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Committee on Herbal Medicinal Products (HMPC)

Assessment report on *Species diureticae*

Draft – Revision 1

Based on Article 16d(1), Article 16f and Article 16h of Directive 2001/83/EC (traditional use)

Herbal substance(s) (binomial scientific name of the plant, including plant part)	<i>Arctostaphylos uva-ursi</i> (L.) Spreng., folium <i>Agropyron repens</i> (L.) P. Beauv., rhizoma <i>Betula pendula</i> Roth; <i>Betula pubescens</i> Ehrh., folium <i>Equisetum arvense</i> L., herba <i>Herniaria glabra</i> L.; <i>Herniaria hirsuta</i> L., <i>Herniaria incana</i> Lam.; herba <i>Ilex paraguariensis</i> St. Hilaire, folium <i>Juniperus communis</i> L., galbulus (pseudo-fructus) <i>Levisticum officinale</i> W.D.J.Koch, radix <i>Ononis spinosa</i> L., radix <i>Orthosiphon aristatus</i> (Blume) Miq. var. <i>Aristatus</i> , folium <i>Phaseolus vulgaris</i> L., fructus (sine semine) <i>Polygonum aviculare</i> L., herba <i>Solidago virgaurea</i> L., herba <i>Urtica dioica</i> L.; <i>Urtica urens</i> L., herba, folium	
Herbal preparation(s)	Combinations of the above-mentioned herbal substances	
Pharmaceutical form(s)	Comminuted herbal substances as herbal tea for oral use	
First assessment	Rapporteur	R. Länger
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Note: This draft assessment report is published to support the public consultation of the draft revised European Union herbal monograph on *Species diureticae*. It is a working document, not yet edited, and shall be further developed after the release for consultation of the monograph. Interested parties are welcome to submit comments to the HMPC secretariat, which will be taken into consideration but no 'overview of comments received during the public consultation' will be prepared on comments that will be received on this assessment report. The publication of this draft assessment report has been agreed to facilitate the understanding by Interested Parties of the assessment that has been carried out so far and led to the preparation of the draft monograph.

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1. Introduction

1.1. Description of the herbal substance(s), herbal preparation(s) or combinations thereof

- Combinations of herbal substance(s) and/or herbal preparation(s) including a description of vitamin(s) and/or mineral(s) as ingredients of traditional combination herbal medicinal products assessed, where applicable.

EU herbal monographs on herbal tea combinations are based on combinations which have been shown to fulfil the applicable criteria according to 2001/83/EC. In addition, the specific herbal preparations included have a documented traditional use on a specific indication already established in previous HMPC assessments for the single substance use. There are data showing their use in combinations in certain ranges that can be considered safe and plausible.

The legislation does not impose any limitation to the number/percentage of combination partners in herbal teas. However, the scientific opinion of the HMPC is:

- Usually not more than 4 herbal substances should be used in an herbal tea as active substance and each substance should represent not less than 10% of the total weight. More combination partners at lower proportions imply technical obstacles in terms of quality testing and raise questions about the plausible contribution and the need/justification. These may be better considered excipients.
- More than 4 substances or less than 10% of the total weight in an herbal tea would in principle not raise concerns from a public health viewpoint provided that the marketing authorisation holder/traditional use registration holder can control the quality of the product and that appropriate justification on the need and the plausibility as active substance as well as the safety for a specific indication, strength and posology is provided.

According to data from marketed products, pharmacopoeias, textbooks and literature, traditional herbal tea combinations in the EU member states contain mostly 3-4 main herbal substances with a well-documented single and combined use and plausibility in a specific indication. Accordingly, HMPC agreed and cover a large proportion of traditional combinations. Such limitation allows also a reasonable reference to previous single substance assessments and appropriate complexity of the monograph for use by applicants and assessors.

Tea combinations in EU herbal monographs can be considered plausible and safe in a certain indication and thus facilitate national registration procedures providing some flexibility for applicants. However, it is not supposed to be exhaustive or exclude other individual combinations. It is always possible to obtain registration/authorisation for a specific combination product provided that all requirements are met - even if not covered by the EU herbal combination monographs. Reference can be made to the established herbal tea monographs with an adequate justification of the deviation (e.g. inclusion of a preparation without an EU monograph or different number of combination partners).

It is further referred to Q&A EMA/HMPC/345132/2010 questions R1 and R8 as well as general HMPC guidance in this respect:

- Guideline on the clinical assessment of fixed combinations of herbal substances / herbal preparations (EMA/HMPC/166326/2005)
- Quality of combination herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/CHMP/CVMP/214869/2006)

This assessment report refers to herbal tea combinations used in the therapeutic area 'urinary tract disorders'. Herbal substances contained in such combinations for which an assessment by the HMPC has been performed are *Betulae folium*, *Equiseti herba*, *Agropyri repentis rhizoma*, *Herniariae herba*, *Juniperi galbulus* (pseudo-fructus), *Levistici radix*, *Mate folium*, *Ononidis radix*, *Orthosiphonis folium*, *Phaseoli fructus*, *Polygoni avicularis herba*, *Solidaginis virgaureae herba*, *Urticae folium*, *Urticae herba* and *Uvae ursi folium*.

Herbal substances linked to the therapeutic area, but for which an EU monograph (for the single herbal substance) has not yet been established, are not considered in this assessment report.

Additional herbal substances which may be combination partners, but which are not linked to the therapeutic area are considered as excipients.

For the description of the herbal substances, their constituents, relevant pharmacopoeia monographs, non-clinical and clinical data please refer to the assessment reports of the single herbal substances.

1.2. Search and assessment methodology

The information regarding herbal tea combinations in the therapeutic area 'urinary tract disorders' was gathered from EU member states and the information provided by interested parties.

Standard handbooks of Phytotherapy and Pharmacognosy were screened manually for relevant information.

Search in scientific databases for combinations did not provide any results.

For the scientific data on safety and efficacy of the single herbal substances contained in the combinations please refer to the assessment reports of the single herbal substances.

1.3. Main changes introduced in the first revision

Due to the publication of the EU Monograph on *Herniaria glabra* L., *H. hirsuta* L., *H. incana* Lam., herba, this herbal substance was included with possible combinations. Furthermore, recently revised Monographs had been updated in the text and tables.

The indication has been updated to reflect the indication of recent revisions of the included single Monographs.

Substances/preparations for which there is insufficient information on preparation, medicinal use and posology, or for which no single monograph exists now, have been deleted and the tables have been cleaned up and updated. The combination of *Ononidis radix* with *Levistici radix* has therefore been deleted.

Furthermore, the 'Standardzulassungen' have been moved from table 2 to table 1, as they are marketed.

2. Data on medicinal use

2.1. Information about products on the market

2.1.1. Information about products on the market in the EU/EEA Member States

Information on medicinal products marketed in the EU/EEA

Not applicable

Information on relevant combination medicinal products marketed in the EU/EEA

Herbal substances mentioned in brackets are considered as excipient (no plausible contribution to the traditional indication).

Table 1: Overview of data obtained from marketed medicinal products

#	Active substance	Indication	Pharmaceutical form	Regulatory Status
1	1 tea bag (2 g) contains: Betulae folium 0.6 g Orthosiphonis folium 0.6 g Solidaginis virg. herba 0.5 g	Traditional herbal medicinal product for flushing of the urinary tract as supportive treatment in mild urinary tract disorders	1 teabag, 3-4 times daily	AT, TUR 2011
2	1 tea bag (2 g) contains: Uvae ursi folium 0.7 g Betulae folium 0.4 g Orthosiphonis folium 0.3 g Solidaginis virg. herba 0.3 g	Traditional herbal medicinal product for flushing of the urinary tract as supportive treatment of recurrent infections after serious conditions have been excluded	1 teabag, 3-4 times daily	AT, TUR 2012
3	1 tea bag (1.3 g) contains: Equiseti herba 0.715 g Urticae folium 0.26 g Ononidis radix 0.195 g	Traditional herbal medicinal product for flushing of the urinary tract as supportive treatment in mild urinary tract disorders	1 teabag, 3-4 times daily	AT, TUR 2011
4	Betulae folium 25 parts Herniariae herba 25 parts Equiseti herba 37.5 parts Callunae herba 10 parts, impregnated with 2.5 parts sodium carbonate	Support of renal function, flushing of the urinary tract, supportive in inflammations of the urinary tract	1 tablespoon (ca. 4 g) as infusion. 3 times daily	AT, WEU 1957

