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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

FINAL

COMMUNITY HERBAL MONOGRAPH ON *ELEUTHEROCOCCUS SENTICOSUS* (RUPR. ET MAXIM.) MAXIM., RADIX

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COMMUNITY HERBAL MONOGRAPH ON
***ELEUTHEROCOCCUS SENTICOSUS* (RUPR. ET MAXIM.) MAXIM., 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. *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix (eleutherococcus root) i) Herbal substance Not applicable ii) Herbal preparations - Comminuted herbal substance - Powdered herbal substance - Liquid extract (1:1, ethanol 30-40 % v/v) - Dry extract (13-25 : 1, ethanol 28-40 % v/v) - Dry extract (17-30 : 1, ethanol 70 % v/v) - Dry aqueous extract (15-17:1) - Tincture (1:5, ethanol 40 % v/v)

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Comminuted herbal substance for preparation of a herbal tea, other herbal preparations in solid or liquid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

[1] The material complies with the Ph. Eur. monograph (ref. 01/2008:1419 corrected 6.0)
[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product for symptoms of asthenia such as fatigue and weakness. 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
	Posology *Adolescents over 12 years of age, adults, elderly* Herbal preparations Daily dose Comminuted herbal substance 0.5-4 g Powdered herbal substance 0.75-3 g Liquid extract: 2-3 ml Dry extracts (ethanol 28-70% v/v) corresponding to 0.5-4 g dried root Dry aqueous extract (15-17:1): 90 – 180 mg Tincture: 10-15 ml The daily dose may be taken in one to three doses. The use is not recommended in children under 12 years of age (see section 4.4 Special warnings and precautions for use). **Duration of use** Not to be taken for more than 2 months. If the symptoms persist for more 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. Tea preparation: 0.5 to 4 g of comminuted herbal substance for infusion in 150 ml of water. Dosage frequency: 150 ml of tea infusion should be divided in one to three doses taken during the day.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance. Arterial hypertension.

4.4. Special warnings and precautions for use.

Well-established use	Traditional use
	The use in children under 12 years of age is not recommended because sufficient experience is not available. 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. 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
	Insomnia, irritability, tachycardia and headaches may occur. The frequency is not known.

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 and carcinogenicity have not been performed. *In vitro* experiments, using the *Salmonella typhimurium* strains TA 100 and TA 98 assay and the micronucleus test in mice, did not reveal any mutagenic potential of aqueous and ethanolic extracts.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

8 May 2008