EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 March 2024
EMA/HMPC/24177/2023
Committee on Herbal Medicinal Products (HMPC)

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

Final – Revision 1

Initial assessment	
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
Rediscussion 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
First systematic review	
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)	19 October 2023
Rediscussion in HMPC	November 2023 January 2024 March 2024
Adoption by HMPC	20 March 2024

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Rhodiola rosea* L., rhizoma et radix; Rhodiolae roseae rhizoma et radix; Arctic rhizome and root

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BG (bălgarski): Златовръх, коренище CS (čeština): kořen rozchodnice růžové DA (dansk): Rosenrodrhizom DE (Deutsch): Rosenwurz-Wurzelstock to Rosenwurz-Wurzelstock mit Wurzeln EL (elliniká): ροδιόλας ρίζωμα EN (English): Arctic root ES (espanol): rhodiola, rizoma de ET (eesti keel): roosilõhnalise kuldjuure juurikas FI (suomi): ruusujuuri, juurakko FR (français): orpin rose (racine d') HR (hrvatski): podanak ružičastog žednjaka HU (magyar): rózsás varjúháj gyökértörzs IT (italiano): Rhodiola rosea rizoma (Scopoli, Radice idea)	LT (lietuvių kalba): Rausvųjų rodiolių šakniastiebiai LV (latviešu valoda): Rožainās rodiolas saknenis MT (malti): għerq tar-rodjola NL (nederlands): Rozewortel PL (polski): Kłącze różeńca PT (português): rhodiola, rizoma RO (română): rizom de Rhodiola rosea SK (slovenčina): podzemok rodioly ružovej SL (slovenščina): korenika in korenina navadnega rožnega korena SV (svenska): rosenrot, jordstam och rot IS (íslenska): NO (norsk): rosenrot

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[1]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC *Rhodiola rosea* 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)[2]

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. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

[1] The declaration of the active substance for an individual finished product should be in accordance with relevant herbal quality guidance.
[2] A narrow DER to be specified for an individual medicinal product.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults and Elderly* Single dose: 144-200 mg Dosage frequency: 1-2 times daily Daily dose: 144 - 400 mg The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** 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. **Method of administration** Oral use

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

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

Well-established use	Traditional use
	No clinically relevant interactions have been observed.

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
	Nervous system disorders: Headache. The frequency is not known. Gastrointestinal disorders: Nausea, abdominal pain, diarrhoea. The frequency is not known. Skin and subcutaneous tissue disorders: Skin rash, itching. 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 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. Tests on reproductive toxicity, genotoxicity and carcinogenicity are not available.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation/last revision

20 March 2024