



23 November 2022
EMA/HMPC/513940/2021
Committee on Herbal Medicinal Products (HMPC)

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

Draft – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	March 2009 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) AR (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). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu .	15 March 2023

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Rosmarinus officinalis</i> L., folium; Rosmarini folium; rosemary leaf
----------	---



BG (bългарski): Розмарин, лист	LT (lietuvių kalba): Rozmarinų lapai
CS (čeština): rozmarýnový list	LV (latviešu valoda): Rozmarīna lapas
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 (español): 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	<i>IS (íslenska):</i>
HU (magyar): rozmaringlevél	<i>NO (norsk): rosmarinblad</i>
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.

1. Qualitative and quantitative composition^{1,2}

Well-established use	Traditional use
	<i>Rosmarinus officinalis</i> L., folium i) Herbal substance Whole or fragmented, dried leaf ii) Herbal preparations a) Comminuted herbal substance b) Liquid extract (DER 1:1), extraction solvent ethanol 45% V/V

2. Pharmaceutical form

Well-established use	Traditional use
	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. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

3. Clinical particulars

3.1. Therapeutic indications

Well-established use	Traditional use
	<i>Adolescents, adults</i> Indication 1) Traditional herbal medicinal product for the symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract.

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.: 01/2013:1560).

Well-established use	Traditional use
	<p>Indication 2)</p> <p>Traditional herbal medicinal product for the relief of minor muscular and articular pain and in minor peripheral circulatory disorders.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

3.2. Posology and method of administration

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, adults, elderly</i></p> <p>Indication 1)</p> <p><u>Oral Use:</u></p> <p>Preparation a) Single dose: 1-2 g in 150-250 ml of boiling water as herbal tea, 2-3 times daily Daily dose: 2-6 g</p> <p>Preparation b) Single dose: 2-4 ml Daily dose: 2-4 ml</p> <p>Indication 2)</p> <p><u>Use as bath additive:</u></p> <p>Preparation a) 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.</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><u>Duration of use</u></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.</p>

Well-established use	Traditional use
	<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.</p> <p><u>Method of administration</u></p> <p>Indication 1)</p> <p>Oral use.</p> <p>Indication 2)</p> <p>Use as bath additive. Recommended bath temperature is 35 – 38°C, for 10 to 20 minutes.</p>

3.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance.</p> <p><u>Use as bath additive</u> Large skin injuries and open wounds, acute skin diseases, high fever, severe infections, severe circulatory disturbances and cardiac failure.</p>

3.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children under 12 years of age is not recommended due to lack of adequate data</p> <p>If symptoms worsen during the use of the medicinal product, a doctor or a qualified health practitioner should be consulted.</p> <p><u>Oral use</u> Obstruction of bile duct, cholangitis, liver disease, gallstones and any other biliary disorders that require medical supervision.</p> <p><u>Use as bath additive</u> Articular pain accompanied by swelling of joint, redness or fever should be examined by a doctor.</p>

Well-established use	Traditional use
	<p>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.</p> <p>In cases of hypertension, a full hot bath should be used with caution.</p>

3.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported.

3.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p>

3.7. 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.

3.8. Undesirable effects

Well-established use	Traditional use
	<p>Immune system disorders: Hypersensitivity (contact dermatitis). The frequency is not known.</p> <p>Respiratory, thoracic and mediastinal disorders: Hypersensitivity (asthma). The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

3.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

4. Pharmacological properties

4.1. Pharmacodynamic properties

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

4.2. Pharmacokinetic properties

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

4.3. 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.

5. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

6. Date of compilation/last revision

23 November 2022