



20 November 2024  
EMA/HMPC/320292/2023  
Committee on Herbal Medicinal Products (HMPC)

## European Union herbal monograph on *Eucalyptus globulus* Labill.; *Eucalyptus polybractea* R.T. Baker; *Eucalyptus smithii* R.T. Baker, aetheroleum

Final - Revision 1

<b>Initial assessment</b>	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	May 2012 September 2012 November 2012 March 2013
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	14 May 2013
End of consultation (deadline for comments)	15 November 2013
Re-discussion in MLWP	January 2014
Adoption by HMPC Monograph (EMA/HMPC/307781/2012) Assessment Report (EMA/HMPC/307782/2012) List of References (EMA/HMPC/307783/2012) Overview of Comments received during the public consultation (EMA/HMPC/32373/2014) HMPC Opinion (EMA/HMPC/283230/2014)	25 March 2014
<b>First revision</b>	
Discussion in HMPC	July 2023 January 2024 March 2024
Adopted by HMPC for release for consultation	20 March 2024
Start of public consultation	15 April 2024
End of consultation (deadline for comments)	15 July 2024
Re-discussion in HMPC	September 2024 November 2024
Adoption by HMPC	20 November 2024



Keywords	Committee on Herbal Medicinal Products; HMPC; European Union herbal monographs; herbal medicinal products; traditional herbal medicinal products; traditional use; <i>Eucalyptus globulus</i> Labill.; <i>Eucalyptus polybractea</i> R.T. Baker; <i>Eucalyptus smithii</i> R.T. Baker, aetheroleum; Eucalypti aetheroleum; Eucalyptus oil
----------	---

BG (bългарски): Евкалипново масло CS (čeština): blahovičnicková silice DA (dansk): Eucalyptusolie DE (Deutsch): Eukalyptusöl EL (elliniká): 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') HR (hrvatska): eukaliptusovo eterično ulje HU (magyar): eukaliptuszolaj IT (italiano): Eucalipto essenza	LT (lietuvių kalba): Eukaliptų eterinis aliejus LV (latviešu valoda): Eikalīpta 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): silica eukalyptu SL (slovenščina): eterično olje evkalipta SV (svenska): eukalyptusolja IS (íslenska): NO (norsk): eukalyptusolje
--	---

# European Union herbal monograph on *Eucalyptus globulus* Labill.; *Eucalyptus polybractea* R.T. Baker; *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<sup>1, 2</sup>

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC</p> <p><i>Eucalyptus globulus</i> Labill.; <i>Eucalyptus polybractea</i> R.T. Baker; <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 preparations in solid dosage forms for oral use.</p> <p>Herbal preparations in liquid dosage forms for inhalation, cutaneous use and bath additive.</p> <p>Herbal preparations in semi-solid dosage forms for cutaneous use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

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

<sup>2</sup> The material complies with the Ph. Eur. monograph (ref.: 07/2021:0390)

## 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 used 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><b>Posology</b></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, 2-5 times daily Daily dose: 200-600 mg</p> <p>The use in children under 24 months of age is contraindicated (see section 4.3 'Contraindication').</p> <p>The use in children between 2 and 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 from 3 years of age, adolescents, adults and elderly</i></p> <p>Single dose: rub a few drops on chest and back, 2-3 times daily</p> <ul style="list-style-type: none"><li>• semi-solid dosage forms (ointments 10% eucalyptus oil)</li></ul> <p><i>Adolescents, adults and elderly and children between 3 and 12 years of age</i></p>

Well-established use	Traditional use
	<p>Single dose: apply a thin layer on chest and back, 2-3 times daily</p> <p>The use in children under 24 months of age is contraindicated (see section 4.3 'Contraindication').</p> <p>The use in children between 2 and 3 years of age is not recommended (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: 3-8 drops per 250 ml boiling water, 3 times daily</p> <p><i>Children between 3 and 11 years of age</i></p> <p>Single dose: up to 2-4 drops per 250 ml boiling water, 3 times daily.</p> <p>The use in children under 24 months of age is contraindicated (see section 4.3 'Contraindications').</p> <p>The use in children between 2 and 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><u>Bath additive</u></p> <ul style="list-style-type: none"> <li>liquid dosage forms</li> </ul> <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 3 and 11 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 35-38°C, 10-20 min</p> <p>The use in children under 24 months of age is contraindicated (see section 4.3 'Contraindications').</p> <p>The use in children between 2 and 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><b>Indication 2)</b></p>

