



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Syzygium aromaticum* (L.) Merrill et L. M. Perry, floris aetheroleum

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	September 2010 November 2010 January 2011
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	27 January 2011
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Syzygium aromaticum</i> (L.) Merrill et L. M. Perry, floris aetheroleum; Caryophylli floris aetheroleum; clove oil
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BG (bългарски): Карамфилово дърво, масло от цвят	LT (lietuvių kalba):
CS (čeština): Silice hřebíčkovcového květu	LV (latviešu valoda): Krustnagliņu [Nagliņkoka ziedu] ēteriskā eļļa
DA (dansk): Nellikeolie	MT (malti):
DE (Deutsch): Nelkenöl	NL (nederlands): Kruidnagelolie
EL (elliniká): Έλαιο καρυφύλλου του αρωματικού-αιθέριο έλαιο του άνθους του καρυοφύλλου	PL (polski): Olejek eteryczny goździkowy
EN (English): Clove oil	PT (português): Óleo essencial de cravinho
ES (español): Clavo, aceite esencial de	RO (română): Ulei volatil de cuișoare
ET (eesti keel): Nelgiõli	SK (slovenčina): Klinčekovcová silica
FI (suomi): Neilikkaöljy	SL (slovenščina): Eterično olje cveta dišečega klinčevca
FR (français): Clou de girofle (huile essentielle de)	SV (svenska): Kryddnejlika, blomma
HU (magyar): Szegfűszegolaj	IS (íslenska):
IT (italiano): Garofano essenza	NO (norsk): Kyddernellikolje



Community herbal monograph on *Syzygium aromaticum* (L.) Merrill et L. M. Perry, floris 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>Syzygium aromaticum</i> (L.) Merrill et L. M. Perry, floris aetheroleum (clove oil)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>Essential oil obtained by steam distillation from the dried flower buds of <i>Syzygium aromaticum</i> (L.) Merrill et L. M. Perry</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparations in liquid dosage forms for dental and oromucosal use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product for the symptomatic treatment of minor inflammations in</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.: 01/2008:1091).

Well-established use	Traditional use
	<p>the mouth or the throat.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for the temporary relief of toothache due to a dental cavity.</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><i>Adults and elderly</i></p> <p>Mouth washes corresponding to 1–5% essential oil. Apply several 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>Indication 2)</p> <p><i>Adults and elderly</i></p> <p>Undiluted essential oil or solutions in a strength of minimum 50% or gels in a strength of 20%.</p> <p>Repeat administration after 20 minutes, then every 2 hours if necessary.</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>Duration of use</p> <p>Indication 1)</p> <p>Not to be used for more than 1 week.</p> <p>If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication 2)</p> <p>Not to be used for more than 1 week.</p>

Well-established use	Traditional use
	<p>The relief of toothache by clove essential oil is only a provisional measure. Dental attention should be sought as soon as possible.</p> <p>Method of administration</p> <p>Indication 1)</p> <p>Oromucosal use.</p> <p>Indication 2)</p> <p>Dental use.</p> <p>A small piece of cotton wool should be soaked in the undiluted oil or in a diluted solution; semi-solid dosage forms should be placed on a cotton bud. Cotton bud or cotton wool should be accurately directed to the decayed part of the tooth.</p>

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s) or to Peru balsam.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>Indications 1) and 2)</p> <p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</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>Indication 2)</p> <p>Avoid contact with gums.</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
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

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
	Mucosal irritations and allergic reactions have been reported. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	No case of overdose from oromucosal or dental use has been reported. After oral administration of 5-10 ml of clove oil in children below 2 years of age, life threatening conditions were observed. Overdose may lead to CNS depression, urinary abnormalities, anion gap acidosis, deterioration of liver function, coma, seizure and low blood glucose levels. Treatment should be supportive and symptomatic; there have been reports in the literature that N-acetylcysteine has been successfully used as an antidote.

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>Eugenol, the main component of clove oil, showed equivocal results in several test systems for genotoxicity and carcinogenicity.</p> <p>Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity of the entire clove oil have not been performed.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

13 September 2011