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EMA/HMPC/321233/2012 *Corr.*<sup>1</sup>  
Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Panax ginseng* C.A.Meyer, radix

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	May 2012 November 2012 January 2013
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BG (bългарски): Жен-шен, корен CS (čeština): všehojoiný kořen DA (dansk): Ginsengrod DE (Deutsch): Ginsengwurzel EL (elliniká): γίνσενγκ πάναξ EN (English): ginseng root ES (español): Ginseng, raíz de ET (eesti keel): ženšennijuur FI (suomi): ginseng, juuri FR (français): Ginseng (racine de) HR (hrvatska): Ginsengov korijen HU (magyar): Ginzenggyökér IT (italiano): Ginseng radice	LT (lietuvių kalba): Ženšenių šaknys LV (latviešu valoda): Žeņšēņa saknes MT (malti): Gherq ta' I-Ġinseng NL (nederlands): Ginseng PL (polski): Korzeń żeń-szenia PT (português): Ginseng RO (română): rădăcină de ginseng SK (slovenčina): Ženšenový koreň SL (slovenščina): korenina pravega ženšena (ginsenga) SV (svenska): Ginsengrot IS (Íslenska): NO (norsk): Ginsengrot
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<sup>1</sup> Correction under 4.2 Posology, point I



# Community herbal monograph on *Panax ginseng* C.A. Meyer, radix

## 1. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>2, 3</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>Panax ginseng</i> C.A. Meyer, radix (Ginseng root)</p> <p>i) Herbal substance Not applicable.</p> <p>ii) Herbal preparations</p> <p><u>White ginseng:</u></p> <p>A) Comminuted herbal substance</p> <p>B) Powdered herbal substance</p> <p>C) Dry extract (DER 2-7:1), extraction solvent ethanol 34-40% V/V</p> <p>D) Dry extract (DER 3-7:1), extraction solvent ethanol 40% V/V, containing 4% ginsenosides (sum of Rb<sub>1</sub>, Rb<sub>2</sub>, Rc, Rd, Re, Rf, Rg<sub>1</sub>, Rg<sub>2</sub>)</p> <p>E) Dry extract (DER 3-7:1), extraction solvent ethanol 57.9% V/V (=50% m/m)-60% V/V</p> <p>F) Dry extract (DER 3.3-5:1), extraction solvent methanol 60% V/V</p> <p>G) Soft extract (DER 1.7-3.2:1), extraction solvent ethanol 60%-70% V/V</p> <p>H) Soft extract (DER 2-6:1), extraction solvent methanol 30% V/V</p> <p>I) Liquid extract (DER 1: 0.8-1.2), extraction solvent ethanol 30.5% V/V (=25% m/m) – 34% V/V</p> <p>J) Liquid extract (DER 1:11-13.6), extraction solvent liquor wine</p>

<sup>2</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

<sup>3</sup> The material complies with the Ph. Eur. monograph (ref.: 7.0/1523)

Well-established use	Traditional use
	<u>Red Ginseng:</u> K) Powdered herbal substance L) Dry extract (DER 2-4.5:1), extraction solvent ethanol 60% V/V

### 3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance (herbal preparation A) as herbal tea for oral use. Herbal preparations F, K, L in solid dosage forms for oral use. Herbal preparations G, H, I, J in liquid dosage forms for oral use. Herbal preparation B, C, D, E in solid and liquid dosage forms. 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 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.

#### 4.2. Posology and method of administration<sup>4</sup>

Well-established use	Traditional use
	<b>Posology</b> <i>Adults and elderly</i> <u>White ginseng:</u> A) Comminuted herbal substance:

<sup>4</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>Herbal tea: 1000-2000 mg of the comminuted herbal substance in 150 ml of water as a decoction 2-3 times daily</p> <p>B) Powdered herbal substance</p> <p>Single dose: 250-1200 mg Daily dose: 600-2000 mg Dosage frequency: once daily (1200 mg), 2-8 times daily</p> <p>C) Dry extract (DER 2-7:1), extraction solvent ethanol 34-40% V/V</p> <p>Single dose: 90-360 mg Daily dose: 200-670 mg Dosage frequency: 1-4 times daily</p> <p>D) Dry extract (DER 3-7:1), extraction solvent ethanol 40% V/V, containing 4% ginsenosides (sum of Rb<sub>1</sub>, Rb<sub>2</sub>, Rc, Rd, Re, Rf, Rg<sub>1</sub>, Rg<sub>2</sub>)</p> <p>Single dose: 40-200 mg Daily dose: 40-200 mg (can be increased up to 600 mg in the first 5 days in special situations) Dosage frequency: 1-2 times daily</p> <p>E) Dry extract (DER 3-7:1), extraction solvent ethanol 57.9 % V/V (=50% m/m) – 60% V/V</p> <p>Single dose: 98-220 mg Daily dose: 196-525 mg Dosage frequency: 2-4 times daily</p> <p>F) Dry extract (DER 3.3-5:1), extraction solvent methanol 60% V/V</p> <p>Single dose: 120 mg Daily dose: 360 mg Dosage frequency: 3 times daily</p> <p>G) Soft extract (DER 1.7-3.2:1), extraction solvent ethanol 60%-70% V/V</p> <p>Single dose: 300-440 mg Daily dose: 440-700 mg Dosage frequency: once daily (440 mg) or 2 times daily</p> <p>H) Soft extract (DER 2-6:1), extraction solvent methanol 30% V/V</p> <p>Single dose: 219.8 mg Daily dose: 439.6 mg</p>

Well-established use	Traditional use
	<p>Dosage frequency: 2 times daily</p> <p>I) Liquid extract (DER 1:0.8-1.2), ethanol 30.5% V/V (=25% m/m) – 34% V/V</p> <p>Single dose: 500 mg - 1250 mg Daily dose: 900 mg – 2500 mg Dosage frequency: 1-2 times daily</p> <p>J) Liquid extract (DER 1:11-13.6), extraction solvent liquor wine</p> <p>Single dose: 19.4 ml Daily dose: 19.4 ml Dosage frequency: once daily</p> <p><u>Red ginseng:</u></p> <p>K) Powdered herbal substance:</p> <p>Single dose: 600 mg Daily dose: 1800 mg Dosage frequency: 3 times daily</p> <p>L) Dry extract (DER 2-4.5:1), extraction solvent ethanol 60% V/V</p> <p>Single dose: 180-500 mg Daily dose: 360-500 mg Dosage frequency: once daily (475 mg or 500 mg) or 2 times daily</p> <p>The use in children and adolescents under 18 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>Duration of use up to 3 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.</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.

#### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children and adolescents under 18 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 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.</p>

#### 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
	Hypersensitivity reactions (urticaria, itching), insomnia and gastrointestinal disorders like stomach discomfort, nausea, vomiting, diarrhoea, and constipation have been reported. The frequency is not known.

Well-established use	Traditional use
	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
	<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>No signs of genotoxicity were observed in an AMES-test (Salmonella typhimurium strains TA 1535, TA 1537, TA 1538, TA 98 and TA 100) with and without metabolic activation using an extract prepared with ethanol 40% V/V (herbal preparation D). This was confirmed with an extract prepared with ethanol 80% in a guideline-conform AMES-test (OECD-471) with and without metabolic activation as well as in a micronucleus test.</p> <p>After 2 years of oral administration of an extract prepared with ethanol 80% in dosages of up to 5000 mg/kg b.w. no signs of carcinogenicity were observed in mice or rats.</p>

Well-established use	Traditional use
	Adequate tests on reproductive toxicity have not been performed.

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

## 7. Date of compilation/last revision

25 March 2014