Well-established use	Traditional use
	<p><b>Cutaneous use</b></p> <p><i>Adolescents, adults and elderly and children between 3 and 12 years of age</i></p> <p>Single dose: rub a few drops on the skin of the affected area, 2-3 times daily</p> <ul style="list-style-type: none"> <li>• semi-solid dosage forms (ointments 10% eucalyptus oil)</li> </ul> <p><i>Adolescents, adults and elderly and children between 3 and 12 years of age</i></p> <p>Single dose: apply a thin layer on the affected area, 2 to 3 times daily</p> <p>The use in children under 24 months of age is contraindicated (see section 4.3 'Contraindications').</p> <p>The use in children between 2 and 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><b>Bath additive</b></p> <ul style="list-style-type: none"> <li>• liquid dosage forms</li> </ul> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose: 2.7-4 g essential oil/100 l water, 3 to 4 times a week</p> <p><i>Children between 3 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 35-38°C, 10-20 min</p> <p>The use in children under 24 months of age is contraindicated (see section 4.3 'Contraindications').</p> <p>The use in children between 2 and 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><b>Duration of use</b></p> <p>Duration of use</p> <p><b>Indication 1)</b></p> <p>If the symptoms persist longer than 1 week during the use of the medicinal product, a</p>

Well-established use	Traditional use
	<p>doctor or a qualified health care practitioner should be consulted.</p> <p><b>Indication 2)</b></p> <p><u>Cutaneous use</u> 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><u>Use as bath additive</u> 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><b>Method of administration</b></p> <p>Oral use (indication 1) Inhalation (indication 1) Cutaneous use (indication 1 and 2) Use as bath additive (indication 1 and 2)</p>

### 4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to eucalyptus oil or 1,8-cineol.</p> <p>Children with history of seizures (febrile or not).</p> <p>Children under 24 months of age, because there is a risk that 1,8-cineole containing preparations, like other essential oils, can induce laryngospasm.</p> <p>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><b>Indication 1)</b></p>

Well-established use	Traditional use
	<p>When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><u>Oral use</u></p> <p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Eucalyptus oil should be used with caution in inflamed and ulcerated conditions of the gastrointestinal tract.</p> <p><u>Inhalation</u></p> <p>The use in children under 3 years of age has not been established due to lack of adequate data.</p> <p>Caution is necessary in inhalations with hot water, to avoid burns. The area of the eyes should be outside of the steam.</p> <p><u>Cutaneous use and use as bath additive</u></p> <p>The use in children between 2 and 3 years of age has not been established due to lack of adequate data.</p> <p>Eye contact with unwashed hands after the application may potentially cause irritation.</p> <p>Eucalyptus oil should not be applied on broken or irritated skin.</p> <p><b>Indication 2)</b></p> <p>When reddening or swelling of the aching parts occur a doctor or a qualified health care practitioner should be consulted.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>The use in children between 2 and 3 years of age has not been established due to lack of adequate data.</p> <p>Eye contact with unwashed hands after the application may potentially cause irritation.</p>



Well-established use	Traditional use
	Eucalyptus oil should not be applied on broken or irritated skin.

#### **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
	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 are available.

#### **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><u>All uses:</u> Immune system disorders allergic reactions including severe allergic reactions as systemic allergic reactions</p> <p><u>Oral use:</u> Gastrointestinal disorders gastrointestinal reactions (as heart burn, abdominal pain, nausea, vomiting, diarrhoea)</p> <p><u>Cutaneous use:</u> Skin and subcutaneous tissue disorders contact eczema</p> <p>The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

## 4.9. Overdose

Well-established use	Traditional use
	<p><u>Oromucosal use:</u> Intake of doses larger than those recommended can provoke gastro-intestinal symptoms (such as abdominal pain, vomiting, diarrhoea, nausea); respiratory problems; central nervous problems (such as CNS depression, loss of consciousness, convulsions, ataxia), constricted pupils.</p> <p><u>Cutaneous use:</u> Accidental overdose of ointments or bath preparations may cause skin irritation.</p>

## 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.

### 5.2. Pharmacokinetic properties

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

### 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, 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

20 November 2024