29 May 2024
EMA/HMPC/513893/2021
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Rosmarinus officinalis* L., aetheroleum

Final – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	May 2009 July 2009
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	16 July 2009
End of consultation (deadline for comments)	15 December 2009
Rediscussion in MLWP	May 2010 Jul 2010
Adoption by HMPC Monograph (EMA/HMPC/235453/2009) Assessment Report (EMA/HMPC/13631/2009) List of references (EMA/HMPC/13632/2009) Overview of comments received during the public consultation (EMA/HMPC/254083/2010) HMPC Opinion (EMA/HMPC/457054/2010)	15 July 2010
First systematic review	
Discussion in HMPC	September 2021 November 2021 January 2022 March 2022 May 2022 July 2022 September 2022 November 2022
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Rosmarinus officinalis* L.*,* aetheroleum; Rosmarini aetheroleum; Rosemary oil

BG (bulgarski): Розмариново масло	LT (lietuvių kalba): Rozmarinų eterinis aliejus
CS (čeština): rozmarýnová silice	LV (latviešu valoda): Rozmarīna ēteriskā eļļa
DA (dansk): Rosmarinolie	MT (Malti): żejt tal-klin
DE (Deutsch): Rosmarinöl	NL (Nederlands): Rozemarijnolie
EL (elliniká): λιβανωτίδος (δενδρολιβάνου) αιθέριο έλαιο	PL (polski): Olejek eteryczny rozmarynowy
EN (English): Rosemary oil	PT (português): óleo essencial de alecrim
ES (español): romero, aceite esencial de	RO (română): ulei volatil de rosmarin
ET (eesti keel): rosmariiniõli	SK (slovenčina): silica rozmarínu
FI (suomi): rosmariiniöljy	SL (slovenščina): eterično olje navadnega rožmarina
FR (français): romarin (huile essentielle de)	SV (svenska): rosmarinolja
HR (hrvatski): ružmarinovo eterično ulje	IS (íslenska):
HU (magyar): rozmaringolaj	NO (norsk): rosmarinolje
IT (italiano): Rosmarino essenza	

European Union 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 *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 preparations in semi-solid dosage forms for cutaneous use. 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
	Traditional herbal medicinal product for 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

[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.: 01/2008:1846).

Well-established use	Traditional use
	exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults, elderly* 6-10% in semi-solid dosage forms, 2-3 times daily 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** 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** Cutaneous use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance. Do not apply to broken or irritated skin.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children and adolescents under 18 years of age has not been established due to the lack of adequate data. If symptoms worsen during the use of the medicinal product, a doctor or a qualified health practitioner should be consulted. Articular pain accompanied by swelling of joint, redness or fever should be examined by a doctor. If there is inflammation of the skin or subcutaneous induration, ulcers, sudden swelling

Well-established use	Traditional use
	of one or both legs particularly associated with redness and heat, cardiac or renal insufficiency, or a sudden sharp pain in the leg when at rest, a doctor should be consulted. Contact with eyes should be avoided. Should not be applied near mucous membranes.

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. 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
	Immune system disorders: Hypersensitivity (contact dermatitis). The frequency is not known. Respiratory, thoracic and mediastinal disorders: Hypersensitivity (asthma). 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.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the safe use of the product. 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

29 May 2024