#	Active substance	Indication	Pharmaceutical form	Regulatory Status
5	Betulae folium 413 mg Uvae ursi folium 337 mg Ononidis radix 150 mg Petroselini radix 150 mg Polygoni avicularis herba 165 mg Urticae herba 150 mg (Millefolii herba 105 mg) (Sambuci flos 30 mg)	An adjuvant for treatment of symptoms of mild lower urinary tract infections such as burning sensation during urination and frequent urination	1 tea bag (1.5 g) or 1 tablespoon (5 g) /250 ml of boiling water as an herbal infusion 3-5 times daily	CZ, in medicinal use since 1969; THMP since 2011
6	Uvae ursi folium 375 mg Equiseti herba 300 mg (Myrtilli herba 225 mg) (Matricariae flos 150 mg) (Sambuci flos 150 mg) Solidaginis herba 150 mg (Thymi herba 150 mg)	An adjuvant for treatment of symptoms of mild lower urinary tract infections such as burning sensation during urination and frequent urination	1 tea bag (1.5 g)/250 ml of boiling water as an herbal infusion 3-5 times daily	CZ, in medicinal since 1989, THMP since 2011
7	Betulae folium 450 mg Uvae ursi folium 450 mg (Menthae piperitae herba 225 mg) Ononidis radix 150 mg Petroselini radix 150 mg Herniariae herba 75 mg	An adjuvant for treatment of symptoms of mild lower urinary tract infections such as burning sensation during urination and frequent urination	1 tea bag (1.5 g)/250 ml of boiling water as an herbal infusion 3-5 times daily	CZ, in medicinal use since 1995, THMP since 2011
8	1 tea bag (1.75 g) contains:	To achieve flushing of the urinary tract in bacterial and	Herbal tea	DE, WEU, at least since 1976

#	Active substance	Indication	Pharmaceutical form	Regulatory Status
	Betulae folium 0.875 g Equiseti herba 0.656 g	inflammatory diseases of the lower urinary tract and in renal gravel.	Adults and adolescents > 12 years: 2 cups of tea from 1 tea bag each 3 times daily Preparation: 1 tea bag + 150 ml boiling water, 15 min steeping time	
9	1 tea bag (1.8 g) contains: Orthosiphonis folium 0.68 g Ononidis radix 0.68 g	To achieve flushing of the urinary tract in bacterial and inflammatory diseases of the lower urinary tract and in renal gravel.	Herbal tea Adults and adolescents > 12 years: 1 cup of tea from 1 tea bag 5 times daily Preparation: 1 tea bag + 150 ml boiling water, 15 min steeping time	DE, WEU, at least since 1976
10	1 tea bag (2 g) contains: Betulae folium 0.6 g Orthosiphonis folium 0.6 g Solidaginis virg. herba 0.5 g	Traditional herbal medicinal product to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints and to decrease sedimentation of renal gravel.	Herbal tea Adults: 1 cup of tea from 1-2 tea bags 3-4 times daily Adolescents > 12 years: 1 cup of tea from 1 tea bag 3-4 times daily No longer than 14 days in self-medication. Preparation: 1-2 tea bags + 150 ml boiling water, 15 min steeping time	DE, TUR, 2012
11	1 tea bag (2 g) contains: Uvae ursi folium 0.7 g Betulae folium 0.4 g	Traditional herbal medicinal product to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints and	Herbal tea Adults: 1-2 cups of tea from 1 tea bag each 3-4 times daily	DE, TUR, 2013

#	Active substance	Indication	Pharmaceutical form	Regulatory Status
	Orthosiphonis folium 0.3 g Solidaginis virg. herba 0.3 g	to decrease sedimentation of renal gravel.	No longer than 7 days and max. 5 times per year without medical supervision. Preparation: 1 tea bag + 150 ml boiling water, 5-10 min steeping time	
12	2 g (1 tablespoon) contain: Betulae folium 0.48 g Solidaginis virg. herba 0.26 g Equiseti herba 0.26 g Orthosiphonis folium 0.22 g Juniperi fructus 0.22 g	Traditional used to support renal excretion function.	Herbal tea Adults: 1 cup of tea from 2 g herbal tea 4-6 times daily Traditional duration of use is 2-4 weeks. Preparation: 1 tablespoon (ca. 2 g) herbal tea + 150 ml boiling water, 5-10 min steeping time	DE, TUR, 2014
13	1 tea bag (2 g) contains: Betulae folium 0.6 g Orthosiphonis folium 0.6 g Solidaginis virg. herba 0.5 g	Traditional herbal medicinal product to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints and to decrease sedimentation of renal gravel.	Herbal tea Adults: 1 cup of tea from 1-2 tea bags 3-4 times daily Adolescents > 12 years: 1 cup of tea from 1 tea bag 3-4 times daily No longer than 14 days in self-medication. Preparation: 1-2 tea bags + 150 ml boiling water, 15 min steeping time	DE, TUR, 2014
14	Equal parts Betulae folium	To increase the amount of urine in inflammation (catarrh)	Herbal tea 2-3 teaspoons ¹ of herbal tea + 150 ml	Braun R. 1987, DE, Standard Marketing Authorisation

¹ The calculation of the mass of the single/daily dose when 'spoon' is referred to is explained in section 2.2

#	Active substance	Indication	Pharmaceutical form	Regulatory Status
	Graminis rhizome Solidaginis gig. herba Ononidis radix (Liquiritiae radix)	of the lower urinary tract. To prevent formation of renal gravel and uroliths.	boiling water, 15 min steeping time 3-4 times daily	according to section 36 of the German Medicinal Products Act Blasen- und Nierentee I
15	Uvae ursi folium 35-50 parts Betulae folium 10-20 parts Phaseoli fructus 10-20 parts Equiseti herba 10-30 parts	As adjuvant treatment in mild inflammation (catarrh) of the bladder and the renal pelvis.	Herbal tea 1 teaspoon (2-4 g) of herbal tea + 150 ml boiling water, 15 min steeping time 3-4 times daily	Braun R. 1988, DE, Standard Marketing Authorisation according to section 36 of the German Medicinal Products Act Blasen- und Nierentee II
16	Betulae folium 10-25 parts Solidaginis gig. herba 10-25 parts Ononidis radix 10-30 parts Equiseti herba 10-30 parts	To increase the amount of urine in inflammation (catarrh) of the lower urinary tract. To prevent formation of renal gravel and uroliths.	Herbal tea 2-3 teaspoons ¹ of herbal tea + 150 ml boiling water, 15 min steeping time 3-4 times daily	Braun R. 1988, DE, Standard Marketing Authorisation according to section 36 of the German Medicinal Products Act Blasen- und Nierentee III
17	Uvae ursi folium 35-50 parts Ononidis radix 10-25 parts Orthosiphonis folium 15-30 parts Graminis rhizoma 10-20 parts	As adjuvant treatment in mild inflammation (catarrh) of the bladder and the renal pelvis.	Herbal tea 1 teaspoon (2-4 g) of herbal tea + 150 ml boiling water, 15 min steeping time 3-4 times daily	Braun R. 1988, DE, Standard Marketing Authorisation according to section 36 of the German Medicinal Products Act Blasen- und Nierentee IV
18	Uvae ursi folium 35-50 parts Phaseoli fructus 10-20 parts Solidaginis gig. herba 10-25 parts	As adjuvant treatment in mild inflammation (catarrh) of the bladder and the renal pelvis.	Herbal tea 1 teaspoon (2-4 g) of herbal tea + 150 ml boiling water, 15 min steeping time 3-4 times daily	Braun R. 1988, DE, Standard Marketing Authorisation according to section 36 of the German Medicinal Products Act

#	Active substance	Indication	Pharmaceutical form	Regulatory Status
	Orthosiphonis folium 10-30 parts			Blasen- und Nierentee V
19	Betulae folium 15-30 parts Solidaginis gig. herba 10-20 parts Ononidis radix 20-30 parts Orthosiphonis folium 20-30 parts	To increase the amount of urine in inflammation (catarrh) of the lower urinary tract. To prevent formation of renal gravel and uroliths.	Herbal tea 2-3 teaspoons ¹ of herbal tea + 150 ml boiling water, 15 min steeping time 3-4 times daily	Braun R. 1988, DE, Standard Marketing Authorisation according to section 36 of the German Medicinal Products Act Blasen- und Nierentee VI
20	Uvae ursi folium 35-50 parts Betulae folium 15-25 parts Graminis rhizoma 15-25 parts	As adjuvant treatment in mild inflammation (catarrh) of the bladder and the renal pelvis.	Herbal tea 1 teaspoon (2-4 g) of herbal tea + 150 ml boiling water, 15 min steeping time 3-4 times daily	Braun R. 1988, DE, Standard Marketing Authorisation according to section 36 of the German Medicinal Products Act Blasen- und Nierentee VII

This overview is not exhaustive. It is provided for information only and reflects the situation at the time when it was established.

Information on other products marketed in the EU/EEA (where relevant)

Not applicable.

2.1.2. Information on products on the market outside the EU/EEA

Not applicable.

2.2. Information on documented medicinal use and historical data from literature

Calculation of the mass of the single dose / daily dose when 'spoon' is referred:

Based on information from pharmaceutical industry the bulk density of herbal teas depends on the individual components as well as on the particle size. Cut herbal teas have a lower bulk density (e.g. less than 1 g for a traditional diuretic tea combination according to a German Standard Marketing Authorisation) compared to fine cut material for tea bags. However, the official information for the German Standard Marketing Authorisation (table 1) mentions an equivalence of 1 teaspoon with 2-4 g of herbal tea combination. A similar calculation is cited in Fischer (1978). Therefore, as a mean 1 teaspoon is calculated as 2 grams.

