



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

**This document was valid from 15 July 2010 until May 2024. It is now superseded by a [new version](#) adopted by the HMPC on 29 May 2024 and published on the EMA website.**

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| Discussion in Working Party on Community monographs and Community list (MLWP)                                                                                                                      | March 2009<br>May 2009<br>July 2009 |
| Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation                                                                                                             | 16 July 2009                        |
| End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a> | 15 December 2009                    |
| Rediscussion in Working Party on Community monographs and Community list (MLWP)                                                                                                                    | May 2010<br>July 2010               |
| Adoption by Committee on Herbal Medicinal Products (HMPC)                                                                                                                                          | 15 July 2010                        |

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|-----------------|--------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Keywords</b> | Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Rosmarinus officinalis</i> L.; Rosmarini folium; rosemary leaf |
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|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| BG (bългарски):<br>CS (čeština): rozmarýnový list<br>DA (dansk): Rosmarinblad<br>DE (Deutsch): Rosmarinblätter<br>EL (elliniká):<br>EN (English): rosemary leaf<br>ES (español):<br>ET (eesti keel):<br>FI (suomi):<br>FR (français): Romarin (feuille de)<br>HU (magyar): rozmaringlevél<br>IT (italiano): | LT (lietuvių kalba): Rozmarinų lapai<br>LV (latviešu valoda): Rozmarīna lapas<br>MT (malti): Weraq tal-klin<br>NL (nederlands): rozemarijnblad<br>PL (polski): liść rozmarynu<br>PT (português): Alecrim<br>RO (română): frunză de rosmarin<br>SK (slovenčina): Rozmarínový list<br>SL (slovenščina):<br>SV (svenska): Rosmarinblad<br>IS (íslenska):<br>NO (norsk): Rosmarinblad |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



# 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<sup>1,2</sup>

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

## 3. Pharmaceutical form

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

<sup>1</sup> The material complies with the Ph. Eur. monograph (ref.: 01/2008: 1560).

<sup>2</sup> 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                      | <p><i>Adolescents, adults</i></p> <p><u>Oral use</u></p> <p><b>Indication 1)</b></p> <p>Traditional herbal medicinal product for symptomatic relief of dyspepsia and mild spasmodic disorders of the gastrointestinal tract.</p> <p><u>Use as bath additive</u></p> <p><b>Indication 2)</b></p> <p>Traditional herbal medicinal product as an adjuvant in 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> |

### 4.2. Posology and method of administration

| Well-established use | Traditional use                                                                                                                                                                                                                                                                                                                                                                               |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                      | <p><b>Posology</b></p> <p><i>Adolescents, adults, elderly</i></p> <p><u>Oral use</u></p> <p><b>Indication 1)</b></p> <p>a) Herbal substance as herbal tea preparation:<br/>Daily dose: 2-6 g<br/>Single dose: 1-2 g in 150-250 ml of boiling water<br/>To be taken 2-3 times daily</p> <p>b) Extract (DER 1:17.5-18.9), extraction solvent: liqueur wine:<br/>10 to 20 ml 2-3 times daily</p> |

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

Use as bath additive

**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                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                      | <p>Hypersensitivity to the active substance.</p> <p><u>Oral use</u></p> <p>Obstruction of bile duct, cholangitis, liver disease, gallstones and any other biliary disorders that require medical supervision and advice.</p> <p><u>Use as bath additive</u></p> <p>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.</p> |

#### 4.4. 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 and because medical advice should be sought.</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>Use as bath additive</u></p> <p>In cases of hypertension, a full hot bath should be used with caution.</p> <p>Articular pain accompanied by swelling of joint, redness or fever should be examined by a doctor.</p> |

#### 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**

| <b>Well-established use</b> | <b>Traditional use</b>                                                                 |
|-----------------------------|----------------------------------------------------------------------------------------|
|                             | No studies on the effect on the ability to drive and use machines have been performed. |

#### **4.8. Undesirable effects**

| <b>Well-established use</b> | <b>Traditional use</b>                                                                                                                                                                                                                          |
|-----------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                             | Hypersensitivity (contact dermatitis and occupational asthma) has been reported. The frequency is not known.<br><br>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted. |

#### **4.9. Overdose**

| <b>Well-established use</b> | <b>Traditional use</b>                 |
|-----------------------------|----------------------------------------|
|                             | No case of overdose has been reported. |

### **5. Pharmacological properties**

#### **5.1. Pharmacodynamic properties**

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

#### **5.2. Pharmacokinetic properties**

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

#### **5.3. Preclinical safety data**

| <b>Well-established use</b> | <b>Traditional use</b>                                                                                                           |
|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------|
|                             | 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

Superseded