>The use is not recommended in children between 2.5 and 4 years of age (see section 4.4 'Special warnings and precautions for use').</p> <p><u>Inhalation</u></p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: up to 3-8 drops per 250 ml boiling water, 3 times a day</p> <p><i>Children between 4 and 12 years of age</i></p> <p>Single dose: up to 2-4 drops per 250 ml boiling water, 3 times a day</p> <p>The use in children under 30 months of age is contraindicated (see section 4.3 'Contraindications').</p> <p>The use in children between 2.5 and 4 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><u>Use as bath additive</u></p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 1.5-6 g essential oil/100 l water, 3 to 4 times a week</p> <p><i>Children between 4 and 12 years of age</i></p> <p>Single dose: 0.5-3 g essential oil/100 l water, 3 to 4 times a week</p> <p>Recommended bath temperature is at 35-38°C for 10-20 minutes.</p> <p>The use in children under 30 months of age is contraindicated (see section 4.3 'Contraindications').</p> <p>The use is not recommended in children between 2.5 and 4 years of age (see section 4.4 'Special warnings and precautions for use').</p> <p>Indication 2)</p> <p><u>Cutaneous use</u></p> <p><i>Children between 4 and 12 years of age, adolescents, adults and elderly</i></p>

Well-established use	Traditional use
	<p>Single dose for liquid dosage forms: a few drops on the affected areas, 2 to 3 times a day</p> <p>Single dose for semi-solid dosage forms (10% eucalyptus oil): apply a thin layer on affected areas, 2 to 3 times a day</p> <p>The use in children under 30 months of age is contraindicated (see section 4.3 'Contraindications').</p> <p>The use is not recommended in children between 2.5 and 4 years of age (see section 4.4 'Special warnings and precautions for use').</p> <p><u>Use as bath additive</u></p> <p><i>Children between 4 and 12 years of age, adolescents, adults and elderly</i></p> <p>Single dose: 1.7-4 g essential oil/100 l water, 3 to 4 times a week</p> <p>Recommended bath temperature is at 35-38°C for 10-20 minutes.</p> <p>The use in children under 30 months of age is contraindicated (see section 4.3 'Contraindications').</p> <p>The use is not recommended in children between 2.5 and 4 years of age (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>Indication 1)</p> <p>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.</p> <p>Indication 2)</p> <p><u>Use as bath additive</u></p> <p>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.</p>

Well-established use	Traditional use
	<p data-bbox="810 259 991 286"><u>Cutaneous use</u></p> <p data-bbox="810 315 1410 454">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.</p> <p data-bbox="810 483 1155 510">Method of administration</p> <p data-bbox="810 539 1091 566">Oral use (indication 1).</p> <p data-bbox="810 595 1214 622">Cutaneous use (indications 1, 2).</p> <p data-bbox="810 651 1114 678">Inhalation (indication 1).</p> <p data-bbox="810 707 1283 734">Use as bath additive (indications 1, 2).</p>

4.3. Contraindications

Well-established use	Traditional use
	<p data-bbox="810 925 1382 952">Hypersensitivity to Eucalyptus oil or 1,8-cineol.</p> <p data-bbox="810 981 1394 1008">Children with history of seizures (febrile or not).</p> <p data-bbox="810 1037 1401 1176">Children under 30 months of age, because there is a risk that 1,8-cineole containing preparations, like other essential oil can induce laryngospasm.</p> <p data-bbox="810 1205 1390 1344">Full hot baths are contraindicated in cases of large skin injuries and open wounds, acute skin diseases, high fever, severe infections, severe circulatory disturbances and cardiac failure.</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p data-bbox="810 1534 1390 1632">The use in children between 2.5 and 4 years of age has not been established due to lack of adequate data.</p> <p data-bbox="810 1662 991 1688"><u>Cutaneous use</u></p> <p data-bbox="810 1718 1426 1816">Eye contact with unwashed hands after the application of eucalyptus oil may potentially cause irritation.</p> <p data-bbox="810 1845 1417 1912">Eucalyptus oil should not be applied on broken or irritated skin.</p> <p data-bbox="810 1942 916 1968"><u>Oral use</u></p>

Well-established use	Traditional use
	<p>Eucalyptus oil should be used with caution in inflamed and ulcerated conditions of the gastrointestinal tract.</p> <p>Indication 1)</p> <p>When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted.</p> <p>The oral use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Indication 2)</p> <p>When reddening or swelling of the aching parts occur a doctor or a qualified health care practitioner should be consulted.</p>

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported.

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</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
	<p>None known.</p> <p>If adverse reactions occur, a doctor or a qualified</p>

Well-established use	Traditional use
	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
	<p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product.</p> <p>Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

15 June 2013