¹ The calculation of the mass of the single/daily dose when 'spoon' is referred to is explained in section 2.2

Herbal substances mentioned in brackets are considered as excipient (no plausible contribution to the traditional indication).

Table 2: Overview of historical data

	Herbal preparation	Indication	Pharmaceutical form	Reference and date of the reference
21	(Scilla siccata 15 parts) (Sennae folium 15 parts) Juniperi galbulus 15 parts Equiseti herba 15 parts Ononidis radix 20 parts Graminis rhizoma 20 parts	Species diureticae	Herbal tea Single dose 0.5-1 g as a decoction Daily dose 5 g as a decoction	Hungarian Pharmacopoeia VI, 1970
22	Equal parts of Ononidis radix (Foeniculi fructus) (Liquiritiae radix) Juniperi fructus	Species diureticae	1 teaspoon (= 2 g) per cup. 2 times daily	Muszynski, 1954 Roeske, 1955
23	Equiseti herba 20 parts Betulae folium 35 parts Uvae ursi folium 20 parts (Cichorii radix 25 parts)	Species diureticae	Decoction of 3 teaspoons (= 6 g) in about 750 ml of hot water (heat slowly under cover, boil 3-5 minutes, let stand for 5-10 min), drink 3-4 times daily for 2/3-1 glass (150-250 ml) of the decoction, between meals.	Ozarowski <i>et al.</i> , 1978
24	Equal parts Betulae folium Uvae ursi folium Herniariae herba Equiseti herba (Rosae pseudo-fructus)	Species urologicae	1 teaspoon (= 2 g) per cup. 3 times daily	Roeske, 1955
25	Mate folium 10 parts	For flushing and as adjuvant for	10 ml of herbal tea as an infusion with	DRF, 1952

	Herbal preparation	Indication	Pharmaceutical form	Reference and date of the reference
	Orthosiphonis folium 10 parts Uvae ursi folium 20 parts Phaseoli fructus 20 parts Equiseti herba 20 parts Betulae folium 20 parts	mild urinary tract complaints and recurring mild urinary tract infections, such as painful sensation during urination, after serious conditions have been excluded by a medical doctor.	150 ml boiling water. 3-5 times daily 10 ml tea mixture = 4 g	Replaced by NRF, 2011
26	Equiseti herba 20 g Levistici radix 10 g Betulae folium 10 g Vitis idaeae folium 10 g	Species diureticae	Herbal tea Single dose: 1 teaspoon (= 2 g) / 250 ml water (one cup) as an infusion Daily dose: 2 cups/day	Janos and Mihaly, 1986
27	Petroselini radix 20 g Levistici radix 10 g (Millefolii flos 5 g) (Liquiritiae radix 5 g) Juniperi fructus 5 g	Species diureticae	Herbal tea Single dose: 1 teaspoon (= 2 g) / 250 ml water (one cup) as an infusion Daily dose: 2 or 3 cups/day	Janos and Mihaly, 1986
28	(Rubiae tinctori radix 10 g) Solidaginis herba 10 g (Trioni herba 10 g) Cerasorum stipetes 10 g Maydis stigmata 5 g Juniperi fructus 5 g	To increase the amount of urine and helps the elimination of renal gravel and small uroliths	Herbal tea Single dose: 1 full teaspoon (= 2 g) is boiled with 250 ml water for 3 minutes, then rested until is just warm Should be used in the morning and with ½ h before meals. Daily dose: 3 cups	Janos and Mihaly, 1986

	Herbal preparation	Indication	Pharmaceutical form	Reference and date of the reference
29	(Cyani flores sine receptaculis 0.5 parts) Betulae folium 2.5 parts Vitis idaeae folium 1 part Equiseti herba 1.5 parts Ononidis radix 1 part Graminis rhizoma 1.5 part (Cynosbati semen 1 part) Maydis stigmata 1 part	Species diureticae	Herbal tea Single dose: 5 g/ 250 ml water as an infusion Daily dose: 2 or 3 cups/day	Produse farmaceutice romanesti, 1970

2.3. Overall conclusions on medicinal use

Table 3: Betulae folium in combinations

Combination partner	Amount Betulae folium in combination (excl. excipients)	Single dose Betulae folium/ daily dose Frequency	Reference (# in tables 1 and 2)
Equiseti herba	26%	1 g / 3 g, 3 times daily	4
	57%	1.75 g / 5.25 g, 3 times daily	8
	33%	0.48 g / 1.9 – 2.9 g, 4-6 times daily	12
	47%	0.7 - 0.9 g / 2.8 g, 3-4 times daily	23
	25%	0.25 g / 0.75 g, 3 times daily	24
	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
	10-20%	0.2 – 0.8 g / 0.6 – 3.2 g, 3-4 times daily	15
	10-25%	0.4 – 1.5 g / 1.2 – 6 g, 3-4 times daily	16
	20%	0.4 g / 0.8 g, 2 times daily	26
Graminis rhizoma	31%	1.5 g / 3 – 4.5 g, 2-3 times daily	29
	25%	1-1.5 g / 3 – 6 g, 3-4 times daily	14
	15-25%	0.3 – 1 g / 0.9 – 4 g, 3-4 times daily	20
Herniariae herba	31%	1.5 g / 3 – 4.5 g, 2-3 times daily	29
	26%	1 g / 3 g, 3 times daily	4

Combination partner	Amount Betulae folium in combination (excl. excipients)	Single dose Betulae folium/ daily dose Frequency	Reference (# in tables 1 and 2)
	30%	0.45 g / 1.35 – 2.25 g, 3-5 times daily	7
	25%	0.25 g / 0.75 g, 3 times daily	24
Juniperi galbulus	33%	0.48 g / 1.9 – 2.9 g, 4-6 times daily	12
Levistici radix	20%	0.4 g / 0.8 g, 2 times daily	26
Mate folium	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
Ononidis radix	30%	0.413 g / 1.24 – 2.1 g, 3-5 times daily	5
	35%	0.45 g / 1.35 – 2.25 g, 3-5 times daily	7
	25%	1-1.5 g / 3 – 6 g, 3-4 times daily	14
	10-25%	0.4 – 1.5 g / 1.2 – 6 g, 3-4 times daily	16
	15-30%	0.6 – 1.8 g / 1.8 – 7.2 g, 3-4 times daily	19
	31%	1.5 g / 3 – 4.5 g, 2-3 times daily	29
Orthosiphonis folium	35%	0.6 g / 2.8-2.4 g, 3-4 times daily	1, 13
	24%	0.4 g / 1.2-1.6 g, 3-4 times daily	2
	35%	0.6 – 1.2 g / 1.8 – 4.8 g, 3-4 times daily	10
	24%	0.4 – 0.8 g/ 1.2 – 3.2 g, 3-4 times daily	11
	33%	0.48 g / 1.9 – 2.9 g, 4-6 times daily	12
	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
	15-30%	0.6 – 1.8 g / 1.8 – 7.2 g, 3-4 times daily	19
Phaseoli fructus	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
	10-20%	0.2 – 0.8 g / 0.6 – 3.2 g, 3-4 times daily	15
Polygoni avic. herba	30%	0.413 g / 1.24 – 2.1 g, 3-5 times daily	5
Solidaginis virg. herba	35%	0.6 g / 2.8-2.4 g, 3-4 times daily	1, 13
	24%	0.4 g / 1.2-1.6 g, 3-4 times daily	2
	35%	0.6 – 1.2 g / 1.8 – 4.8 g, 3-4 times daily	10
	24%	0.4 – 0.8 g/ 1.2 – 3.2 g, 3-4 times daily	11
	33%	0.48 g / 1.9 – 2.9 g, 4-6 times daily	12
Urticae herba/folium	27%	0.413 g / 1.24 – 2.1 g, 3-5 times daily	5
Uvae ursi folium	24%	0.4 g / 1.2-1.6 g, 3-4 times daily	2

Combination partner	Amount Betulae folium in combination (excl. excipients)	Single dose Betulae folium/ daily dose Frequency	Reference (# in tables 1 and 2)
	30%	0.413 g / 1.24 – 2.1 g, 3-5 times daily	5
	35%	0.45 g / 1.35 – 2.25 g, 3-5 times daily	7
	24%	0.4 – 0.8 g/ 1.2 – 3.2 g, 3-4 times daily	11
	47%	0.7 - 0.9 g / 2.8 g, 3-4 times daily	23
	25%	0.25 g / 0.75 g, 3 times daily	24
	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
	10-20%	0.2 – 0.8 g / 0.6 – 3.2 g, 3-4 times daily	15
	15-25%	0.3 – 1 g / 0.9 – 4 g, 3-4 times daily	20
Summary	10-57%	Single dose 0.2 – 1.8 g Daily dose 1.8 – 7.2 g Frequency: 3-6 times daily Monograph on Betulae folium: Single dose 2-3 g Daily dose: up to 12 g Frequency: up to 4 times daily	

