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Committee on Herbal Medicinal Products (HMPC)

## European Union herbal monograph on *Species amarae*

Draft

<b>Initial assessment</b>	
Discussion in Working Party on European Union monographs and list (MLWP)	November 2017 January 2018 May 2019 Jan 2020 March 2020 May 2020
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Start of public consultation	31 May 2020
End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a>	31 August 2020
Re-discussion in MLWP	
Adoption by HMPC	

<b>Keywords</b>	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Species amarae</i> ; herbal tea combinations for use in loss of appetite
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<p>BG (bulgarski): Чай при загуба на апетит, комбинации</p> <p>CS (čeština): hořká čajová směs</p> <p>DA (dansk): Bitterte</p> <p>DE (Deutsch): Tees zur Appetitanregung</p> <p>EL (elliniká): Μίγματα φυτικών ειδών για εγχύματα/αφεψήματα ορεξιογόνα (πικρήσ γεύσης)</p> <p>EN (english): herbal tea combinations for use in loss of appetite</p> <p>ES (español): combinaciones de sustancias vegetales para uso en tisana con acción estimulante del apetito</p> <p>ET (eesti keel):</p> <p>FI (suomi): ruokahaluttomuudessa perinteisesti käytetyt yhdistelmäteevalmisteet</p> <p>FR (français): espèces amères</p> <p>HR (hrvatski): gorke čajevi</p> <p>HU (magyar): Étvágyjavító teakeverék</p> <p>IT (italiano): Specie composte per tisane a principi amari</p> <p>LT (lietuvių kalba): Apetitą žadinantis mišinys</p>	<p>LV (latviešu valoda): Tēja ēstgribas veicināšanai</p> <p>MT (Malti): speċi morri</p> <p>NL (Nederlands): Bittere kruiden</p> <p>PL (polski):</p> <p>PT (português): Associações de substâncias vegetais para utilização em tisanas com acção estimulante do apetite</p> <p>RO (română): ceai tonic (amar)</p> <p>SK (slovenčina): horká čajovina</p> <p>SL (slovenščina): zdravilni grenki čaji</p> <p>SV (svenska): örtteer vid nedsatt aptit</p> <p>IS (íslenska):</p> <p>NO (norsk):</p>
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# European Union herbal monograph on *Species amarae*

## 1. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>1,2,3</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>Herbal tea combinations containing several herbal substances out of the following list:</p> <ul style="list-style-type: none"><li><i>Achillea millefolium</i> L. herba</li><li><i>Artemisia absinthium</i> L., herba</li><li><i>Centaureum erythraea</i> Rafn. s.l., herba</li><li><i>Cichorium intybus</i> L., radix</li><li><i>Gentiana lutea</i> L., radix</li><li><i>Marrubium vulgare</i> L., herba</li><li><i>Menyanthes trifoliata</i> L., folium</li><li><i>Taraxacum officinale</i> Weber ex Wigg., radix cum herba</li></ul> <p>i) Herbal substance</p> <p>Not applicable</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 respective monographs in Ph. Eur.

<sup>3</sup> 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

<b>Traditional use</b>										
ii) Herbal preparations Combinations of the comminuted herbal substances.										
	Absinthii herba	Centaurii herba	Cichorii radix	Gentianae radix	Marrubii herba	Millefolii herba	Menyanthis folium	Taraxaci radix cum herba		Range in a combination (excl. excipients)
Absinthii herba		+		+	+	+	+			10-50%
Centaurii herba	+		+	+	+	+	+	+		10-50%
Cichorii radix		+		+	+					22%
Gentianae radix	+	+	+		+	+	+	+		10-33%
Marrubii herba	+	+	+	+						22-33%
Menyanthis folium	+	+		+		+				10-50%
Millefolii herba	+	+		+			+			10-54%
Taraxaci radix cum herba		+		+						10-35%
<p>A + indicates the evidence of traditional medicinal use of a certain combination.</p> <p>Out of these documented combinations the combination partners for an application for a traditional herbal medicinal product may be chosen.</p> <p>The number of active substances in a herbal tea combination should be limited to a <b>maximum of 4</b>. Further herbal substances may be added as excipients. Their number, amount and function should be justified.</p> <p>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.</p>										

