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EMA/HMPC/554043/2018
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Herniaria glabra* L., *H. hirsuta* L., *H. incana* Lam., herba

Draft

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP) and Committee on Herbal Medicinal Products (HMPC)	September 2018 May 2019 July 2019 November 2019
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Re-discussion in HMPC/MLWP	
Adoption by HMPC	

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Herniaria glabra</i> L., <i>H. hirsuta</i> L., <i>H. incana</i> Lam., herba; Herniariae herba; rupturewort
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BG (bulgarski): Изсипливче, стрък CS (čeština): průtržníková nať DA (dansk): Brudurt DE (Deutsch): Bruchkraut EL (elliniká): EN (English): rupturewort ES (español): Herniaria, parte aérea de ET (eesti keel): FI (suomi): tyräruoho, verso FR (français): herniaire HR (hrvatski): kilavičina zelen HU (magyar): porcikafű IT (italiano):	LT (lietuvių kalba): Skleistenių žolė LV (latviešu valoda): trūkumzālītes laksti MT (Malti): Ħaxixa tal-Ħerniarja NL (Nederlands): Breukkruid, kruid PL (polski): ziele połonicznika PT (português): RO (română): iarbă de feciorică SK (slovenčina): vňať prietržníka SL (slovenščina): SV (svenska): knyttling, ört IS (íslenska): NO (norsk):
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European Union herbal monograph on *Herniaria glabra* L., *H. hirsuta* L., *H. incana* Lam., herba

1. Name of the medicinal product

To be specified for the individual finished product.

1. Qualitative and quantitative composition^{1, 2}

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC <i>Herniaria glabra</i> L., <i>H. hirsuta</i> L., <i>H. incana</i> Lam., herba (rupturewort) or a mixture of them i) Herbal substance Not applicable ii) Herbal preparations Comminuted herbal substance

2. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

3. Clinical particulars

3.1. Therapeutic indications

Well-established use	Traditional use
	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 product is a traditional herbal medicinal

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 Monograph in the Austrian Pharmacopoeia (monograph ÖAB 2010/056)

Well-established use	Traditional use
	product for use in the specified indication exclusively based upon long-standing use.

3.2. Posology and method of administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and Elderly</i> Herbal tea: 1.5-3 g of comminuted herbal substance in 150 ml of boiling water as a herbal infusion or in 150 ml water as decoction 3-5 times daily.</p> <p>Maximum daily dose: 10 g.</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>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>

3.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance.</p> <p>Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).</p>

3.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.

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>To ensure an increase of the amount of urine, adequate fluid intake is required during the treatment.</p> <p>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.</p>

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

Well-established use	Traditional use
	None reported

3.6. 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>

3.7. 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.

3.8. Undesirable effects

Well-established use	Traditional use
	<p>None known</p> <p>If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.</p>

3.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

4. Pharmacological properties

4.1. Pharmacodynamic properties

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

4.2. Pharmacokinetic properties

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

4.3. 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>Adequate tests on genotoxicity have not been performed.</p> <p>Tests on reproductive toxicity and carcinogenicity have not been performed.</p>

5. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

6. Date of compilation/last revision

20 November 2019