Table 4: Equiseti herba in combinations

Combination partner	Amount Equiseti herba in combination (excl. excipients)	Single dose Equiseti herba / daily dose Frequency	Reference (# in tables 1 and 2)
Betulae folium	39%	1.5 g / 4.5 g, 3 times daily	4
	43%	0.6 – 1.2 g/ 1.8 – 3.6 g, 3 times daily	8
	18%	0.26 g / 1 – 1.6 g, 4-6 times daily	12
	27%	0.4 – 0.55 g / 1.6 g, 3-4 times daily	23
	25%	0.25 g / 0.75 g, 3 times daily	24
	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
	10-30%	0.2 – 1.2 g / 0.6 – 4.8 g, 3-4 times daily	15

	10-30%	0.4 – 1.8 g / 1.2 – 7.2 g, 3-4 times daily	16
	40%	0.8 g / 1.6 g, 2 times daily	26
	18%	1 g / 2 – 3 g, 2-3 times daily	29
Graminis rhizoma	15%	0.075 – 0.15 g / 0.75 g, 5 times daily	20
	18%	1 g / 2 – 3 g, 2-3 times daily	29
Herniariae herba	39 %	1.5 g / 4.5 g, 3 times daily	4
	25%	0.25 g / 0.75 g, 3 times daily	24
Juniperi galbulus	18%	0.26 g / 1 – 1.6 g, 4-6 times daily	12
	15%	0.075 – 0.15 g / 0.75 g, 5 times daily	20
Levistici radix	40%	0.8 g / 1.6 g, 2 times daily	26
Mate folium	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
Ononidis radix	61%	0.715 g / 2.1 – 2.9 g, 3-4 times daily	3
	15%	0.075 – 0.15 g / 0.75 g, 5 times daily	20
	10-30%	0.4 – 1.8 g / 1.2 – 7.2 g, 3-4 times daily	16
	18%	1 g / 2 – 3 g, 2-3 times daily	29
Orthosiphonis folium	18%	0.26 g / 1 – 1.6 g, 4-6 times daily	12
	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
Phaseoli fructus	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
	10-30%	0.2 – 1.2 g / 0.6 – 4.8 g, 3-4 times daily	15
Solidaginis virg. herba	36%	0.3 g/ 0.9 – 1.5 g, 3-5 times daily	6
	18%	0.26 g / 1 – 1.6 g, 4-6 times daily	12
Urticae herba/folium	61%	0.715 g / 2.1 – 2.9 g, 3-4 times daily	3
Uvae ursi folium	36%	0.3 g/ 0.9 – 1.5 g, 3-5 times daily	6
	27%	0.4 – 0.55 g / 1.6 g, 3-4 times daily	23
	25%	0.25 g / 0.75 g, 3 times daily	24
	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
	10-30%	0.2 – 1.2 g / 0.6 – 4.8 g, 3-4 times daily	15
Summary	10-61%	Single dose 0.075 – 1.8 g Daily dose 0.6 – 7.2 g Frequency: 3-6 times daily Monograph on Equiseti herba:	

		Single dose 1-4 g Daily dose: up to 16 g Frequency: 3-4 times daily	
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Table 5: Graminis rhizoma in combinations

Combination partner	Amount Graminis rhizome in combination (excl. excipients)	Single dose Graminis rhizoma / daily dose Frequency	Reference (# in tables 1 and 2)
Betulae folium	25%	1-1.5 g / 3 – 6 g, 3-4 times daily	14
	15-25%	0.3 - 1 g / 0.9 – 4 g, 3-4 times daily	20
	18%	1 g / 2 – 3 g, 2-3 times daily	29
Equiseti herba	20%	0.1 – 0.2 g / 1 g, 5 times daily	20
	18%	1 g / 2 – 3 g, 2-3 times daily	29
Juniperi galbulus	20%	0.1 – 0.2 g / 1 g, 5 times daily	20
Ononidis radix	20%	0.1 – 0.2 g / 1 g, 5 times daily	20
	25%	1-1.5 g / 3 – 6 g, 3-4 times daily	14
	10-20%	0.2 – 0.8 g / 0.6 – 3.2 g, 3-4 times daily	17
	18%	1 g / 2 – 3 g, 2-3 times daily	29
Orthosiphonis folium	10-20%	0.2 – 0.8 g / 0.6 – 3.2 g, 3-4 times daily	17
Uvae ursi folium	10-20%	0.2 – 0.8 g / 0.6 – 3.2 g, 3-4 times daily	17
	15-25%	0.3 - 1 g / 0.9 – 4 g, 3-4 times daily	20
Summary	10-25%	Single dose 0.1-1.5 g Daily dose 0.6 – 6 g Frequency: 3-5 times daily Monograph on Graminis rhizoma: Single dose 3-6 g Daily dose: up to 20 g Frequency: several times daily	

Table 6: Herniariae herba in combinations

Combination partner	Amount Herniariae herba in combination (excl. excipients)	Single dose Herniariae herba / daily dose Frequency	Reference (# in tables 1 and 2)
Betulae folium	26%	1 g / 3 g, 3 times daily	4
	6%	0.075 g / 0.225 – 0.375 g, 3-5 times daily	7
	25%	0.5 g / 1.5 g, 3 times daily	24
Equiseti herba	26%	1 g / 3 g, 3 times daily	4
	25%	0.5 g / 1.5 g, 3 times daily	24
Ononidis radix	6%	0.075 g / 0.225 – 0.375 g, 3-5 times daily	7
Uvae ursi folium	6%	0.075 g / 0.225 – 0.375 g, 3-5 times daily	7
	25%	0.5 g / 1.5 g, 3 times daily	24
Summary	6-26%	Single dose 0.075 - 1 g Daily dose 0.225 - 3 g Frequency: 3-5 times daily Monograph on Herniariae herba: Single dose 1.5-3 g Daily dose: up to 10 g Frequency: 3-5 times daily	

Table 7: Juniperi galbulus (pseudo-fructus) in combinations

Combination partner	Amount Juniperi galbulus in combination (excl. excipients)	Single dose Juniperi galbulus / daily dose Frequency	Reference (# in tables 1 and 2)
Betulae folium	15%	0.22 g / 0.9 – 1.3 g	12
Equiseti herba	15%	0.22 g / 0.9 – 1.3 g	12
	15%	0.075 – 0.15 g / 0.75 g, 5 times daily	21
Graminis rhizoma	15%	0.075 – 0.15 g / 0.75 g, 5 times daily	21
Levistici radix	14%	0.3 g / 0.6 – 0.9 g, 2-3 times daily	27

Combination partner	Amount Juniperi galbulus in combination (excl. excipients)	Single dose Juniperi galbulus / daily dose Frequency	Reference (# in tables 1 and 2)
Ononidis radix	15%	0.075 – 0.15 g / 0.75 g, 5 times daily	21
	50%	0.5 g 1 g, 2 times daily	22
Orthosiphonis folium	15%	0.22 g / 0.9 – 1.3 g	12
Solidaginis virg. herba	15%	0.22 g / 0.9 – 1.3 g	12
	10%	0.2 g / 0.6 g, 3 times daily	28
Summary	10-50%	Single dose 0.075 – 0.5 g Daily dose 0.6 – 1.3 g Frequency: 3-5 times daily Monograph on Juniperi galbulus (pseudo-fructus): Single dose 2 g Daily dose: up to 6 g Frequency: 2-3 times daily	

Table 8: Levistici radix in combinations

Combination partner	Amount Levistici radix in combination (excl. excipients)	Single dose Levistici radix / daily dose Frequency	Reference (# in tables 1 and 2)
Betulae folium	20%	0.4 g / 0.8 g, 2 times daily	26
Equiseti herba	20%	0.4 g / 0.8 g, 2 times daily	26
Juniperi galbulus	29%	0.5 g / - 0.6 g / 1.2 – 1.8 g, 2-3 times daily	27
Summary	20-29%	Single dose 0.4 – 0.6 g Daily dose: 0.8 – 1.8 g Frequency: 2-3 times daily Monograph on Levistici radix:	

		Single dose 2-3 g Daily dose: up to 6 g Frequency: up to 2 times daily	
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Table 9: Mate folium in combinations

Combination partner	Amount Mate folium in combination (excl. excipients)	Single dose Mate folium / daily dose Frequency	Reference (# in tables 1 and 2)
Betulae folium	10%	0.4 g / 1.2 – 2 g, 3-5 times daily	25
Equiseti herba	10%	0.4 g / 1.2 – 2 g, 3-5 times daily	25
Orthosiphonis folium	10%	0.4 g / 1.2 – 2 g, 3-5 times daily	25
Phaseoli fructus	10%	0.4 g / 1.2 – 2 g, 3-5 times daily	25
Uvae ursi folium	10%	0.4 g / 1.2 – 2 g, 3-5 times daily	25
Summary	10%	Single dose 0.4 g Daily dose: 1.2 – 2 g Frequency: 3-5 times daily Monograph on Mate folium: Single dose 2.5 g Daily dose: up to 5 g Frequency: 1-2 times daily	

