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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Species diureticae*

Draft

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Re-discussion in MLWP	
Adoption by HMPC	

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BG (bulgarski): CS (čeština): močopudná čajová směs DA (dansk): vanddrivende urtete DE (Deutsch): Durchspülungstees EL (elliniká): Διουρητικά είδη EN (english): diuretic herbal tea combinations ES (español): ET (eesti keel): diureetilise toimega taimed FI (suomi): FR (français): HR (hrvatski): diuretički čajevi HU (magyar): IT (italiano): LT (lietuvių kalba): Šlapimo išsiskyrimą skatinantis mišinys	LV (latviešu valoda): MT (Malti): Pjanti b'effett dijuretiku NL (Nederlands): urineafdrijvende kruiden PL (polski): PT (português): Associações de substâncias vegetais para utilização em tisanas com acção na diurese RO (română): SK (slovenčina): močopudná čajovina SL (slovenščina): zdravilni čaji za odvajanje seča SV (svenska): Örtte vid urinvägsbesvär IS (íslenska): NO (norsk):
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European Union herbal monograph on *Species diureticae*

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 as amended</p> <p>Herbal tea combinations containing several herbal substances out of the following list:</p> <p><i>Arctostaphylos uva-ursi</i> (L.) Spreng., folium</p> <p><i>Agropyron repens</i> (L.) P. Beauv., rhizoma</p> <p><i>Betula pendula</i> Roth and/or <i>Betula pubescens</i> Ehrh., folium</p> <p><i>Equisetum arvense</i> L., herba</p> <p><i>Ilex paraguariensis</i> St. Hilaire, folium</p> <p><i>Juniperus communis</i> L., galbulus (synonym: <i>Juniperus communis</i> L., pseudo-fructus)</p> <p><i>Levisticum officinale</i> Koch, radix</p> <p><i>Ononis spinosa</i> L., radix</p> <p><i>Orthosiphon stamineus</i> Benth., folium</p> <p><i>Phaseolus vulgaris</i> L., fructus sine semine</p> <p><i>Polygonum aviculare</i> L., herba</p> <p><i>Solidago virgaurea</i> L., herba</p> <p><i>Urtica dioica</i> L. and <i>Urtica urens</i> L., herba, folium</p> <p>i) Herbal substance</p> <p>Not applicable</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 Ph. Eur. monograph <insert reference number of the herbal substances included in the combination>

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

Traditional use														
ii) Herbal preparations														
Combinations of the comminuted herbal substances.														
	Betulae folium	Equiseti herba	Graminis rhizoma	Juniperi galbulus	Levistici radix	Mate folium	Ononidis radix	Orthosiphonis folium	Phaseoli fructus	Polygoni avicul. herba	Solidaginis virg. herba	Urticae herba / folium	Uvae ursi folium	Range in a combination (excl. excipients)
Betulae folium		+	+	+	+	+	+	+	+	+	+	+	+	10-57%
Equiseti herba	+		+	+	+	+	+	+	+		+	+	+	10-61%
Graminis rhizoma	+	+		+			+	+					+	10-50%
Juniperi galbulus	+	+	+		+		+	+			+			10-50%
Levistici radix	+	+		+			+							20-33%
Mate folium	+	+						+	+				+	10%
Ononidis radix	+	+	+	+	+			+		+		+	+	10-50%
Orthosiphonis folium	+	+	+	+		+	+		+		+		+	10-50%
Phaseoli fructus	+	+				+		+					+	10-20%
Polygoni avicul. herba	+						+					+	+	12-50%
Solidaginis virg. herba	+	+		+				+					+	18-29%
Urticae herba/folium	+	+					+			+			+	11-22%
Uvae ursi folium	+	+	+			+	+	+	+	+	+	+		20-50%
<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 maximum of 4. 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

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
	<p>Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints.</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 administration⁴

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and elderly</i></p> <p>Combinations containing (among other active ingredients) Juniperi galbulus, Levistici radix, Mate folium, Orthosiphonis folium, Phaseoli fructus or Uvae ursi folium</p> <p><i>Adolescents, adults and elderly</i></p> <p>Combinations containing none of the above mentioned herbal substances</p> <p>Herbal tea: 1.5-2 g of the herbal tea combination in 150 ml of boiling water as an herbal infusion 3-4 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>

⁴ 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>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
	<p>All combinations:</p> <p style="padding-left: 40px;">Hypersensitivity to the active substances. Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).</p> <p>Combinations containing <i>Betulae folium</i>:</p> <p style="padding-left: 40px;">Additionally: Hypersensitivity to birch pollen.</p> <p>Combinations containing <i>Levistici radix</i>:</p> <p style="padding-left: 40px;">Additionally: Hypersensitivity to other plants of the <i>Apiaceae</i> family or to anethole.</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>Depending on the herbal substances included:</p> <p style="padding-left: 40px;"><The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.></p> <p style="padding-left: 40px;"><i>or</i></p> <p style="padding-left: 40px;"><The use in children under 12 years of age has not been established due to lack of adequate data.></p> <p>If urinary tract complaints worsen or symptoms such as fever, dysuria, spasm, or blood in the urine occur during the use of 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>Combinations without <i>Uvae ursi folium</i>:</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.</p> <p>No fertility data available.</p> <p>Combinations containing <i>Uvae ursi folium</i>:</p> <p>Safety during pregnancy and lactation has not been established. The use should be avoided during pregnancy.</p> <p>In the absence of sufficient data the use during 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
	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.

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>Combinations without <i>Uvae ursi folium</i>:</p> <p>Adequate tests/tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p> <p>Combinations containing <i>Uvae ursi folium</i>:</p> <p>Available tests on genotoxicity of water and ethanolic extracts of <i>Uvae ursi folium</i> are inadequate. Reproductive toxicity has not been studied. Available carcinogenicity studies have been negative. Arbutin, the principal component of <i>Uvae ursi folium</i>, displayed some maternal and fetal toxicity in rats after subcutaneous administration of 400 mg/kg/day. No effect on reproduction has been observed at doses of 100 mg/kg/day. Toxicity tests with hydroquinone, a hydrolysis product of arbutin, have demonstrated some evidence of genotoxicity and carcinogenicity. Risks posed by the exposure of hydroquinone during the short-term treatment with <i>Uvae ursi folium</i> preparations are considered minimal.</p>

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation/last revision

20 September 2016