



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Rosmarinus officinalis* L., aetheroleum

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2009 July 2009
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BG (bългарски): CS (čeština): rozmarýnová silice DA (dansk): Rosmarinolie DE (Deutsch): Rosmarinöl EL (elliniká): EN (English): rosemary oil ES (español): ET (eesti keel): FI (suomi): FR (français): Huile essentielle de romarin HU (magyar): rozmaringolaj IT (italiano):	LT (lietuvių kalba): Rozmarinų eterinis aliejus LV (latviešu valoda): Rozmarīna ēteriskā eļļa MT (malti): ejt tal-klin NL (nederlands): rozemarijolie PL (polski): olejek eteryczny rozmarynowy PT (português): Óleo essencial de alecrim RO (română): ulei volatil de rozmarin SK (slovenčina): Rozmarínová silica SL (slovenščina): SV (svenska): Rosmarinolja IS (íslenska): NO (norsk): Rosmarinolja
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Community herbal monograph on *Rosmarinus officinalis* L., 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
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended <i>Rosmarinus officinalis</i> L., aetheroleum (rosemary oil) i) Herbal substance Not applicable. ii) Herbal preparations Essential oil

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in liquid or semi-solid dosage forms for oral use, cutaneous use and/or use as bath additive. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<u>Oral use</u> Indication 1) Traditional herbal medicinal product for symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract.

¹ The material complies with the Ph. Eur. monograph (ref.: 01/2008:1846).

² The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

Well-established use	Traditional use
	<p><u>Cutaneous use & use as bath additive</u></p> <p>Indication 2)</p> <p>Traditional herbal medicinal product as an adjuvant in the relief of minor muscular and articular pain and in minor peripheral circulatory disorders.</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><i>Adults, elderly</i></p> <p>Indication 1)</p> <p><u>Oral use</u></p> <p>2 drops daily</p> <p>Indication 2)</p> <p><u>Cutaneous use</u></p> <p>6-10 % in semi-solid and liquid dosage forms, 2-3 times daily</p> <p><u>Use as bath additive</u></p> <p>10-27 mg per litre</p> <p>One bath every 2 to 3 days</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>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>Indication 2)</p> <p>If the symptoms persist longer than 4 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be</p>

Well-established use	Traditional use
	<p>consulted.</p> <p>Method of administration</p> <p>Oral use.</p> <p>Cutaneous use.</p> <p>Use as bath additive.</p> <p>Recommended bath temperature is 35 – 38°C, for 10 to 20 minutes.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance.</p> <p><u>Oral use</u></p> <p>Obstruction of bile duct, cholangitis, liver disease, gallstones and any other biliary disorders that require medical supervision and advice.</p> <p><u>Use as bath additive</u></p> <p>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>The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data.</p> <p>If symptoms worsen during the use of the medicinal product, a doctor or a qualified health practitioner should be consulted.</p> <p>Indication 2)</p> <p>Articular pain accompanied by swelling of joint, redness or fever should be examined by a doctor.</p> <p><u>Use as bath additive</u></p> <p>In cases of hypertension, a full hot bath should be used with caution.</p>

Well-established use	Traditional use
	<p data-bbox="810 255 991 282"><u>Cutaneous use</u></p> <p data-bbox="810 311 1401 412">Contact with eyes should be avoided. Semi solid form should not be applied near mucous membranes.</p>

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	<p data-bbox="810 857 1390 994">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>

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	<p data-bbox="810 1189 1426 1252">No studies on the effect on the ability to drive and use machines have been performed.</p>

4.8. Undesirable effects

Well-established use	Traditional use
	<p data-bbox="810 1442 1410 1505">Hypersensitivity (contact dermatitis and asthma) has been reported. The frequency is not known.</p> <p data-bbox="810 1534 1394 1635">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 data-bbox="810 1830 1299 1856">No case of overdose has been reported.</p>

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
	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 July 2010