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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## European Union herbal monograph on Species diureticae Final

Discussion in Working Party on European Union monographs and list (MLWP)	April 2016 May/June 2016 July 2016
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; Species diureticae; diuretic herbal tea combinations
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<p>BG (bulgarski): Комбинации на растителни вещества, предназначени за приготвяне на чай с диуретично действие</p> <p>CS (čeština): močopudná čajová směs</p> <p>DA (dansk): Vanddrivende urtete</p> <p>DE (Deutsch): Durchspülungstees</p> <p>EL (elliniká): διουρητικά είδη</p> <p>EN (english): diuretic herbal tea combinations</p> <p>ES (español): combinaciones de sustancias vegetales para uso en tisana con acción en la diuresis</p> <p>ET (eesti keel): diureetilise toimega taimed</p> <p>FI (suomi): virtsatieoireissa perinteisesti käytetyt yhdistelmäteevalmisteet</p> <p>FR (français): espèces diurétiques, mélange de plantes pour tisanes diurétiques</p> <p>HR (hrvatski): diuretički čajevi</p> <p>HU (magyar): diuretički čajevi</p> <p>IT (italiano): Specie composte per tisane diuretiche</p> <p>LT (lietuvių kalba): Šlapimo išsiskyrimą skatinantis mišinys</p>	<p>LV (latviešu valoda): Urīndzenošā tēja</p> <p>MT (Malti): pjanti b'effett dijuretiku</p> <p>NL (Nederlands): urineafdrijvende kruiden</p> <p>PL (polski): mieszanki ziołowe moczopędne</p> <p>PT (português): associações de substâncias vegetais para utilização em tisanas com acção na diurese</p> <p>RO (română): ceaiuri diuretice</p> <p>SK (slovenčina): močopudná čajovina</p> <p>SL (slovenščina): zdravilni čaji za odvajanje seča</p> <p>SV (svenska): örtteer vid urinvägsbesvär</p> <p>IS (íslenska):</p> <p>NO (norsk): urteteer for urinveiene</p>
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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<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</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>
<b>Traditional use</b>	
ii) Herbal preparations	
Combinations of the comminuted herbal substances.	

<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.

Well-established use								Traditional use						
	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	+	+		+			+	+					+	10–25%
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%
Solidaginis virg. herba	+	+		+				+					+	18–29%
Urticae herba/folium	+	+					+			+			+	11–22%
Uvae ursi folium	+	+	+			+	+	+	+	+	+	+		20–50%

A + indicates the evidence of traditional medicinal use of a certain combination.

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 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.

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.

### 3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substances as herbal tea 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
	<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 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) 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> <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</p>

<sup>4</sup> For guidance on herbal substance/herbal preparation administered as a 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>consulted.</p> <p><b>Method of administration</b></p> <p>Oral use</p>

### 4.3. Contraindications

Well-established use	Traditional use
	<p>All combinations:</p> <p>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>Additionally: Hypersensitivity to birch pollen.</p> <p>Combinations containing <i>Levistici radix</i>:</p> <p>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>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>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

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.

### 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
	<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>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 foetal 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

28 March 2017