



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 July 2011  
EMA/HMPC/232091/2011  
Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Rhodiola rosea* L., rhizoma et radix

Draft

|  |                        |
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| Discussion in Working Party on Community monographs and Community list (MLWP)  | March 2011<br>May 2011 |
| Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation   | 12 July 2011           |
| 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 2011       |
| Redisussion in Working Party on Community monographs and Community list (MLWP)   |                        |
| Adoption by Committee on Herbal Medicinal Products (HMPC)  |                        |

|                 |   |
|-----------------|---|
| <b>Keywords</b> | Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Rhodiola rosea</i> L., rhizoma et radix; Rhodiolae roseae rhizoma et radix; Arctic rhizome and root |
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| BG (bългарски):<br>CS (čeština): Kořen rozchodnice růžové<br>DA (dansk): Rosenrodrhizom<br>DE (Deutsch): Rosenwurz wurzelstock<br>EL (elliniká):<br>EN (English): Arctic root<br>ES (español): Rhodiola, rizoma de<br>ET (eesti keel): Roosilõhnalise kuldjuure juurikas<br>FI (suomi):<br>FR (français): Orpin rose (racine d')<br>HU (magyar): Rózsás varjúháj gyökértörzs<br>IT (italiano): | LT (lietuvių kalba):<br>LV (latviešu valoda): Rožainās rodiolas sakneņi<br>MT (malti):<br>NL (nederlands): Rozewortel<br>PL (polski): Kłącze różeńc<br>PT (português): Rhodiola, rizoma<br>RO (română):<br>SK (slovenčina): Podzemok rodioly ružovej<br>SL (slovenščina): korenika navadnega rožnega korena<br>SV (svenska): Rosenrot<br>IS (íslenska):<br>NO (norsk): Rosenrot |
|--|---|



# Community herbal monograph on *Rhodiola rosea* L., rhizoma et radix

## 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>Rhodiola rosea</i> L., rhizoma et radix (Arctic rhizome and root)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>Dry extract (DER 1.5-5:1), extraction solvent ethanol 67-70% v/v</p> |

## 3. Pharmaceutical form

| Well-established use | Traditional use   |
|----------------------|---|
|                      | <p>Herbal preparations in solid dosage forms for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p> |

## 4. Clinical particulars

### 4.1. Therapeutic indications

| Well-established use | Traditional use  |
|----------------------|--|
|                      | <p>Traditional herbal medicinal product for relief of symptoms of asthenia such as fatigue and weakness.</p> <p>The product is a traditional herbal medicinal product for use in the specified indications</p> |

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<sup>1</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                           |
|----------------------|---|
|                      | exclusively based upon long-standing use. |

#### 4.2. Posology and method of administration

| Well-established use | Traditional use  |
|----------------------|--|
|                      | <p><b>Posology</b></p> <p><i>Adults and Elderly</i></p> <p>Single dose 144 -200 mg<br/>Daily dose 144 – 400 mg</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><b>Duration of use</b></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> <p><b>Method of administration</b></p> <p>Oral use.</p> |

#### 4.3. Contraindications

| Well-established use | Traditional use                           |
|----------------------|---|
|                      | Hypersensitivity to the active substance. |

#### 4.4. Special warnings and precautions for use

| Well-established use | Traditional use  |
|----------------------|--|
|                      | <p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> |

#### 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. |

#### 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  |
|----------------------|--|
|                      | None known.<br>If adverse reactions 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 |
|----------------------|-----------------|
|----------------------|-----------------|

| Well-established use | Traditional use  |
|----------------------|--|
|                      | <p>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.</p> <p>Data on adequate tests on reproductive toxicity, genotoxicity and carcinogenicity are not publicly available.</p> |

## 6. Pharmaceutical particulars

| Well-established use | Traditional use |
|----------------------|-----------------|
|                      | Not applicable. |

## 7. Date of compilation/last revision

12 July 2011