



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix

Final

<b>Initial assessment</b>	
Discussion in Working Party on Community monographs and Community list (MLWP)	October 2006 March 2007 May 2007 July 2007
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	5 July 2007
End of consultation (deadline for comments)	15 October 2007
Rediscussion in Working Party on Community monographs and Community list (MLWP)	January 2008 May 2008
Adoption by Committee on Herbal Medicinal Products (HMPC) Monograph (EMA/HMPC/244569/2006) AR (EMA/HMPC/232403/2006) List of references (EMA/HMPC/249428/2007) Overview of comments received during the public consultation (EMA/HMPC/591758/2007) HMPC Opinion (EMA/HMPC/590998/2007)	8 May 2008
<b>First systematic review</b>	
Discussion in Working Party on Community monographs and Community list (MLWP)	November 2013 January 2014
Adoption by Committee on Herbal Medicinal Products (HMPC)	25 March 2014

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Eleutherococcus senticosus</i> (Rupr. et Maxim.) Maxim.; Eleutherococci radix; eleutherococcus root
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<p>BG (bългарski): Елеутерокок, корен  CS (čeština): Eleuterokokový kořen  DA (dansk): Russisk rod  DE (Deutsch): Taigawurzel  EL (elliniká): Ρίζα Ελευθεροκόκκου  EN (English): Eleutherococcus root  ES (español): Eleuterococo, raíz de  ET (eesti keel): eleuterokokijuur  FI (suomi): Venäjänjuuri  FR (français): Eleuthérocoque (racine d') (racine de ginseng sibérien)  HR (hrvatska): Korijen sibirskog ginsenga  HU (magyar): Szibériai ginszeng gyökér (tajga gyökér)</p>	<p>IT (italiano): Eleuterococco radice  LT (lietuvių kalba): Eleuterokoku šaknys  LV (latviešu valoda): Eleiterokoka sakne  MT (malti): Għerq ta' l-eleuterokokku  NL (nederlands): Siberische/Russische Ginseng  PL (polski): Korzeń eleuterokoka  PT (português): Eleuterococo  RO (română): Rădăcină de ginseng siberian  SK (slovenčina): Koreň eleuterokoka  SL (slovenščina): korenina elevterokoka  SV (svenska): Rysk rot  IS (íslenska): Síberíu ginseng, rót  NO (norsk): Russisk rot</p>
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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<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>Eleutherococcus senticosus</i> (Rupr. et Maxim.) Maxim., radix (Eleutherococcus root)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Powdered herbal substance</p> <p>c) Liquid extract (DER 1: 1, extraction solvent ethanol 30-40% v/v)</p> <p>d) Dry extract (DER 13-25: 1, extraction solvent ethanol 28-40% v/v)</p> <p>e) Dry extract (DER 17-30: 1, extraction solvent ethanol 70% v/v)</p> <p>f) Dry aqueous extract (DER 15-17: 1)</p> <p>g) Tincture (ratio of herbal substance to extraction solvent 1: 5, extraction solvent ethanol 40% v/v)</p> <p>h) Liquid extract (DER 1: 11), extraction solvent sweet wine</p> <p>i) Liquid extract (DER 1: 20), extraction solvent sweet wine</p>

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

<sup>2</sup> The material complies with the Ph.Eur. monograph (ref: 01/2008: 1419)

### 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance as herbal tea for oral use.</p> <p>Herbal preparations in liquid or 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 symptoms of asthenia such as fatigue and weakness.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.</p>

#### 4.2. Posology and method of administration<sup>3</sup>

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><i>Adolescents, Adults and elderly</i></p> <p>Daily dose</p> <p>a) Herbal tea: 0.5-4 g of the comminuted herbal substance in 150 ml of boiling water as herbal infusion (divided in one to three doses)</p> <p>b) Powdered herbal substance: 0.75-3 g</p> <p>c) Liquid extract (DER 1:1, extraction solvent ethanol 30-40% v/v): 2-3 ml</p> <p>d) Dry extract (DER 13-25:1, extraction solvent ethanol 28-40% v/v): doses corresponding to 0.5-4 g dried root</p> <p>e) Dry extract (DER 17-30:1, extraction solvent ethanol 70% v/v): doses corresponding to</p>

<sup>3</sup> For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

Well-established use	Traditional use
	<p>0.5-4 g dried root</p> <p>f) Dry aqueous extract: 90-180 mg</p> <p>g) Tincture: 10-15 ml</p> <p>h) Liquid extract (DER 1:11.3), extraction solvent sweet wine: 30 ml</p> <p>i) Liquid extract (DER 1:20), extraction solvent sweet wine: 25-33 g</p> <p>The daily dose may be taken in one to three doses.</p> <p>The use in children under 12 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>Not to be taken for more than 2 months.</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(s).

### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children under 12 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> <p>For tinctures and extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must</p>

Well-established use	Traditional use
	be included.

#### **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
	<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**

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
	<p>Insomnia, irritability, tachycardia and headaches may occur. 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
	<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>Adequate tests on reproductive toxicity and carcinogenicity have not been performed.</p> <p>In vitro experiments, using the <i>Salmonella typhimurium</i> strains TA 100 and TA 98 assay and the micronucleus test in mice, did not reveal any mutagenic potential of aqueous and ethanolic extracts.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

## 7. Date of compilation/last revision

25 March 2014