Table 10: Ononidis radix in combinations

Combination partner	Amount Ononidis radix in combination (excl. excipients)	Single dose Ononidis radix / daily dose Frequency	Reference (# in tables 1 and 2)
Betulae folium	11%	0.15 g / 0.45 – 0.75 g, 3-5 times daily	5
	12%	0.15 g / 0.45 – 0.75 g, 3-5 times daily	7
	25%	1-1.5 g / 3 – 6 g, 3-4 times daily	14
	10-30%	0.4 – 1.8 g / 1.2 – 7.2 g, 3-4 times daily	16
	20-30%	0.8 – 1.8 g / 2.4 – 7.2 g, 3-4 times daily	19

	12%	0.6 g / 1.2 – 1.8 g, 2-3 times daily	29
Equiseti herba	17%	0.195 g / 0.58 – 0.78 g, 3-4 times daily	3
	20%	0.1 – 0.2 g / 1 g, 5 times daily	21
	10-30%	0.4 – 1.8 g / 1.2 – 7.2 g, 3-4 times daily	16
	12%	0.6 g / 1.2 – 1.8 g, 2-3 times daily	29
Graminis rhizoma	20%	0.1 – 0.2 g / 1 g, 5 times daily	21
	25%	1-1.5 g / 3 – 6 g, 3-4 times daily	14
	10-25%	0.2 – 1 g / 0.6 – 4 g, 3-4 times daily	17
	12%	0.6 g / 1.2 – 1.8 g, 2-3 times daily	29
Herniariae herba	12%	0.15 g / 0.45 – 0.75 g, 3-5 times daily	7
Juniperi galbulus	20%	0.1 – 0.2 g / 1 g, 5 times daily	21
	50%	1 g / 2 g, 2 times daily	22
Orthosiphonis folium	50%	0.68 g / 3.4 g, 5 times daily	9
	10-25%	0.2 – 1 g / 0.6 – 4 g, 3-4 times daily	17
	20-30%	0.8 – 1.8 g / 2.4 – 7.2 g, 3-4 times daily	19
Polygoni avic. herba	11%	0.15 g / 0.45 – 0.75 g, 3-5 times daily	5
Urticae herba/folium	17%	0.195 g / 0.58 – 0.78 g, 3-4 times daily	3
	11%	0.15 g / 0.45 – 0.75 g, 3-5 times daily	5
Uvae ursi folium	11%	0.15 g / 0.45 – 0.75 g, 3-5 times daily	5
	12%	0.15 g / 0.45 – 0.75 g, 3-5 times daily	7
	12%	-	19
	10-25%	0.2 – 1 g / 0.6 – 4 g, 3-4 times daily	17
Summary	10-50%	Single dose 0.1 – 1.8 g Daily dose 0.45 – 7.2 g Frequency: 2-5 times daily Monograph on Ononidis radix: Single dose 2-3 g Daily dose: up to 12 g Frequency: 3-4 times daily	

Table 11: Orthosiphonis folium in combinations

Combination partner	Amount Orthosiphonis folium in combination (excl. excipients)	Single dose Orthosiphonis folium / daily dose Frequency	Reference (# in tables 1 and 2)
Betulae folium	35% 18% 35% 18% 15% 10% 20-30%	0.6 g / 1.8 – 2.4 g, 3-4 times daily 0.3 g / 0.9 – 1.2 g, 3-4 times daily 0.6 - 1.2 g/ 1.8 – 4.8 g, 3-4 times daily 0.3 – 0.6 g / 0.9 – 2.4 g, 3-4 times daily 0.22 g / 0.88 – 1.32 g, 4-6 times daily 0.4 g / 1.2 – 2 g, 3-5 times daily 0.8 – 1.8 g / 2.4 – 7.2 g, 3-4 times daily	1 2 10 11 12 25 19
Equiseti herba	15% 10%	0.22 g / 0.88 – 1.32 g, 4-6 times daily 0.4 g / 1.2 – 2 g, 3-5 times daily	12 25
Graminis rhizoma	15-30%	0.3 – 1.2 g / 0.9 – 4.8 g, 3-4 times daily	17
Juniperi galbulus	15%	0.22 g / 0.88 – 1.32 g, 4-6 times daily	12
Mate folium	10%	0.4 g / 1.2 – 2 g, 3-5 times daily	25
Ononidis radix	50% 15-30% 20-30%	0.68 g / 3.4 g, 5 times daily 0.3 – 1.2 g / 0.9 – 4.8 g, 3-4 times daily 0.8 – 1.8 g / 2.4 – 7.2 g, 3-4 times daily	9 17 19
Phaseoli fructus	10% 10-30%	0.4 g / 1.2 – 2 g, 3-5 times daily 0.2 – 1.2 g / 0.6 – 4.8 g, 3-4 times daily	26 18
Solidaginis virg. herba	35% 18% 35% 18% 15%	0.6 g / 1.8 – 2.4 g, 3-4 times daily 0.3 g / 0.9 – 1.2 g, 3-4 times daily 0.6 - 1.2 g/ 1.8 – 4.8 g, 3-4 times daily 0.3 – 0.6 g / 0.9 – 2.4 g, 3-4 times daily 0.22 g / 0.88 – 1.32 g, 4-6 times daily	1 2 10 11 12
Uvae ursi folium	18% 18% 10% 15-30% 10-30%	0.3 g / 0.9 – 1.2 g, 3-4 times daily 0.3 – 0.6 g / 0.9 – 2.4 g, 3-4 times daily 0.4 g / 1.2 – 2 g, 3-5 times daily 0.3 – 1.2 g / 0.9 – 4.8 g, 3-4 times daily 0.2 – 1.2 g / 0.6 – 4.8 g, 3-4 times daily	2 11 25 17 18
Summary	10-50%	Single dose 0.2 – 1.8 g Daily dose 0.6 – 7.2 g Frequency: 3-6 times daily Monograph on Orthosiphonis folium: Daily dose 6-12 g in divided doses	

Table 12: Phaseoli fructus in combinations

Combination partner	Amount Phaseoli fructus in combination (excl. excipients)	Single dose Phaseoli fructus / daily dose Frequency	Reference (# in tables 1 and 2)
Betulae folium	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
	10-20%	0.2 – 0.8 g / 0.6 – 3.2 g, 3-4 times daily	15
Equiseti herba	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
	10-20%	0.2 – 0.8 g / 0.6 – 3.2 g, 3-4 times daily	15
Mate folium	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
Orthosiphonis folium	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
	10-20%	0.2 – 0.8 g / 0.6 – 3.2 g, 3-4 times daily	18
Uvae ursi folium	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
	10-20%	0.2 – 0.8 g / 0.6 – 3.2 g, 3-4 times daily	15
	10-20%	0.2 – 0.8 g / 0.6 – 3.2 g, 3-4 times daily	18
Summary	10-20%	Single dose 0.2 – 0.8 g Daily dose 0.6 – 4 g Frequency: 3-4 times daily Monograph on Phaseoli fructus: Single dose 2.5 g Daily dose up to 15 g Frequency: 2 - 6 times daily	

Table 13: Polygoni avicularis herba in combinations

Combination partner	Amount Polygoni herba in combination (excl. excipients)	Single dose Polygoni herba / daily dose Frequency	Reference (# in tables 1 and 2)
Betulae folium	12%	0.165 g / 0.49 – 0.85 g, 3-5 times daily	5
Ononidis radix	12%	0.165 g / 0.49 – 0.85 g, 3-5 times daily	5
Urticae herba/folium	12%	0.165 g / 0.49 – 0.85 g, 3-5 times daily	5
Uvae ursi folium	12%	0.165 g / 0.49 – 0.85 g, 3-5 times daily	5

Summary	12%	Single dose 0.165 g Daily dose 0.49 – 0.85 g Frequency: 3-5 times daily Monograph on Polygoni avicularis herba: Single dose 3 g Daily dose 6 g Frequency: 2 times daily	
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Table 14: Solidaginis virgaureae herba in combinations

Combination partner	Amount Solidaginis virg. herba in combination (excl. excipients)	Single dose Solidaginis virg. herba / daily dose Frequency	Reference (# in tables 1 and 2)
Betulae folium	29%	0.5 g / 1.5 – 2 g, 3-4 times daily	1
	18%	0.3 g / 0.9 – 1.2 g, 3-4 times daily	2
	29%	0.5 – 1 g / 1.5 – 4 g, 3-4 times daily	10
	18%	0.3-0.6 g / 0.9 – 2.4 g, 3-4 times daily	11
	18%	0.22 g / 0.88 – 1.32 g, 4-6 times daily	12
Equiseti herba	18%	0.15 g / 0.45 – 0.75 g, 3-5 times daily	6
	18%	0.22 g / 0.88 – 1.32 g, 4-6 times daily	12
Juniperi galbulus	18%	0.22 g / 0.88 – 1.32 g, 4-6 times daily	12
	20%	0.4 g/ 1.2 g, 3 times daily	28
Orthosiphonis folium	29%	0.5 g / 1.5 – 2 g, 3-4 times daily	1
	18%	0.3 g / 0.9 – 1.2 g, 3-4 times daily	2
	29%	0.5 – 1 g / 1.5 – 4 g, 3-4 times daily	10
	18%	0.3-0.6 g / 0.9 – 2.4 g, 3-4 times daily	11
	18%	0.22 g / 0.88 – 1.32 g, 4-6 times daily	12
Uvae ursi folium	18%	0.3 g / 0.9 – 1.2 g, 3-4 times daily	2
	18%	0.15 g / 0.45 – 0.75 g, 3-5 times daily	6
	18%	0.3-0.6 g / 0.9 – 2.4 g, 3-4 times daily	11
Summary	18-29%	Single dose 0.15 - 1 g	

