



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Species diureticae* Draft – Revision 1

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First revision	
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BG (bulgarski): Диуретичен чай, комбинации	LT (lietuvių kalba): Šlapimo išsiskyrimą skatinantis mišinys
CS (čeština): močopudná čajová směs	LV (latviešu valoda): Urīndzenošā tēja
DA (dansk): Vanddrivende urtete	MT (Malti): Pjanti b'effett dijuretiku
DE (Deutsch): Durchspülungstees	NL (Nederlands): urineafdrijvende kruiden
EL (elliniká): Μείγματα φυτικών ειδών για εγχύματα/αφεψήματα με διουρητική δράση	PL (polski): mieszanki ziołowe moczopędne
EN (english): diuretic herbal tea combinations	PT (português): Associações de substâncias vegetais para utilização em tisanas com acção na diurese
ES (español): combinaciones de sustancias vegetales para uso en tisana con acción en la diuresis	RO (română): ceaiuri diuretice
ET (eesti keel): diureetilise toimega taimed	SK (slovenčina): močopudná čajovina
FI (suomi): virtsatieoireissa perinteisesti käytetyt yhdistelmäteevalmisteet	SL (slovenščina): zdravilni čaji za odvajanje seča
FR (français): Espèces diurétiques, mélange de plantes pour tisanes diurétique	SV (svenska): Örtteer vid urinvägsbesvär
HR (hrvatski): diuretički čajevi	IS (íslenska):
HU (magyar): Vizelethajtó teakeverék	NO (norsk): vanndrivende urteteer
IT (italiano): Specie composte per tisane diuretiche	

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}

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; <i>Betula pubescens</i> Ehrh., folium</p> <p><i>Equisetum arvense</i> L., herba</p> <p><i>Herniaria glabra</i> L.; <i>Herniaria hirsuta</i> L.; <i>Herniaria incana</i> Lam., herba</p> <p><i>Ilex paraguariensis</i> St. Hilaire, folium</p> <p><i>Juniperus communis</i> L., galbulus (pseudo-fructus)</p> <p><i>Levisticum officinale</i> W.D.J.Koch, radix</p> <p><i>Ononis spinosa</i> L., radix</p> <p><i>Orthosiphon aristatus</i> (Blume) Miq. var. <i>aristatus</i>, 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.; <i>Urtica urens</i> L., herba; folium</p> <p>i) Herbal substance</p> <p>Not applicable</p> <p>ii) Herbal preparations</p> <p>Combinations of the comminuted herbal substances (see combinations table below)</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 quality references given in the corresponding Monographs.

Traditional use															
ii) Herbal preparations															
Combinations of the comminuted herbal substances.															
	Betulae folium	Equiseti herba	Graminis rhizoma	Herniariae herba	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%
Herniariae herba	+	+						+						+	6-26%
Juniperi galbulus	+	+	+			+		+	+			+			10-50%
Levistici radix	+	+			+										20-29%
Mate folium	+	+							+	+				+	10%
Ononidis radix	+	+	+	+	+	+			+		+		+	+	10-50%
Orthosiphonis folium	+	+	+		+		+	+		+		+		+	10-50%
Phaseoli fructus	+	+					+		+					+	10-20%
Polygoni avic. herba	+							+					+	+	12%
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 an 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 the European Pharmacopoeia full standard term.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product used for the relief of symptoms associated with minor urinary complaints in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine. 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 administration³

Well-established use	Traditional use
	Posology <i>Adults and elderly</i> Combinations containing (among other active ingredients) <i>Herniariae herba</i> , <i>Juniperi galbulus</i> , <i>Levistici radix</i> , <i>Mate folium</i> , <i>Orthosiphonis folium</i> , <i>Phaseoli fructus</i> , <i>Urticae herba/folium</i> or <i>Uvae ursi folium</i> <i>Adolescents, adults and elderly</i> Combinations containing none of the above-mentioned herbal substances 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. Duration of use

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
	<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>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 Apiaceae family or to anethole.</p> <p>Combinations containing <i>Solidaginis viragureae herba</i>:</p> <p>Additionally: Hypersensitivity to other plants of the Asteraceae (Compositae) family.</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 is not recommended due to lack of adequate data.</p> <p>or</p> <p>The use in children under 12 years of age is not recommended due to lack of adequate data.</p>

Well-established use	Traditional use
	<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> <p>Because adequate fluid intake is required during treatment, the use of the tea is not recommended for patients with conditions where reduced fluid intake was advised.</p>

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	No adequate interaction studies have been performed.

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
	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>All combinations:</p> <p>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p> <p>For the individual combination the combined information regarding undesirable effects taken</p>

Well-established use	Traditional use
	from the European Union herbal monographs for the single ingredients have to be used.

4.9. Overdose

Well-established use	Traditional use
	No information available.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	No information required.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	No information required.

5.3. Preclinical safety data

Well-established use	Traditional use
	Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

Additional information

Well-established use	Traditional use
	Not applicable.