29 May 2024
EMA/HMPC/513940/2021
Committee on Herbal Medicinal Products (HMPC)

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

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 July 2010
Adoption by HMPC Monograph (EMA/HMPC/13633/2009) Assessment Report (EMA/HMPC/13631/2009) List of references (EMA/HMPC/13632/2009) Overview of comments received during the public consultation (EMA/HMPC/254082/2010) HMPC Opinion (EMA/HMPC/457257/2010)	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
Adopted by HMPC for release for consultation	23 November 2022
Start of public consultation	15 December 2022
End of consultation (deadline for comments[1])	15 March 2023

[1] No comments were received during the period of public consultation. Therefore the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Rosmarinus officinalis* L.*, folium;* Rosmarini folium; Rosemary leaf

BG (bălgarski): Розмарин, лист	LT (lietuvių kalba): Rozmarinų lapai
CS (čeština): rozmarýnový list	LV (latviešu valoda): Rozmarīna lapa
DA (dansk): Rosmarinblad	MT (malti): werqa u fjura tal-klin
DE (Deutsch): Rosmarinblätter	NL (nederlands): Rozemarijn
EL (elliniká): λιβανωτίδος φύλλο	PL (polski): Liść rozmarynu
EN (English): rosemary leaf	PT (português): alecrim
ES (espanol): romero, hoja de	RO (română): frunză de rosmarin
ET (eesti keel): rosmariinileht	SK (slovenčina): list rozmarínu
FI (suomi): rosmariini, lehti	SL (slovenščina): list navadnega rožmarina
FR (français): romarin (feuille de)	SV (svenska): rosmarin, blad
HR (hrvatski): ružmarinov list	*IS (íslenska)*:
HU (magyar): rozmaringlevél	*NO (norsk):* rosmarinblad
IT (italiano): Rosmarino foglia	

European Union 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[2, 3]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC *Rosmarinus officinalis* L., folium (rosemary leaf) i) Herbal substance Whole or fragmented, dried leaf ii) Herbal preparations Comminuted herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use and 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
	Indication 1) Traditional herbal medicinal product for the symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract. Indication 2)

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

[3] The material complies with the Ph. Eur. monograph (ref.: 01/2013:1560).

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 exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology Indication 1) *Adolescents, adults, elderly* <u>Oral use:</u> Single dose: 1-2 g in 150-250 ml of boiling water as herbal tea, 2-3 times daily Daily dose: 2-6 g Indication 2) *Adolescents, adults, elderly* <u>Use as bath additive:</u> 50 g either as decoction (in 1 l of boiling water) or direct in the bath. Usage should be 2-3 times a week, if necessary 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)

Well-established use	Traditional use
	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. Do not apply to broken or irritated skin.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	If symptoms worsen during the use of the medicinal product, a doctor or a qualified health practitioner should be consulted. <u>Oral use</u> The use in children under 12 years of age is not recommended due to lack of adequate data. Obstruction of bile duct, cholangitis, liver disease, gallstones and any other biliary disorders that require medical supervision. <u>Use as bath additive</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. 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 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. In cases of hypertension, a full hot bath should be used with caution.

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. 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