Combination partner	Amount Solidaginis virg. herba in combination (excl. excipients)	Single dose Solidaginis virg. herba / daily dose Frequency	Reference (# in tables 1 and 2)
		Daily dose 0.45 – 4 g Frequency: 3-6 times daily Monograph on Solidaginis virgaurea herba: Single dose 3-5 g Daily dose up to 20 g Frequency: 2-4 times daily	

Table 15: Urticae herba / folium in combinations

Combination partner	Amount Urticae herba / folium in combination (excl. excipients)	Single dose Urticae herba / folium / daily dose Frequency	Reference (# in tables 1 and 2)
Betulae folium	11%	0.15 g / 1.2 – 2.1 g, 3-5 times daily	5
Equiseti herba	22%	0.26 g / 0.78 – 1.05 g, 3-4 times daily	3
Ononidis radix	22%	0.26 g / 0.78 – 1.05 g, 3-4 times daily	3
	11%	0.15 g / 1.2 – 2.1 g, 3-5 times daily	5
Polygoni avic. herba	11%	0.15 g / 1.2 – 2.1 g, 3-5 times daily	5
Uvae ursi folium	11%	0.15 g / 1.2 – 2.1 g, 3-5 times daily	5
Summary	11-22 %	Single dose 0.15 – 0.50 g Daily dose 0.78 – 2.1 g Frequency: 3-5 times daily Monograph on Urticae herba / folium: Single dose 1.5 g Daily dose up to 24 g (Urticae folium), 6 g (Urticae herba) Frequency:	

		3-6 times daily (Urticae folium), 3-4 times daily (Urticae herba)	
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Table 16: Uvae ursi folium in combinations

Combination partner	Amount Uvae ursi folium in combination (excl. excipients)	Single dose Uvae ursi folium / daily dose Frequency	Reference (# in tables 1 and 2)
Betulae folium	41%	0.7 g / 2.1 – 2.8 g, 3-4 times daily	2
	25%	0.34 g / 1 – 1.7 g, 3-5 times daily	5
	35%	0.45 g / 1.35 – 2.25 g, 3-5 times daily	7
	41%	0.7 – 1.4 g / 2.1 – 5.6 g, 3-4 times daily	11
	27%	0.4 – 0.55 g / 1.6 g, 3-4 times daily	23
	25%	0.25 g / 0.75 g, 3 times daily	24
	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
	35-50%	0.7 – 2 g/ 2.1 – 8 g, 3-4 times daily	15
	35-50%	0.7 – 2 g/ 2.1 – 8 g, 3-4 times daily	20
Equiseti herba	46%	0.375 g/ 1.12 – 1.9 g, 3-5 times daily	6
	27%	0.4 – 0.55 g / 1.6 g, 3-4 times daily	23
	25%	0.25 g / 0.75 g, 3 times daily	24
	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
	35-50%	0.7 – 2 g/ 2.1 – 8 g, 3-4 times daily	15
Graminis rhizoma	35-50%	0.7 – 2 g/ 2.1 – 8 g, 3-4 times daily	17
	35-50%	0.7 – 2 g/ 2.1 – 8 g, 3-4 times daily	20
Herniariae herba	35%	0.45 g / 1.35 – 2.25 g, 3-5 times daily	7
	25%	0.25 g / 0.75 g, 3 times daily	24
Mate folium	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
Ononidis radix	25%	0.34 g / 1 – 1.7 g, 3-5 times daily	5
	35%	0.45 g / 1.35 – 2.25 g, 3-5 times daily	7
	35-50%	0.7 – 2 g/ 2.1 – 8 g, 3-4 times daily	17
Orthosiphonis folium	41%	0.7 g / 2.1 – 2.8 g, 3-4 times daily	2
	41%	0.7 – 1.4 g / 2.1 – 5.6 g, 3-4 times daily	11
	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25

Combination partner	Amount Uvae ursi folium in combination (excl. excipients)	Single dose Uvae ursi folium / daily dose Frequency	Reference (# in tables 1 and 2)
	35-50%	0.7 – 2 g/ 2.1 – 8 g, 3-4 times daily	17
	35-50%	0.7 – 2 g/ 2.1 – 8 g, 3-4 times daily	18
Phaseoli fructus	20%	0.8 g / 2.4 – 4 g, 3-5 times daily	25
	35-50%	0.7 – 2 g/ 2.1 – 8 g, 3-4 times daily	15
	35-50%	0.7 – 2 g/ 2.1 – 8 g, 3-4 times daily	18
Polygoni avic. herba	25%	0.34 g / 1 – 1.7 g, 3-5 times daily	5
Solidaginis virg. herba	41%	0.7 g / 2.1 – 2.8 g, 3-4 times daily	2
	46%	0.375 g/ 1.12 – 1.9 g, 3-5 times daily	6
	41%	0.7 – 1.4 g / 2.1 – 5.6 g, 3-4 times daily	11
Urticae herba/folium	25%	0.34 g / 1 – 1.7 g, 3-5 times daily	5
Summary	20-50%	Single dose 0.25 - 2 g Daily dose 0.75 – 8 g Frequency: 3 – 5 times daily Monograph on Uvae ursi folium: Single dose 1.5 - 4 g Maximum daily dose 8 g Frequency: 2 - 4 times daily	

Table 17: Numbers indicate the percentage of an herbal substance (left row) in a combination with other herbal substances (excipients excluded) based on documented traditional medicinal use. (Instructions and an example how to apply the table are given on the following page.)

Example: When *Betulae folium* is combined with *Ononidis radix* then 10-35% of *Betulae folium* is traditionally used in combinations. This combination contains 10-30% *Ononidis radix*.

	<i>Betulae folium</i>	<i>Equiseti herba</i>	<i>Graminis rhizoma</i>	<i>Herniariae herba</i>	<i>Juniperi galbulus</i>	<i>Levistici radix</i>	<i>Mate folium</i>	<i>Ononidis radix</i>	<i>Orthosiphonis folium</i>	<i>Phaseoli fructus</i>	<i>Polygoni avicul. herba</i>	<i>Solidaginis virg. herba</i>	<i>Urticae herba / folium</i>	<i>Uvae ursi folium</i>	Range
<i>Betulae folium</i>	-	10-57%	15-31%	26-35%	25-33%	20-25%	20%	10-35%	15-35%	10-20%	30%	24-35%	27%	10-47%	10-57%
<i>Equiseti herba</i>	10-43%	-	15-18%	25-39%	15-18%	40%	20%	10-61%	18-20%	10-30%	-	18-36%	61%	10-36%	10-61%
<i>Graminis rhizoma</i>	15-25%	18-20%	-		20%	-	-	10-25%	10-20%	-		-	-	10-25%	10-25%
<i>Herniariae herba</i>	6-25%	25-26%		-				6%						6-25%	6-26%
<i>Juniperi galbulus</i>	15-25%	15%	15%		-	14-33%	-	15-50%	15%	-	-	10-15%	-	-	10-50%
<i>Levistici radix</i>	20-25%	20%	-		25-29%	-	-	-	-	-	-	-	-	-	20-29%
<i>Mate folium</i>	10%	10%	-		-	-	-	-	10%	10%	-	-	-	10%	10%
<i>Ononidis radix</i>	10-30%	10-30%	10-25%	12%	20-50%	25%	-	-	10-50%	-	11%	-	11-17%	10-25%	10-50%
<i>Orthosiphonis folium</i>	10-35%	10-15%	15-30%		15%	-	10%	15-50%	-	10-30%	-	15-35%	-	10-30%	10-50%
<i>Phaseoli fructus</i>	10-20%	10-20%	-		-	-	20%	-	10-20%	-	-	-	-	10-20%	10-20%
<i>Polygoni avic. herba</i>	12%	-	-		-	-	-	12%	-	-	-	-	12%	12%	12%
<i>Solidaginis virg. herba</i>	18-29%	18%	-		18-20%	-	-	-	18-29%	-	-	-	-	18%	18-29%
<i>Urticae herba/folium</i>	11%	22%	-		-	-	-	11-22%	-	-	11%	-	-	11%	11-22%
<i>Uvae ursi folium</i>	20-50%	20-50%	35-50%	25-35%	-	-	20%	25-50%	20-50%	20-50%	25%	41-46%	25%	-	20-50%

How to use the information on traditional medicinal use of these combinations?

Evidence for combination: the grey shaded fields in table 16 indicate combinations with evidence of traditional medicinal use. Example: *Solidaginis virgaureae herba* has evidence of combination with *Betulae folium*, *Equiseti herba*, *Juniperi galbulus*, *Orthosiphonis folium* and *Uvae ursi folium*. Out of these documented combinations the combination partners for an application for a traditional herbal medicinal product may be chosen.

