EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Eucalyptus globulus* Labill., folium

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	November 2011 January 2012
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BG (bălgarski): Евкалипт, лист	LT (lietuvių kalba): Eukaliptų lapai
CS (čeština): blahovičníkový list	LV (latviešu valoda): Eikalipta lapas
DA (dansk): Eucalyptusblad	MT (malti): Werqa tal-Ewkaliptus
DE (Deutsch): Eucalyptusblätter	NL (nederlands): Eucalyptus
EL (elliniká): φύλλο ευκαλύπτου	PL (polski): Liść eukaliptusa
EN (English): Eucalytus leaf	PT (português): Eucalipto, folha
ES (espanol): Eucalipto, hoja de	RO (română): frunză de eucalipt
ET (eesti keel): eukalüptileht	SK (slovenčina): Eukalyptový list
FI (suomi): eukalyptusöljy	SL (slovenščina): list modrega evkalipta
FR (français): Eucalyptus (feuille d')	SV (svenska): Eukalyptusblad
HU (magyar): Eukaliptuszlevél	*IS (íslenska)*:
IT (italiano): Eucalipto foglia	*NO (norsk):* Eukalyptusblad

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Community herbal monograph on *Eucalyptus globulus* Labill., folium

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
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Eucalyptus globulus* Labill., folium (Eucalyptus leaf) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 68-80% (V/V)

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use or for infusion preparation for inhalation. Herbal preparations in liquid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard form.

[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 European Pharmacopoeia monograph (ref.: 01/2008:1320)

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product used for relief of cough associated with cold. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology[4] a) Comminuted herbal substance *Adolescents, adults and elderly* ***Oral use*** Herbal tea: 1.5 - 3 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion, up to 4 times daily. Daily dose 4.5 - 12 g the comminuted herbal substance ***Inhalation*** Comminuted herbal substance for infusion preparation for inhalation: 3 g of the comminuted herbal substance in boiling water, up to 3 times daily. Daily dose 3 - 9 g of the comminuted herbal substance The use in children under 30 months of age is contraindicated (see 4.3. 'Contraindications'). The use in children under 12 years of age is not recommended (see section 4.4. 'Special warnings and precautions for use').

[3] For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).
[4] The posology has to be specified in a tighter range for the individual product.

Well-established use	Traditional use
	b) Tincture *Adults and elderly* ***Oral use*** Single dose: 2.5 g, up to 4 times daily. Daily dose 2.5 - 10 g The use in children under 30 months of age is contraindicated (see 4.3. 'Contraindications'). The use in children and adolescents under 18 years of age is not recommended (see section 4.4. 'Special warnings and precautions for use'). **Duration of use** 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. **Method of administration** Oral use. Inhalation.

4.3. Contraindications

Well-established use	Traditional use
	Children under 30 months of age, because there is a risk that cineole containing preparations, like other essential oils, can induce laryngospasm. Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted. For tinctures containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

Well-established use	Traditional use
	a) Comminuted herbal substance The use in children under 12 years of age has not been established due to lack of adequate data. b) Tincture The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.

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 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
	None known. If adverse reactions 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 necessary for the safe use of the product. 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

15 April 2013