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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *ROSMARINUS OFFICINALIS* L., FOLIUM

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	March 2009 May 2009 July 2009
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REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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Fax: +44 20 75 23 70 51

KEYWORDS	Herbal medicinal products; HMPC; Community herbal monograph; traditional use; <i>Rosmarinus officinalis</i> L.; Rosmarini folium; rosemary leaf
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COMMUNITY HERBAL MONOGRAPH ON *ROSMARINUS OFFICINALIS* L., FOLIUM

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION^{1,2}

<u>Well-established use</u>	<u>Traditional use</u>
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Rosmarinus officinalis</i> L., folium (rosemary leaf)</p> <p>i) Herbal substance Whole or fragmented, dried leaf</p> <p>ii) Herbal preparations Comminuted herbal substance Extract (1:17.5-18.9), extraction solvent: liqueur wine Extract (1:12.5-13.5), extraction solvent: liqueur wine Expressed juice (1:1.8-2.2) from <i>Rosmarini herba recens</i></p>

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Herbal substance and/or comminuted herbal substance as herbal tea for oral and cutaneous use.</p> <p>Herbal preparations in solid or liquid dosage forms for oral use.</p> <p>Herbal preparations in liquid or semi-solid dosage forms for cutaneous use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

¹ The material complies with the Eur. Ph. monograph (ref.: 01/2008: 1560)

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u> <i>Adolescents, adults</i> <u>Oral use</u> 1. Traditional herbal medicinal product for symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract. <u>Cutaneous use</u> 2. As adjuvant in the relief of minor muscle and articular pain. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.
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4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u> Posology <i>Adolescents, adults</i> Indication 1) <u>Oral use</u> a. Herbal substance as herbal tea preparation: Daily dose: 2-6 g Single dose: 2 g in 150 ml of boiling water To be taken 2-3 times daily b. Extract (1:17.5-18.9), extraction solvent: liqueur wine: 10 to 20 ml 2-3 times daily c. Extract (1:12.5-13.5), extraction solvent: liqueur wine: 20 ml 1-2 times daily d. Expressed juice (1:1.8-2.2): 5 ml containing 100% expressed juice 2-3 times daily <u>Cutaneous use</u> Indication 2) e. 1 litre of decoction of herbal substance/comminuted herbal substance (1:20) added to bath water (twice weekly)
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	<p>f. 50 g of herbal substance for a full bath (once daily)</p> <p>The use in children under 12 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 (see section 4.4 ‘Special warnings and precautions for use’).</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 consulted (see section 4.4 ‘Special warnings and precautions for use’).</p> <p>Method of administration</p> <p>Indication 1)</p> <p>Oral use.</p> <p>Indication 2)</p> <p>Cutaneous use.</p> <p>Recommended bath temperature is 35 – 38 °C, for 10 to 20 minutes.</p>
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4.3. Contraindications

<p><u>Well-established use</u></p>	<p><u>Traditional use</u></p> <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>Cutaneous use</u></p> <p>Bronchial asthma, whooping cough and pseudocroup.</p> <p>Full 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>
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4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u> The use in children under 12 years of age is not recommended due to lack of adequate data and because medical advice should be sought. If symptoms worsen during the use of the medicinal product, a doctor or a qualified health practitioner should be consulted. <u>Cutaneous use</u> Articular pain accompanied by swelling of joint, redness or fever should be examined by a doctor. In cases of hypertension, a full hot bath should be used with caution.
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4.5. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u> None reported.
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4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u> Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.
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4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u> No studies on the effect on the ability to drive and use machines have been performed.
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4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u> Hypersensitivity (contact dermatitis and occupational asthma) has 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.
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4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u> No case of overdose has been reported.
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5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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5.2. Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u> 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 mutagenicity, genotoxicity and reproductive toxicity have not been performed.
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6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u> Not applicable.
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7. DATE OF COMPILATION/LAST REVISION

16 July 2009