



20 March 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

Draft - Revision 1

Initial assessment	
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
Rediscussion 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
First systematic review	
Discussion in MLWP	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). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 July 2024
Keywords	Committee on Herbal Medicinal Products; HMPC; European Union herbal monographs; 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 (bългарski): Евкалипново масло	LT (lietuvių kalba): Eukaliptų eterinis aliejus
CS (čeština): blahovičnicková silice	LV (latviešu valoda): Eikalīpta ēteriskā eļļa
DA (dansk): Eucalyptusolie	MT (malti): Żejt tal-Ewkaliptus
DE (Deutsch): Eukalyptusöl	NL (nederlands): Eucalyptusolie
EL (elliniká): αιθέριο έλαιο ευκαλύπτου	PL (polski): Olejek eteryczny eukaliptusowy
EN (English): Eucalyptus oil	PT (português): Óleo essencial de eucalipto
ES (español): Eucalipto, aceite esencial de	RO (română): ueli volatil de eucalipt
ET (eesti keel): eukalüptiõli	SK (slovenčina): Eukalyptová silica
FI (suomi): eukalyptusöljy	SL (slovenščina): eterično olje evkalipta
FR (français): Eucalyptus (huile essentielle d')	SV (svenska): Eukalyptusolja
HU (magyar): Eukaliptuszolaj	IS (íslenska):
HR (hrvatska): Eukaliptusovo eterično ulje	NO (norsk): Eukalyptusolje
IT (italiano): Eucalipto essenza	

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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</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>

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.: 07/2021:0390)

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>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, 2-5 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> <ul style="list-style-type: none">liquid dosage forms (pure eucalyptus oil) <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">semi-solid dosage forms (10% eucalyptus oil) <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> <ul style="list-style-type: none"> liquid dosage forms (pure eucalyptus oil) <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"> liquid dosage forms <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>

Well-established use	Traditional use
	<p data-bbox="810 286 970 315">Indication 2)</p> <p data-bbox="810 342 994 371"><u>Cutaneous use</u></p> <ul data-bbox="810 383 1350 412" style="list-style-type: none"> • liquid dosage forms (pure eucalyptus oil) <p data-bbox="810 439 1350 501"><i>Adolescents, adults and elderly and children between 3 and 12 years of age</i></p> <p data-bbox="810 528 1385 591">Single dose: rub a few drops on the skin of the affected area, 2-3 times daily</p> <ul data-bbox="810 618 1385 680" style="list-style-type: none"> • in semi-solid dosage forms (ointments 10% eucalyptus oil) <p data-bbox="810 707 1350 770"><i>Adolescents, adults and elderly and children between 3 and 12 years of age</i></p> <p data-bbox="810 797 1385 860">Single dose: apply a thin layer on the affected area, 2 to 3 times daily</p> <p data-bbox="810 887 1385 949">The use in children under 24 months of age is contraindicated (see section 4.3 'Contraindications').</p> <p data-bbox="810 976 1385 1039">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 data-bbox="810 1066 975 1095"><u>Bath additive</u></p> <ul data-bbox="810 1122 1090 1151" style="list-style-type: none"> • liquid dosage forms <p data-bbox="810 1178 1193 1207"><i>Adolescents, adults and elderly</i></p> <p data-bbox="810 1234 1409 1296">Single dose: 2.7-4 g essential oil/100 l water, 3 to 4 times a week</p> <p data-bbox="810 1323 1302 1352"><i>Children between 3 and 12 years of age</i></p> <p data-bbox="810 1379 1409 1442">Single dose: 0.5-3 g essential oil/100 l water, 3 to 4 times a week</p> <p data-bbox="810 1469 1366 1532">Recommended bath temperature is 35-38°C, 10-20 min</p> <p data-bbox="810 1559 1385 1621">The use in children under 24 months of age is contraindicated (see section 4.3 'Contraindications').</p> <p data-bbox="810 1648 1385 1711">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 data-bbox="810 1738 1018 1767">Duration of use</p> <p data-bbox="810 1794 1002 1823">Duration of use</p>

Well-established use	Traditional use
	<p data-bbox="810 253 970 286"><u>Indication 1)</u></p> <p data-bbox="810 309 1353 454">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 data-bbox="810 477 970 510"><u>Indication 2)</u></p> <p data-bbox="810 533 994 566"><u>Cutaneous use</u></p> <p data-bbox="810 566 1361 712">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="810 734 1066 768"><u>Use as bath additive</u></p> <p data-bbox="810 768 1353 913">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 data-bbox="810 936 1145 969">Method of administration</p> <p data-bbox="810 992 1090 1025">Oral use (indication 1)</p> <p data-bbox="810 1048 1106 1081">Inhalation (indication 1)</p> <p data-bbox="810 1104 1241 1137">Cutaneous use (indication 1 and 2)</p> <p data-bbox="810 1160 1313 1193">Use as bath additive (indication 1 and 2)</p>

4.3. Contraindications

Well-established use	Traditional use
	<p data-bbox="810 1379 1385 1413">Hypersensitivity to eucalyptus oil or 1,8-cineol.</p> <p data-bbox="810 1435 1401 1469">Children with history of seizures (febrile or not).</p> <p data-bbox="810 1491 1409 1637">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 data-bbox="810 1659 1393 1805">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="805 320 957 353"><u>Indication 1</u></p> <p data-bbox="805 376 1332 488">When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="805 510 1396 622">If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="805 645 917 678"><u>Oral use</u></p> <p data-bbox="805 678 1372 790">The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p data-bbox="805 813 1364 925">Eucalyptus oil should be used with caution in inflamed and ulcerated conditions of the gastrointestinal tract.</p> <p data-bbox="805 947 933 981"><u>Inhalation</u></p> <p data-bbox="805 981 1404 1048">The use in children under 3 years of age has not been established due to lack of adequate data.</p> <p data-bbox="805 1070 1348 1182">Caution is necessary in inhalations with hot water, to avoid burns. The area of the eyes should be outside of the steam.</p> <p data-bbox="805 1205 1300 1238"><u>Cutaneous use and use as bath additive</u></p> <p data-bbox="805 1238 1364 1350">The use in children between 2 and 3 years of age has not been established due to lack of adequate data.</p> <p data-bbox="805 1373 1340 1440">Eye contact with unwashed hands after the application may potentially cause irritation.</p> <p data-bbox="805 1462 1380 1529">Eucalyptus oil should not be applied on broken or irritated skin.</p> <p data-bbox="805 1585 957 1619"><u>Indication 2</u></p> <p data-bbox="805 1641 1388 1753">When reddening or swelling of the aching parts occur a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="805 1776 1396 1888">If the symptoms worsen 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>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>

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 are 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><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</p>

Well-established use	Traditional use
	<p>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>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>Accidental overdose of liniments or bath preparations may cause skin irritation.</p>

5. Pharmacological properties

5.1. Pharmacodynamic properties

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

5.2. Pharmacokinetic properties

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

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>

Well-established use	Traditional use
	Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

20 March 2024