



6 May 2020
EMA/HMPC/438183/2017
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Species sedativae* Draft

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	July 2017 September 2017 November 2017 January 2018 March 2020 May 2020
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	6 May 2020
Start of public consultation	31 May 2020
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	31 August 2020
Re-discussion in MLWP	
Adoption by HMPC	

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Species sedativae</i> ; sedative herbal tea combinations
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<p>BG (bulgarski): Успокояващ чай, комбинации CS (čeština): čajová směs na uklidnění DA (dansk): Beroligende urtete DE (Deutsch): Beruhigungstees EL (elliniká): Μίγματα φυτικών ειδών για εγχύματα/αφεψήματα με ηεραμιστική δράση EN (English): sedative herbal tea combinations ES (español): combinaciones de sustancias vegetales para uso en tisana con acción sedante ET (eesti keel): FI (suomi): nukahtamista helpottavat perinteisesti käytetyt yhdistelmäteevalmisteet FR (français): espèces sédatives HR (hrvatski): čajevi za umirenje HU (magyar): Nyugtató teakeverék IT (italiano): Specie composta per tisane calmanti</p>	<p>LT (lietuvių kalba): Raminantis mišinys LV (latviešu valoda): Nomierinošā tēja MT (Malti): speċi sedattivi NL (Nederlands): Kalmerende kruiden PL (polski): mieszanki ziołowe uspokajające PT (português): Associações de substâncias vegetais para utilização em tisanas com acção sedativa RO (română): ceai calmant (sedativ) SK (slovenčina): čajovina na upokojenie SL (slovenščina): zdravilni čaji za pomirjanje SV (svenska): örtteer vid lindrig oro och insomningsbesvär IS (íslenska): NO (norsk):</p>
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European Union herbal monograph on *Species sedativae*

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{1,2,3}

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC</p> <p>Herbal tea combinations containing 3 or 4 herbal substances out of the following list:</p> <p><i>Humulus lupulus</i> L., flos</p> <p><i>Lavandula angustifolia</i> Mill., flos</p> <p><i>Melissa officinalis</i> L., folium</p> <p><i>Passiflora incarnata</i> L., herba</p> <p><i>Valeriana officinalis</i> L., radix</p> <p>i) Herbal substance</p> <p>Not applicable</p> <p>ii) Herbal preparations</p> <p>Combinations of the comminuted herbal substances</p>

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 respective monographs in Ph.Eur.

³ Detailed specifications for the herbal substance shall be given by references to bibliographic sources in absence of a monograph in the European Pharmacopoeia, a national pharmacopoeia or national codex currently used officially in a Member State.

	Valerianae radix	Melissae folium	Lupuli flos	Lavandulae flos	Passiflorae herba	Range in a combination (excl. excipients)
Amount of Valerianae radix in combination with:	-	15-57%	15-57%	15-57%	33-57%	15-57% ⁴
Amount of Melissae folium in combination with:	11-30%	-	11-30%	11-30%	27-57%	11-57%
Amount of Lupuli flos in combination with:	15-43%	15-43%	-	15-40%	21-36%	15-43%
Amount of Lavandulae flos in combination with:	15-36%	15-36%	15-30%	-	-	15-36%
Amount of Passiflorae herba in combination with:	11-34%	11-34%	11-28%	-	-	11-34%

The grey shaded fields indicate combinations with evidence of traditional medicinal use.

Out of these documented combinations the combination partners for an application for a traditional herbal medicinal product may be chosen.

The number of active substances in an herbal tea combination should be 3 or 4. Further herbal substances may be added as excipients.

The very right row indicates the traditional amount of the herbal substance in the combinations. The calculation is based on those combination partners only, which contribute to the plausibility of efficacy. The amount in a traditional herbal medicinal product should be within this range. The sum of active ingredients should end up with 100%. Excipients are not considered in this range.

Usually, the sum of all excipients should not exceed 30% in the final combination and no more than 3 excipients should be used (see also Regulatory Q&A on herbal medicinal products, EMA/HMPC/345132/2010 Rev. 4).

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substances as herbal tea for oral use.
	The pharmaceutical form should be described by

Well-established use	Traditional use
	the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep. 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 administration⁵

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, Adults and Elderly</i></p> <p>Herbal tea: 2–4 g of the herbal tea combination in 150 ml of boiling water as a herbal infusion 3–4 times daily, the last dose before going to bed.</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>Duration of use</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>Method of administration</p> <p>Oral use</p>

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substances.

⁵ 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).

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>

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
	<p>May impair ability to drive and use machines.</p> <p>Affected patients should not drive or operate machinery.</p>

4.8. Undesirable effects

Well-established use	Traditional use
	<p>None known</p> <p>In herbal tea combinations containing <i>Valeriana officinalis</i> L., radix, gastrointestinal symptoms (e.g. nausea, abdominal cramps) may occur. The frequency is not known.</p> <p>If adverse reactions 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.

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. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation/last revision

6 May 2020