### 3. Pharmaceutical form

<b>Well-established use</b>	<b>Traditional use</b>
	<p>Comminuted herbal substances as herbal tea 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 used for temporary loss of appetite.</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>4</sup>

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><i>Adults and elderly</i></p> <p>Combinations containing (among other active ingredients) Absinthii herba, Centaurii herba or Gentianae radix</p> <p><i>Adolescents, adults and elderly</i></p> <p>Combinations containing none of the above mentioned herbal substances</p> <p>Herbal tea: 2 g of the herbal tea combination in 150 ml of boiling water as an herbal infusion 3 times daily.</p> <p>Depending on the herbal substances included:</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><i>or</i></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>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>

<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><b>Method of administration</b></p> <p>Oral use</p> <p>To be taken 30 minutes before meals.</p>

### 4.3. Contraindications

Well-established use	Traditional use
	<p>All combinations:</p> <p>Hypersensitivity to the active substances.</p> <p>Combinations containing <i>Millefolii herba</i> or <i>Cichorii radix</i>:</p> <p>Additionally: Hypersensitivity to other plants of the Asteraceae (Compositae) family.</p> <p>Combinations containing <i>Taraxaci radix cum herba</i>:</p> <p>Additionally: Hypersensitivity to other plants of the Asteraceae (Compositae) family.</p> <p>Obstructions of bile ducts, cholangitis, liver diseases, gallstones, active peptic ulcer and any other biliary diseases.</p> <p>Combinations containing <i>Absinthii herba</i>:</p> <p>Additionally: Hypersensitivity to other plants of the Asteraceae (Compositae) family. Obstruction of the bile duct, cholangitis or liver disease.</p> <p>Combinations containing <i>Centaurii herba</i>:</p> <p>Additionally: Peptic ulcer.</p> <p>Combinations containing <i>Marrubii herba</i>:</p> <p>Additionally: Hypersensitivity to other plants of the Lamiaceae (Labiatae) family. Obstruction of the bile duct, cholangitis, liver disease, ileus</p> <p>Combinations containing <i>Menyanthidis folium</i>:</p> <p>Additionally: Patients with active gastric or duodenal ulcer.</p>

### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Depending on the herbal substances included:

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><i>or</i></p> <p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Combinations containing Absinthii herba:</p> <p>Additionally: Patients with gallstones and any other biliary disorders should consult a doctor before using Absinthii herba preparations.</p> <p>Combinations containing Marrubii herba:</p> <p>Additionally: Patients with active peptic ulcer, gallstones and any other biliary disorders should consult a doctor before using Marrubii herba preparations.</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>All combinations:</p> <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. 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>For an individual combination the combined information regarding undesirable effects taken from the European Union herbal monographs for the single ingredients have to be used.</p> <p>If other adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

#### 4.9. Overdose

Well-established use	Traditional use
	<p>All combinations except for those containing <i>Centaurii herba</i> should include the statement:</p> <p>No case of overdose has been reported.</p> <p>Combinations containing <i>Centaurii herba</i>:</p> <p>Stomach disturbances and nausea have been reported.</p>

### 5. Pharmacological properties

#### 5.1. Pharmacodynamic properties

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

#### 5.2. Pharmacokinetic properties

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

#### 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, unless necessary for the safe use of the product.</p> <p>Combinations without <i>Absinthii herba</i> have to</p>

Well-established use	Traditional use
	<p>include the statement:</p> <p>Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p> <p>Combinations containing Absinthii herba:</p> <p>Thujone is reported to be neurotoxic and chemotypes with low content of thujone should be preferred. Thujone is known for its uterus stimulating activity</p> <p>Combinations containing Gentianae radix:</p> <p>Additionally: For some xanthenes which are among the constituents of <i>Gentiana lutea</i>, positive results were found in the AMES test pre-incubation method).</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	<p>Combination without Absinthii herba:</p> <p>Not applicable.</p> <p>Combinations containing Absinthii herba:</p> <p>The amount of thujone has to be specified in the given product. The daily exposure has to be below 6.0 mg. For more details see the "Public statement on the use of herbal medicinal products containing thujone)" (EMA/HMPC/732886/2010).</p>

## 7. Date of compilation/last revision

6 May 2020