



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Melaleuca alternifolia* (Maiden and Betch) Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and/or other species of *Melaleuca*, *aetheroleum*

Draft

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<p>BG (bългарski): Чаено дърво, масло CS (čeština): silice kajerutu střídavidolistého DA (dansk): Tetræolie DE (Deutsch): Teebaumöl EL (elliniká): Μελαλεύκης αιθέριο έλαιο EN (English): Tea tree oil ES (español): Melaleuca alternifolia, aceite esencial de ET (eesti keel): teepuuõli FI (suomi): teepuuöljy FR (français): Mélaleuca (arbre à thé) (huile essentielle de) HU (magyar): Teafa-olaj HR (hrvatska): IT (italiano): Melaleuca essenza</p>	<p>LT (lietuvių kalba): Arbatmedžių eterinis aliejus LV (latviešu valoda): Tējaskoka ēteriskā eļļa MT (malti): Żejt tal-Melaleuca NL (nederlands): Theeboomolie PL (polski): Olejek eteryczny drzewa herbacianego PT (português): Óleo essencial de melaleuca RO (română): SK (slovenčina): Silica melaleuky SL (slovenščina): eterično olje melalevke SV (svenska): Teträdsolja IS (íslenska): NO (norsk): Tetreolje</p>
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Community herbal monograph on (Maiden and Betch) Cheel, *M. linariifolia* Smith, *M. dissitiflora* F. Mueller and/or other species of *Melaleuca*, 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>Melaleuca alternifolia</i> (Maiden and Betch) Cheel, <i>M. linariifolia</i> Smith, <i>M. dissitiflora</i> F. Mueller and/or other species of <i>Melaleuca</i>, aetheroleum (tea tree 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 foliage and terminal branchlets</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparation in liquid and semi-solid dosage forms for cutaneous use (indication 1-3) or in liquid dosage form for oromucosal use (indication 4).</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.: 01/2008: 1837).

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product for treatment of small superficial wounds and insect bites.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for treatment of small boils (furuncles and mild acne).</p> <p>Indication 3)</p> <p>Traditional herbal medicinal product for the relief of itching and irritation in cases of mild athlete's foot.</p> <p>Indication 4)</p> <p>Traditional herbal medicinal product for symptomatic treatment of minor inflammation of the oral mucosa.</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>Adolescents, adults and elderly</i></p> <p>Liquid preparations containing 0.5% to 10% of essential oil to be applied on the affected area 1-3 times daily.</p> <p>Indication 2)</p> <p><i>Adolescents, adults and elderly</i></p> <p>Oily liquid or semi-solid preparations containing 10% of essential oil, to be applied on the affected area 1-3 times daily or</p> <p>0.7-1 ml of essential oil stirred in 100 ml of lukewarm water to be applied as an impregnated dressing to the affected areas of the skin.</p>

Well-established use	Traditional use
	<p data-bbox="810 255 967 286">Indication 3)</p> <p data-bbox="810 313 1422 454"><i>Adolescents, adults and elderly</i> Oily liquid or semi-solid preparations containing 10% of essential oil, to be applied on the affected area 1-3 times daily.</p> <p data-bbox="810 481 967 512">Indication 4)</p> <p data-bbox="810 539 1422 640"><i>Adolescents, adults and elderly</i> 0.17–0.33 ml of essential oil to be mixed in 100 ml of water for rinse or gargle several times daily.</p> <p data-bbox="810 689 1409 790">The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p data-bbox="810 817 1015 848">Duration of use</p> <p data-bbox="810 875 967 907">Indication 1)</p> <p data-bbox="810 934 1409 1070">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 1097 1054 1128">Indication 2) and 3)</p> <p data-bbox="810 1155 1265 1187">Not to be used for more than 1 month.</p> <p data-bbox="810 1214 1398 1314">If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 1341 967 1373">Indication 4)</p> <p data-bbox="810 1400 1426 1536">If the symptoms persist longer than 5 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 1563 1145 1594">Method of administration</p> <p data-bbox="810 1621 1098 1653">Indication 1), 2) and 3)</p> <p data-bbox="810 1680 999 1711">Cutaneous use.</p> <p data-bbox="810 1738 967 1769">Indication 4)</p> <p data-bbox="810 1796 1015 1827">Oromucosal use.</p>

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to colophonium.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Not to be used orally or as inhalation. Not to be used in eyes or in ears.</p> <p>If symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication 1) Not to be used on burn wounds.</p> <p>If fever or signs of exacerbating skin infection are observed, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication 2) In cases with severe acne a doctor or a qualified healthcare practitioner shall be consulted.</p> <p>Indication 3) For the eradication of fungal infection a doctor or a qualified healthcare practitioner shall be consulted.</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.

Well-established use	Traditional use
	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
	<p>Adverse skin reactions like smarting pain, mild pruritus, burning sensation, irritation, itching, stinging, erythema, oedema and allergic reactions have been reported. The frequency is not known.</p> <p>Burn-like skin reaction has been reported. The frequency is rare (<1/1.000).</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
	Accidental poisonings following ingestion of 10-25 ml have shown that <i>Melaleuca aetheroleum</i> causes Central Nervous System depression and muscle weakness. However, these symptoms had generally resolved within 36 hours.

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
	Melaleuca aetheroleum was not genotoxic in <i>in-vivo</i> mouse micronucleus test (up to 1750 mg/kg). Ames test data are incomplete. Tests on reproductive toxicity and on carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Store in air-tight containers, protected from light and heat. Proper storage and handling should avoid the formation of oxidation products which have greater potential of skin sensitisation.

7. Date of compilation/last revision

9 July 2013