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EMA/HMPC/24177/2023  
Committee on Herbal Medicinal Products (HMPC)

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

Draft – Revision 1

<b>Initial assessment</b>	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	March 2011 May 2011
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	12 July 2011
End of consultation (deadline for comments)	15 December 2011
Redisussion in MLWP	January 2012
Adoption by HMPC Monograph (EMA/HMPC/232091/2011) Assessment Report (EMA/HMPC/232100/2011) List of references (EMA/HMPC/232102/2011) Overview of comments received during the public consultation (EMA/HMPC/26431/2012) HMPC Opinion (EMA/HMPC/216955/2012)	27 March 2012
<b>First systematic review</b>	
Discussion in HMPC	January 2023 March 2023 May 2023 July 2023
Adopted by HMPC for release for consultation	19 July 2023
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> .	19 October 2023

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Rhodiola rosea</i> L., rhizoma et radix; Rhodiola roseae rhizoma et radix; Arctic rhizome and root
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BG (bългарski): Златовръх, коренище	LT (lietuvių kalba): Rausvųjų rodiolių šakniastiebiai
CS (čeština): kořen rozchodnice růžové	LV (latviešu valoda): Rožainās rodiolas sakneis
DA (dansk): Rosenrod rhizom	MT (malti): għerq tar-rodjola
DE (Deutsch): Rosenwurz-Wurzelstock to Rosenwurz-Wurzelstock mit Wurzeln	NL (nederlands): Rozewortel
EL (elliniká): ροδιόλας ριζωμα	PL (polski): Kłącze różeńc
EN (English): Arctic root	PT (português): rhodiola, rizoma
ES (español): rhodiola, rizoma de	RO (română): rizom de Rhodiola rosea
ET (eesti keel): roosilõhnalise kuldjuure juurikas	SK (slovenčina): podzemok rodioly ružovej
FI (suomi): ruusujuuri, juurakko	SL (slovenščina): korenika navadnega rožnega korena
FR (français): orpin rose (racine d')	SV (svenska): rosenrot, jordstam
HR (hrvatski): podanak ružičastog žednjaka	IS (íslenska):
HU (magyar): rózsás varjúháj gyökértörzs	NO (norsk): rosenrot
IT (italiano): Rhodiola rosea rizoma (Scopoli, Radice idea)	

# European Union 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</sup>

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended <i>Rhodiola rosea</i> L., rhizoma et radix (Arctic rhizome and root) i) Herbal substance Not applicable ii) Herbal preparations Dry extract (DER 1.5-5:1), extraction solvent ethanol 67-70% (V/V) <sup>2</sup>

## 3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in solid dosage forms for oral 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 symptoms of stress, such as fatigue and exhaustion.

<sup>1</sup> The declaration of the active substance for an individual finished product should be in accordance with relevant herbal quality guidance.

<sup>2</sup> A narrow DER to be specified for an individual medicinal product.

Well-established use	Traditional use
	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
	<p><b>Posology</b></p> <p><i>Adults and Elderly</i></p> <p>Single dose: 144-200 mg            Dosage frequency: 1-2 times daily            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**

<b>Well-established use</b>	<b>Traditional use</b>
	<p><i>Rhodiola rosea</i> may decrease the activity of CYP2C9. With simultaneous treatment, there is a risk of an increase in the plasma concentration of medicinal substances that are metabolized by CYP2C9 (e.g. warfarin and phenytoin). In case a drug is converted to its active metabolite via CYP2C9 (e.g. losartan) the effect may be decreased during simultaneous treatment with <i>Rhodiola rosea</i>.</p>

#### **4.6. Fertility, pregnancy and lactation**

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

#### **4.7. Effects on ability to drive and use machines**

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

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

<b>Well-established use</b>	<b>Traditional use</b>
	<p>Nervous system disorders: Headache, nervousness, insomnia, dizziness</p> <p>Gastrointestinal disorders: Nausea, vomiting</p> <p>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>

#### 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
	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.  Data on adequate tests on reproductive toxicity, genotoxicity and carcinogenicity are not publicly available.

### 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

### 7. Date of compilation/last revision

19 July 2023