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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

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BG (bălgarski): CS (čeština): Kořen rozchodnice růžové DA (dansk): Rosenrodrhizom DE (Deutsch): Rosenwurzwurzelstock EL (elliniká): EN (English): Arctic root ES (espanol): Rhodiola, rizoma de ET (eesti keel): Roosilõhnalise kuldjuure juurikas FI (suomi): Ruusujuuri FR (français): Orpin rose (racine d') HU (magyar): Rózsás varjúháj gyökértörzs IT (italiano):	LT (lietuvių kalba): LV (latviešu valoda): Rožainās rodiolas saknenis MT (malti): NL (nederlands): Rozewortel PL (polski): Kłącze różeńc PT (português): Rhodiola, rizoma RO (română): SK (slovenčina): Podzemok rodioly ružovej SL (slovenščina): Korenika navadnega rožnega korena SV (svenska): Rosenrot *IS (íslenska)*: *NO (norsk):* Rosenrot

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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[1,2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *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[3]

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 temporary relief of symptoms of stress, such as fatigue and sensation of weakness. The product is a traditional herbal medicinal

[1]The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[3] A narrow range of the DER and a fixed strength of the ethanol used for extraction to be specified for each medicinal product

Well-established use	**Traditional use**
	product for use in the specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	**Traditional use**
	Posology *Adults and Elderly* Single dose 144-200 mg 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
	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. 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**
	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

27 March2012