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Committee on Herbal Medicinal Products (HMPC)

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

Draft

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End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a>	15 October 2012
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# 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<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 as amended</p> <p><i>Eucalyptus globulus</i> Labill., folium (Eucalyptus leaf)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent diluted wine spirit</p> <p>c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70-80% (V/V)</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance as herbal tea for oral use or for infusion for inhalation.</p> <p>Herbal preparations in liquid dosage forms for oral use.</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 European Pharmacopoeia monograph (ref.: 01/2008:1320)

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Traditional herbal medicinal product used for the relief of symptoms of cold, including cough.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.</p>

### 4.2. Posology and method of administration<sup>3</sup>

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><i>Adults, elderly</i></p> <p><u>Oral use</u><sup>4</sup></p> <p>Single dose</p> <p>a) 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</p> <p>b-c) Tincture: 2.5 g (up to 4 times daily)</p> <p>Daily dose</p> <p>a) Comminuted herbal substance: 4.5-12 g</p> <p>b-c) Tincture: 2.5 -10 g</p> <p><u>Inhalation</u></p> <p>Single dose</p> <p>2-3 g of the comminuted herbal substance in 150 ml of boiling water, up to 3 times daily</p> <p>The use in children and adolescents under 18 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>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>

<sup>3</sup> 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).

<sup>4</sup> The posology has to be specified in a tighter range for the individual product.

Well-established use	Traditional use
	<p><b>Method of administration</b></p> <p>Oral use.</p> <p>Inhalation.</p>

#### **4.3. Contraindications**

Well-established use	Traditional use
	<p>Children under 2 years of age, because there is a risk that cineole containing preparations, like other essential oils, can induce laryngospasm.</p> <p>Hypersensitivity to the active substance.</p>

#### **4.4. Special warnings and precautions for use**

Well-established use	Traditional use
	<p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p>When dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted.</p> <p>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.</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
	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

27 March 2012