Number of combination partners: The number of active substances in an herbal tea combination should be limited to a maximum of 4 based on the corresponding products and the references used for assessment. Further herbal substances may be added as excipients, their number, amount and function should be justified.

Amount of each herbal substance in the combination: The very right row indicates the traditional percentages of the herbal substance in the combinations. The calculation is based on those combination partners only, which are mentioned in the table. 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 10% in the final combination.

Example: Combination of *Solidaginis virgaureae herba* + *Betulae folium* + *Orthosiphonis folium*. The combination should contain 18-29% *Solidaginis virgaureae herba*, 10-57% *Betulae folium* and 10-50% *Orthosiphonis folium*. Therefore, a combination of 25% *Solidaginis virgaureae herba*, 40% *Betulae folium* and 35% *Orthosiphonis folium* is covered by this assessment and by the European Union monograph. Excipients: e.g. *Menthae piperitae folium* may be added for flavouring purposes.

Information from published European Union herbal monographs

Indication

Currently, the following indications are included in published EU monographs of the herbal substances considered for *Species diureticae*:

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.

Traditional herbal medicinal product to increase the amount of urine (to achieve flushing of the urinary tract) as an adjuvant in minor urinary (tract) complaints.

*Traditional herbal medicinal product used for relief of symptoms of mild recurrent lower urinary tract infections such as burning sensation during urination and/or frequent urination in women, after serious conditions have been excluded by a medical doctor. (indication only for *Uvae ursi folium*, please refer to the comments below regarding *Uvae ursi folium*)*

Assessment for combinations:

According to the indications of medicinal products on the market and according to the terminology of the herbal tea combinations in pharmacopoeias and textbooks and the general recommendation of a sufficient fluid intake due to the diuretic effect and to achieve flushing - and the new agreed indication in the recent revisions of the included single Monographs - the following indication appears appropriate to all combinations:

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.

Posology

Assessment for combinations:

Based on the information from marketed products the single dose of herbal tea combinations is in the range between 1.3 and 2 g, in some combinations up to 4 g. With the exception of *Uvae ursi folium*, where the maximum daily dosage reported from marketed products is equal to the one stated in the European Union herbal monograph, the single and daily dosages of all other herbal substances are clearly below the dosages stated in the monographs for the single herbal substances. The single dose for new combinations should be set to about 1.5 – 2 g (active herbal substances, excluding excipients).

The mean dosage frequency is 3-5 times daily. Only one combination product is recommended up to 6 times daily. Many references do not report a concrete dosage frequency. It can be assumed that the traditional use of herbal teas in general is linked to a '3 times daily' dosage frequency. Particularly in the case of 'Species diureticae' a higher frequency can be assumed as in literature the sufficient uptake of fluid was related with the traditional efficacy. Considering the European Union herbal monographs for the single herbal substances the dosage frequency is set to 3-4 times daily for all combinations.

The possible daily dosages of the herbal substances in combination products are clearly below the maximum posology as given in the HMPc monographs for the single active substances:

Table 18: Comparison of the daily dose in the combinations with the upper limit according to the HMPc monographs

	Range in a combination (excl. excipients)	Daily dose (2 g combination, 4 times daily)	Maximum daily dose HMPc monograph
Betulae folium	10-57%	0.8 – 4.56 g	Up to 12 g
Equiseti herba	10-61%	0.8 – 4.88 g	Up to 12 g
Graminis rhizoma	10-50%	0.8 – 4 g	Up to 24 g
Herniariae herba	6-25%	0.72 - 2 g	Up to 10 g
Juniperi galbulus	10-50%	0.8 – 4 g	Up to 6 g
Levistici radix	20-33%	1.6 – 2.64 g	Up to 6 g
Mate folium	10%	0.8 g	Up to 5 g
Ononidis radix	10-50%	0.8 – 4 g	Up to 12 g
Orthosiphonis folium	10-50%	0.8 – 4 g	Up to 12 g
Phaseoli fructus	10-20%	0.8 – 1.6 g	Up to 15 g
Polygoni avic. herba	12	0.96 g – 4 g	Up to 6 g
Solidaginis virg. herba	18-29%	1.44 – 2.32 g	Up to 20 g
Urticae herba/folium	11-22%	0.88 – 1.76 g	Up to 12 g (<i>Urticae folium</i>) Up to 6 g (<i>Urticae herba</i>)

Uvae ursi folium	20-50%	1.6 – 4 g	Up to 8 g
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Age limits

Betulae folium Equiseti herba Graminis rhizoma Ononidis radix Polygoni avicularis herba Solidaginis viragureae herba Urticae folium	Adolescents, adults and elderly
Herniariae herba Juniperi galbulus Levistici radix Mate folium Orthosiphonis folium Phaseoli fructus Urticae herba	Adults and elderly
Uvae ursi folium	Female adults and elderly

Assessment for combinations:

Tea combinations containing Herniariae herba, Juniperi galbulus, Levistici radix, Mate folium, Orthosiphonis folium, Phaseoli fructus or Uvae ursi folium are restricted to the use in adults and elderly. Other combinations may be used in adolescents.

The restriction of combinations containing Uvae ursi folium to female adults is not applicable due to the indication.

Duration of use

Betulae folium Equiseti herba Graminis rhizoma Solidaginis viragureae herba	2-4 weeks
Herniariae herba Juniperi galbulus Mate folium Orthosiphonis folium	2 weeks

Phaseoli fructus Polygoni avicularis herba Urticae herba	
Ononidis radix	1 week
Levistici radix Urticae folium	Not to be used for more than 2-4 weeks
Uvae ursi folium	Not to be used for more than 1 week

Assessment for combinations:

The restriction to 1 week in case of Uvae ursi folium in the European Union herbal monograph is justified by the indication. As the indication for the combinations is different no such restriction applies. As a suitable compromise duration of use of 2 weeks is justified.

Contraindications

Betulae folium	Hypersensitivity to the active substance or to birch pollen. Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).
Equiseti herba Herniariae herba Ononidis radix Orthosiphonis folium Solidaginis viragureae herba Urticae folium	Hypersensitivity to the active substance. Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).
Levistici radix	Hypersensitivity to the active substance and to other plants of the Apiaceae (Umbelliferae) family or to anethole.
Mate folium	Hypersensitivity to the active substance. Gastric and duodenal ulcers, cardiovascular disorders such as hypertension and arrhythmia, hyperthyroidism. Conditions where a reduced fluid intake is recommended e.g. obstruction of the urinary tract.
Graminis rhizoma Juniperi galbulus Phaseoli fructus Urticae herba	Hypersensitivity to the active substance.
Polygoni avicularis herba	Hypersensitivity to the active substance.

	Conditions where reduced fluid intake is recommended (e.g. severe cardiac diseases).
Solidaginis viragureae herba	Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family. Conditions where a reduced fluid intake is recommended, e.g. severe cardiac or renal diseases.
Uvae ursi folium	Hypersensitivity to the active substance. Kidney disorders.

Assessment for combinations:

All combinations have to include the contraindications:

- Hypersensitivity to the active substance.
- Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).

Combinations including Betulae folium:

Additionally: Hypersensitivity to birch pollen.

Combinations containing Levistici radix:

Additionally: Hypersensitivity to other plants of the Apiaceae family or to anethole.

Combinations containing Mate folium:

According to the data obtained Mate folium is contained in an amount of 10% in traditional herbal tea combinations. A mean single dose of 2 g herbal tea combination would result in a single dose of 0.2 g Mate folium which is 5-10% of the recommended dose of Mate folium as only active ingredient. This considerably reduced posology compared to the traditional use as single active ingredient justifies that the special contraindications are not taken into account for herbal tea combinations.

Combinations containing Solidaginis viragureae herba

Additionally: Hypersensitivity to other plants of the Asteraceae (Compositae) family.

Combinations containing Uvae ursi folium:

The general contraindication 'kidney disorders' is summarised in the contraindication related to conditions where a reduced fluid intake is recommended.

