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EMA/HMPC/143658/2015
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Polygonum aviculare* L., herba

Draft

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Rediscussion in MLWP	
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BG (bulgarski): Пача трева, стрък CS (čeština): nař rdesna ptačího DA (dansk): Vejpileurt DE (Deutsch): Vogelknöterichkraut EL (elliniká): Πόα πολυγόνου του άρρενος EN (english): Knotgrass herb ES (español): Centinodia, partes aéreas de ET (eesti keel): linnurohuürt FI (suomi): pihatatar, verso FR (français): Renouée des oiseaux (parties aériennes de) HR (hrvatski): oputinova zelen HU (magyar): madárkeserűfű virágos hajtás	IT (italiano): Centinodio (Correggiola) parti aeree fiorite LT (lietuvių kalba): Takažolių žolė LV (latviešu valoda): Maura sūrenes laksts MT (Malti): ħaxixa tal-Lewża Tar-Raba' NL (Nederlands): Gewoon varkensgras, kruid PL (polski): Ziele rdestu ptasiego PT (português): Corriola-bastarda, partes aéreas RO (română): Iarbă de troscot SK (slovenčina): Vňať stavikrva vtáčieho SL (slovenščina): zel ptičje dresni SV (svenska): Trampgräs, ört IS (íslenska): NO (norsk): Tungress
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European Union herbal monograph on *Polygonum aviculare* L., herba

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
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended <i>Polygonum aviculare</i> L., herba (Knotgrass herb) i) Herbal substance Not applicable. ii) Herbal preparations Comminuted herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Comminuted herbal substance for decoction preparation for oromucosal 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
	Indication 1) Traditional herbal medicinal product used for the relief of symptoms of common cold.

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

² The material complies with the Ph. Eur. monograph (ref.: 1885)

Well-established use	Traditional use
	<p data-bbox="810 255 967 286">Indication 2)</p> <p data-bbox="810 313 1390 416">Traditional herbal medicinal product used for symptomatic treatment of minor inflammations in the mouth or the throat.</p> <p data-bbox="810 443 967 474">Indication 3)</p> <p data-bbox="810 501 1401 640">Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints.</p> <p data-bbox="810 667 1350 770">The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration³

Well-established use	Traditional use
	<p data-bbox="810 958 935 990">Posology</p> <p data-bbox="810 1016 1193 1048"><i>Adolescents, adults and elderly</i></p> <p data-bbox="810 1075 967 1106">Indication 1)</p> <p data-bbox="810 1133 1401 1272">Single dose Herbal tea: 1.5 - 2 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion 3 - 4 times daily.</p> <p data-bbox="810 1299 1062 1330">Daily dose: 4.5 - 8 g</p> <p data-bbox="810 1357 967 1388">Indication 2)</p> <p data-bbox="810 1415 1410 1621">Single dose Comminuted herbal substance for decoction preparation for oromucosal use: 1.5 g of the comminuted herbal substance in 200 - 250 ml of water 4 - 5 times daily for gargling of the mouth and throat.</p> <p data-bbox="810 1648 1062 1680">Daily dose: 6 - 7.5 g</p>

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 data-bbox="810 259 967 286">Indication 3)</p> <p data-bbox="810 318 1350 452">Single dose Herbal tea: 3 g of the comminuted herbal substance in 200 ml of water as a decoction 2 times daily.</p> <p data-bbox="810 483 995 510">Daily dose: 6 g</p> <p data-bbox="810 542 1098 568">Indication 1), 2) and 3)</p> <p data-bbox="810 600 1407 694">The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p data-bbox="810 725 1015 752">Duration of use</p> <p data-bbox="810 784 1053 810">Indication 1) and 2)</p> <p data-bbox="810 842 1410 976">If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 1008 967 1034">Indication 3)</p> <p data-bbox="810 1066 1410 1200">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 data-bbox="810 1232 1145 1258">Method of administration</p> <p data-bbox="810 1290 1053 1317">Indication 1) and 3)</p> <p data-bbox="810 1348 922 1375">Oral use.</p> <p data-bbox="810 1406 967 1433">Indication 2)</p> <p data-bbox="810 1464 1015 1491">Oromucosal use.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p data-bbox="810 1666 1334 1693">Hypersensitivity to the active substance(s).</p> <p data-bbox="810 1724 967 1751">Indication 3)</p> <p data-bbox="810 1783 1362 1841">Conditions where reduced fluid intake is recommended (e.g. severe cardiac diseases).</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>Indication 1), 2) and 3)</p> <p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>Indication 1), 2)</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication 3)</p> <p>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.</p> <p>To ensure an increase of the amount of urine, adequate fluid intake is required during treatment.</p>

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

Well-established use	Traditional use
	None reported.

4.6. Fertility, pregnancy and lactation

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

4.9. Overdose

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

5. Pharmacological properties

5.1. Pharmacodynamic properties

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

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

29 September 2015