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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

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

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	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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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monograph; traditional use; *Rosmarinus officinalis* L.; Rosmarini aetheroleum; rosemary oil

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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 marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Rosmarinus officinalis* L., aetheroleum (rosemary oil) i) Herbal substance Not applicable. ii) Herbal preparations Essential oil.

3. PHARMACEUTICAL FORM

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

[1] The material complies with the Eur. Ph. 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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	Oral use 1. Traditional herbal medicinal product for symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract. Cutaneous use 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.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults, elderly* Oral use Indication 1) 2 drops daily Cutaneous use Indication 2) 6-10% in semi-solid and liquid dosage forms, 2-3 times daily Use as bath additive: 10-27 mg per litre One bath every two to three days The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1) 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'). Indication 2) 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'). **Method of administration** Oral use. Cutaneous use. Recommended bath temperature is 35 – 38 °C, for 10 to 20 minutes.

4.3. Contraindications

Well-established use	Traditional use Hypersensitivity to the active substance. Oral use Obstruction of bile duct, cholangitis, liver disease, gallstones and any other biliary disorders that require medical supervision and advice. Cutaneous use Not to be used in bronchial asthma, whooping cough and pseudocroup. 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.

4.4. Special warnings and precautions for use

Well-established use	Traditional use The use in children and adolescents under 18 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.

	Cutaneous use In cases of hypertension, a full hot bath should be used with caution. Articular pain accompanied by swelling of joint, redness or fever shoud be examined by a doctor.

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
	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
	Hypersensitivity (contact dermatitis and 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.

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
	Tests on genotoxiciry, carcinogenicity and reproductive toxicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

16 July 2009