Special warnings and precautions for use:

Betulae folium Equiseti herba	The use in children under 12 years of age has not been established due to lack of adequate data. If complaints or symptoms such as fever, dysuria, spasms or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.
Graminis rhizoma	The use in children under 12 years of age has not been established due to lack of adequate data. If the symptoms such as fever, dysuria, spasms or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

	Because adequate fluid intake is required during treatment (see section 4.2. 'Method of administration'), couch grass rhizome preparations are not recommended for patients with conditions where reduced fluid intake is advised by a medical doctor.
Herniariae herba	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. To ensure an increase of the amount of urine, adequate fluid intake is required during the treatment. If urinary tract complaints worsen and 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.
Juniperi galbulus	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Not recommended to be used in case of severe renal disease including infectious interstitial nephritis, pyelitis and pyelonephritis. If complaints or symptoms such as fever, dysuria, spasms or blood in the urine occur during the use of the medicinal product, a doctor or a qualified health care professional should be consulted. Because adequate fluid intake is required during treatment (see section 4.2. 'Method of administration'), Juniperus communis L., galbulus is not recommended for patients with conditions where reduced fluid intake is advised by a medical doctor.
Levistici radix	The use in children and adolescents under 18 years of age is not recommended because of concerns requiring medical advice. If complaints or symptoms such as fever, dysuria, spasms, or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.
Orthosiphonis folium	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. If complaints or symptoms such as fever, dysuria, spasms or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.
Mate folium	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. Not recommended before bedtime as it may cause sleep disturbances. If complaints or symptoms such as fever, dysuria, spasms or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Ononidis radix Polygoni avicularis herba	The use in children under 12 years of age has not been established due to lack of adequate data. To ensure an increase of the amount of urine, adequate fluid intake is required during the treatment. If urinary tract complaints worsen and 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.
Phaseoli fructus Urticae herba	The use in children and adolescents under 18 years of age has not been established due to lack of data. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.
Solidaginis viragureae herba	The use in children under 12 years of age has not been established due to lack of available experience. If complaints of symptoms such as fever, dysuria, spasms or blood in the urine occur during the use of the medicinal product, a doctor or a qualified health care professional should be consulted. Concomitant treatment with synthetic diuretics is not recommended.
Urticae folium	The use in children under 12 years of age has not been established due to lack of adequate data. If minor urinary tract complaints worsen and 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 professional should be consulted.
Uvae ursi folium	The use in children and adolescents under 18 years of age is not recommended because of concerns requiring medical advice. The use in men is not recommended because of concerns requiring medical supervision. If the symptoms worsen or if complaints such as fever, dysuria, spasms, or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Uvae ursi folium may cause a greenish-brown coloration of the urine.

Assessment for combinations:

All combinations have to include the warning statements:

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.

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.

Based on the age limit specified above the respective warning has to be given:

“The use in children under 12 years of age is not recommended due to lack of adequate data.” or “The use in children and adolescents under 18 years of age is not recommended due to lack of adequate data.” (new template)

Combinations containing Uvae ursi folium:

The warning related to the use in men is not relevant due to the different indication.

Combinations including Juniperi galbulus:

According to the data obtained Juniperi galbulus is included in herbal tea combinations with a single dose of up to 0.22 g and a daily dose of up to 1.3 g. This considerably reduced posology compared to the traditional use as single active ingredient justifies that the special warnings (in case of severe renal disease including infectious interstitial nephritis, pyelitis and pyelonephritis) are not taken into account for herbal tea combinations.

Interactions

Betulae folium Equiseti herba Graminis rhizoma Herniariae herba Juniperi galbulus Levistici radix Ononidis radix Orthosiphonis folium Phaseoli fructus Polygoni avicularis herba Solidaginis viragureae herba Urticae folium Urticae herba Uvae ursi folium	None reported
Mate folium	Persons taking MAO-inhibitor drugs should use mate with caution. Caffeine containing preparations reduce sedatives action and increase side effects caused by sympathomimetic drugs.

Assessment for combinations:

All combinations have to include the statement: No adequate interaction studies have been performed. (revised template)

Combinations containing Mate folium:

According to the data obtained Mate folium is contained in an amount of 10% in traditional herbal tea combinations. A mean single dose of 2 g herbal tea combination would result in a single dose of 0.2 g Mate folium which is 5-10% of the recommended dose of Mate folium as only active ingredient. This

considerably reduced posology compared to the traditional use as single active ingredient justifies that the special interactions are not taken into account for herbal tea combinations.

Fertility, pregnancy and lactation

Betulae folium Equiseti herba Graminis rhizoma Herniariae herba Juniperi galbulus Levistici radix Ononidis radix Orthosiphonis folium Phaseoli fructus Polygoni avicularis herba Urticae folium Urticae herba Uvae ursi folium	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.
Mate folium	There are no or limited data from use during pregnancy and lactation. Use should be avoided during pregnancy and lactation. (Pharmacokinetic properties: Caffeine crosses the placenta and is distributed in breast milk.)
Solidaginis viragureae herba	In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

Combinations containing Mate folium:

According to the data obtained Mate folium is contained in an amount of 10% in traditional herbal tea combinations. A mean single dose of 2 g herbal tea combination would result in a single dose of 0.2 g Mate folium which is 5-10% of the recommended dose of Mate folium as only active ingredient. This considerably reduced posology compared to the traditional use as single active ingredient justifies that the different wording regarding Fertility, pregnancy and lactation are not taken into account for herbal tea combinations.

Assessment for combinations:

All combinations have to include the statement:

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.

Effects on ability to drive and use machines

Betulae folium Equiseti herba Graminis rhizoma Herniariae herba Juniperi galbulus Levistici radix Mate folium Ononidis radix Orthosiphonis folium Polygoni avicularis herba Solidaginis viragureae herba Urticae folium Urticae herba Uvae ursi folium	No studies on the effect on the ability to drive and use machines have been performed.
Phaseoli fructus	Not relevant.

Assessment for combinations:

All combinations have to include the statement:

No studies on the effect on the ability to drive and use machines have been performed.

Undesirable effects

Betulae folium	Gastrointestinal complaints (nausea, vomiting, diarrhoea) and allergic reactions (itching, rash, urticaria, allergic rhinitis) have been reported. The frequency is not known.
Equiseti herba	Mild gastrointestinal complaints and allergic reactions (e.g. rash, swelling of the face) have been reported. The frequency is not known.
Graminis rhizoma Herniariae herba Levistici radix Juniperi galbulus Mate folium Ononidis radix Orthosiphonis folium Phaseoli fructus	None known.

Polygoni avicularis herba	
Solidaginis viragureae herba	Hypersensitivity reactions or gastrointestinal disorders may occur. The frequency is not known.
Urticae folium	Mild gastrointestinal complaints (e.g. nausea, vomiting, diarrhoea) and skin reactions (e.g. itching, exanthema, hives) may occur. The frequency is not known.
Urticae herba	Gastrointestinal disorders: Nausea, vomiting and diarrhoea. The frequency is not known. Skin and subcutaneous tissue disorders: allergic pruritus, rash and urticaria. The frequency is not known.
Uvae ursi folium	Nausea, vomiting, stomach-ache have been reported. The frequency is not known.

Assessment for combinations:

The section 'Undesirable effects' should contain the combined information taken from the European Union herbal monographs for the single ingredients.

For all combinations: The frequency is not known.

Overdose

Betulae folium Equiseti herba Graminis rhizoma Herniariae herba Juniperi galbulus Levistici radix Mate folium Ononidis radix Orthosiphonis folium Phaseoli fructus Solidaginis viragureae herba Urticae folium Urticae herba Uvae ursi folium	No case of overdose has been reported.
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Assessment for combinations:

All combinations should include the statement:

No information available. (revised template)

Preclinical safety data

Betulae folium Equiseti herba Herniariae herba Ononidis radix Orthosiphonis folium Uvae ursi folium	Adequate tests on genotoxicity have not been performed. Tests on reproductive toxicity and carcinogenicity have not been performed.
Juniperi galbulus	No adequate tests on reproductive toxicity and no tests on genotoxicity and carcinogenicity have been performed.
Graminis rhizoma Levistici radix Mate folium	Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.
Phaseoli fructus Polygoni avicularis herba Solidaginis viragureae herba Urticae folium Urticae herba	Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

Assessment for combinations:

All combinations have to include the statement:

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

3. Non-Clinical Data

Please refer to the assessment reports of the individual herbal substances.

4. Clinical Data

Please refer to the assessment reports of the individual herbal substances.

5. Clinical Safety/Pharmacovigilance

Please refer to the assessment reports of the individual herbal substances.

6. Overall conclusions

The herbal substances Betulae folium, Equiseti herba, Graminis rhizoma (Agropyri repentis rhizoma), Herniariae herba, Juniperi galbulus (pseudo-fructus), Levistici radix, Mate folium, Ononidis radix, Orthosiphonis folium, Phaseoli fructus, Polygoni avicularis herba, Solidaginis virgaureae herba, Urticae folium, Urticae herba and Uvae ursi folium, for which a EU herbal monograph has been established, are

traditionally used in herbal tea combinations with the indication 'Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints'.

The evidence on traditional medicinal use of the single herbal substances is discussed and justified in the assessment reports. The evidence on traditional medicinal use of the combinations is based on marketed products in the member states, on monographs in national pharmacopoeias, on standard marketing authorisations and on publications.

Based on the composition of traditionally used combinations a matrix is developed indicating what herbal substances are traditionally combined and in what percentage they are traditionally combined. This matrix can be used as basis for evidence of traditional medicinal use for individual applications for registration as traditional herbal medicinal product.

The traditional medicinal use is plausible due to the longstanding medicinal use in the proposed indication: *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 safety of the individual herbal substances has been assessed in the assessment reports published together with the respective European Union monographs. Potential risks and undesirable effects are properly addressed in the proposed European Union monograph for the combinations. Based on the longstanding medicinal use no potentiation of undesirable effects due to the combination is to be expected.

Depending on the safety data of the individual herbal substances the medicinal use of the combinations is restricted to adults or adolescents and adults.

As the data on genotoxicity are limited no European Union list entry can be proposed.

Annex

List of references