29 May 2024
EMA/HMPC/27744/2023
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Panax ginseng* C.A.Mey., radix

Final – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	May 2012 November 2012 January 2013
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	12 March 2013
End of consultation (deadline for comments)	15 July 2013
Re-discussion in MLWP	September 2013 November 2013 January 2014
Adoption by HMPC Monograph (EMA/HMPC/321233/2012) Assessment Report (EMA/HMPC/321232/2012) List of References (EMA/HMPC/321234/2012) Overview of comments received during the public consultation (EMA/HMPC/679424/2013) HMPC Opinion (EMA/HMPC/270952/2014)	25 March 2014
First systematic review	
Discussion in HMPC	January 2023 March 2023 May 2023
Adopted by HMPC for release for consultation	12 May 2023
Start of public consultation	15 October 2023
End of consultation (deadline for comments[1])	15 January 2024
Re-discussion in HMPC	March 2024 May 2024
Adoption by HMPC	29 May 2024
Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Panax ginseng* C.A.Mey., radix, Ginseng radix, Ginseng

[1] No comments were received during the period of public consultation. Therefore the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'

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BG (bulgarski): Жен-шен, корен CS (čeština): všehojový kořen DA (dansk): Ginsengrod DE (Deutsch): Ginsengwurzel EL (elliniká): γινσεγκ πάναξ ρίζα EN (English): Ginseng ES (español): ginseng, raíz de ET (eesti keel): ženšennijuur FI (suomi): ginseng, juuri FR (français): ginseng (racine de) HR (hrvatski): ginsengov korijen HU (magyar): ginzenggyökér IT (italiano): Ginseng radice	LT (lietuvių kalba): Ženšenių šaknys LV (latviešu valoda): Žeņšeņa sakne MT (Malti): għerq ta' l-ġinseng NL (Nederlands): Ginseng PL (polski): Korzeń żeń-szenia PT (português): ginseng RO (română): rădăcină de ginseng SK (slovenčina): koreň všehoja (ženšenový koreň) SL (slovenščina): korenina pravega ženšena (ginsenga) SV (svenska): ginseng, rot IS (íslenska): NO (norsk): ginsengrot

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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 *Panax ginseng* C.A. Mey., radix (Ginseng) i) Herbal substance Not applicable. ii) Herbal preparations <u>White ginseng:</u> a) Comminuted herbal substance b) Powdered herbal substance c) Dry extract (DER 2-7:1), extraction solvent ethanol 34-40% V/V d) Dry extract (DER 3-7:1), extraction solvent ethanol 40% V/V, containing 4% ginsenosides (sum of Rb_1, Rb_2, Rc, Rd, Re, Rf, Rg_1, Rg_2) e) Dry extract (DER 3-7:1), extraction solvent ethanol 57.9% V/V (=50% m/m)-60% V/V f) Dry extract (DER 3.3-5:1), extraction solvent methanol 60% V/V g) Soft extract (DER 1.7-3.2:1), extraction solvent ethanol 60%-70% V/V h) Soft extract (DER 2-6:1), extraction solvent methanol 30% V/V i) Liquid extract (DER 1: 0.8-1.2), extraction solvent ethanol 30.5% V/V

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

[2] The material complies with the Ph. Eur. monograph (ref.: 1523)

Well-established use	Traditional use
	(=25% m/m) – 34% m/m j) Liquid extract (DER 1:11-13.6), extraction solvent liquor wine <u>Red Ginseng:</u> k) Powdered herbal substance l) Dry extract (DER 2-4.5:1), extraction solvent ethanol 60% V/V m) Soft extract (DER 2.5-3.2:1), 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), m) in liquid dosage forms for oral use. Herbal preparations b), c), d), e) in solid and liquid 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 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[3]

Well-established use	Traditional use
	Posology *Adults and elderly* <u>White ginseng:</u> a) Comminuted herbal substance: Herbal tea: 1000-2000 mg of the comminuted herbal substance in 150 ml of water as a decoction 2-3 times daily b) Powdered herbal substance: Single dose: 250-1200 mg Daily dose: 600-2000 mg Dosage frequency: once daily (1200 mg), 2-8 times daily c) Dry extract (DER 2-7:1), extraction solvent ethanol 34-40% V/V Single dose: 90-360 mg Daily dose: 200-670 mg Dosage frequency: 1-4 times daily d) Dry extract (DER 3-7:1), extraction solvent ethanol 40% V/V, containing 4% ginsenosides (sum of Rb_1, Rb_2, Rc, Rd, Re, Rf, Rg_1, Rg_2) 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 e) Dry extract (DER 3-7:1), extraction solvent ethanol 57.9 % V/V (=50% m/m) – 60% V/V Single dose: 98-360 mg Daily dose: 196-525 mg Dosage frequency: 1-4 times daily

[3] 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
	f) Dry extract (DER 3.3-5:1), extraction solvent methanol 60% V/V Single dose: 120 mg Daily dose: 360 mg Dosage frequency: 3 times daily g) Soft extract (DER 1.7-3.2:1), extraction solvent ethanol 60%-70% V/V Single dose: 300-440 mg Daily dose: 440-700 mg Dosage frequency: once daily (440 mg) or 2 times daily h) Soft extract (DER 2-6:1), extraction solvent methanol 30% V/V Single dose: 219.8 mg Daily dose: 439.6 mg Dosage frequency: 2 times daily i) Liquid extract (DER 1:0.8-1.2), ethanol 30.5% V/V (=25% m/m) – 34% m/m Single dose: 500 mg - 1250 mg Daily dose: 900 mg – 2500 mg Dosage frequency: 1-2 times daily j) Liquid extract (DER 1:11-13.6), extraction solvent liquor wine Single dose: 9.90 g Daily dose: 19.80 g Dosage frequency: 2 times daily <u>Red ginseng:</u> k) Powdered herbal substance: Single dose: 600 mg -1200 mg Daily dose: 1200 mg - 1800 mg Dosage frequency: 1-3 times daily l) Dry extract (DER 2-4.5:1), extraction solvent ethanol 60% V/V

Well-established use	Traditional use
	Single dose: 180-500 mg Daily dose: 360-500 mg Dosage frequency: once daily (475 mg or 500 mg) or 2 times daily m) Soft extract (DER 2.5-3.2:1), extraction solvent ethanol 60% V/V Single dose: 440 mg Daily dose: 440 mg Dosage frequency: once daily 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** Duration of use up to 3 months. 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. For extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and

Well-established use	Traditional use
	package leaflet of medicinal products for human use', must 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
	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.

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
	Gastrointestinal disorders: stomach discomfort, nausea, vomiting, diarrhoea, and constipation have been reported. The frequency is not known. Immune system disorders: Hypersensitivity reactions (urticaria, itching) have been reported: The frequency is not known. Nervous system disorders: Insomnia has been reported. The frequency is not known. 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.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the safe use of the product. 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. 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. 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

29 May 2024