



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Herbal Medicinal Products (HMPC)

European Union list entry on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix

Draft

Initial assessment	
Discussion in Working Party on European Union monographs and European Union 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
Redisussion in MLWP	January 2008 May 2008
Adoption by HMPC of opinion on list entry for transmission to EU	8 May 2008
Adoption by European Commission	9 December 2009
First systematic review	
Discussion MLWP	November 2013 January 2014
Adoption by HMPC of opinion on revised list entry for transmission to EU	25 March 2014

Keywords	Herbal medicinal products; HMPC; European Union list of herbal substance(s), preparation(s) and combinations thereof for use in traditional herbal medicinal products; traditional use; <i>Eleutherococcus senticosus</i> (Rupr. et Maxim.) Maxim.; Eleutherococci radix; eleutherococcus root
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Entry to list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products on *Eleutherococcus senticosus* (Rupr. et Maxim.) Maxim., radix

Scientific name of the plant	
<i>Eleutherococcus senticosus</i> (Rupr. et Maxim.) Maxim.	
Botanical family	
Araliaceae	
Herbal substance	
Eleutherococcus root	
Common name of herbal substance in all EU official languages	
BG (bългарски): 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)	IT (italiano): Eleuterococco radice LT (lietuvių kalba): Eleuterokokų 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
Herbal preparations	
Comminuted herbal substance Liquid extract (DER 1:1, extraction solvent ethanol 30-40% v/v) Dry extract (DER 13-25:1, extraction solvent ethanol 28-40% v/v) Dry extract (DER 17-30:1, extraction solvent ethanol 70% v/v) Dry aqueous extract (DER 15-17:1) Tincture (ratio of herbal substance to extraction solvent 1:5, extraction solvent ethanol 40% v/v)	
European Pharmacopoeia monograph reference	
Eleutherococcus – Eleutherococci radix (ref.: 01/2008: 1419 corrected 7.0)	

Indication(s)
Traditional herbal medicinal product for symptoms of asthenia such as fatigue and weakness. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.
Type of tradition
European, Chinese
Specified strength
Please see 'Specified posology'.
Specified posology
<i>Adolescents, adults and elderly</i> Average daily dose Comminuted herbal substance as herbal tea: 0.5-4 g Tea preparation: 0.5 to 4 g of comminuted herbal substance for infusion in 150 ml of boiling water. Dosage frequency: 150 ml of tea infusion should be divided in one to three doses taken during the day. 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 in children under 12 years of age is not recommended (see section 'Special warnings and precautions for use').
Route of administration
Oral use
Duration of use or any restrictions on the 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.
Any other information necessary for the safe use
Contraindication Hypersensitivity to the active substance.

Special warnings and precautions for use

The use in children under 12 years of age is not recommended 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.

For tinctures 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 be included.

Interactions with other medicinal products and other forms of interaction

None reported.

Fertility, pregnancy and lactation

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.

Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

Undesirable effects

Insomnia, irritability, tachycardia and headaches may occur. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

Overdose

No case of overdose has been reported.

Pharmaceutical particulars [If necessary]

Not applicable.

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience [If necessary for the safe use of the product]

Not applicable.

Date of compilation / Last revision

25 March 2014