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Committee on Herbal Medicinal Products (HMPC)

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

Final

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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]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Rosmarinus officinalis* L., folium (rosemary leaf) i) Herbal substance Whole or fragmented, dried leaf ii) Herbal preparations a) Comminuted herbal substance b) Extract (DER 1:17.5-18.9), extraction solvent: liqueur wine c) Extract (DER 1:12.5-13.5), extraction solvent: liqueur wine d) Expressed juice (DER 1:1.8-2.2) from Rosmarini herba recens e) Liquid extract (DER 1:1), extraction solvent ethanol 45% V/V

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal substance and/or comminuted herbal substance as herbal tea for oral use and use as bath additive. Herbal preparations in solid or liquid dosage forms for oral use. Herbal preparations in liquid dosage forms for use as bath additive. The pharmaceutical form should be described by

1 The material complies with the Ph. Eur. 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.

Well-established use	Traditional use
	the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Adolescents, adults Oral use Indication 1) Traditional herbal medicinal product for symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract. Use as bath additive Indication 2) Traditional herbal medicinal product as an adjuvant in the relief of minor muscular and articular pain and in minor peripheral circulatory disorders. 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 *Adolescents, adults, elderly* Oral use Indication 1) a) Herbal substance as herbal tea preparation: Daily dose: 2-6 g Single dose: 1-2 g in 150-250 ml of boiling water To be taken 2-3 times daily b) Extract (DER 1:17.5-18.9), extraction solvent: liqueur wine: 10 to 20 ml 2-3 times daily

	c) Extract (DER 1:12.5-13.5), extraction solvent: liqueur wine: 20 ml 1-2 times daily d) Expressed juice (DER 1:1.8-2.2): 5 ml containing 100% expressed juice 2-3 times daily e) Liquid extract (DER 1:1, 45% ethanol V/V): 2-4 ml daily <u>Use as bath additive</u> Indication 2) f) 1 litre of decoction of herbal substance/comminuted herbal substance (1:20) added to bath water (twice weekly) g) 50 g of herbal substance for a full bath (once daily) The use in children under 12 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. 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. **Method of administration** Indication 1) Oral use. Indication 2) Use as bath additive. 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. Use as bath additive 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.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	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. Use as bath additive In cases of hypertension, a full hot bath should be used with caution. Articular pain accompanied by swelling of joint, redness or fever should 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 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.

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
	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 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