5 April 2016
EMA/HMPC/143658/2015
Committee on Herbal Medicinal Products (HMPC)

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

Final

Discussion in Working Party on European Union monographs and list (MLWP)	March 2015 May 2015 July 2015
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	29 September 2015
Start of public consultation	19 October 2015
End of consultation (deadline for comments)[1]	15 January 2016
Re-discussion in MLWP	4 February 2016
Adoption by HMPC	5 April 2016

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Polygonum aviculare* L., herba; Polygoni avicularis herba; Knotgrass herb

[1] No comments were received during the period of public consultation. Therefore the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

BG (bulgarski): Пача трева, стрък CS (čeština): nať 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 stavikrvu vtáčieho SL (slovenščina): zel ptičje dresni SV (svenska): Trampgräs, ört IS (íslenska): NO (norsk): Tungress

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[2, 3]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Polygonum aviculare* 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.

[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[3] The material complies with the Ph. Eur. monograph (ref.: 1885)

Well-established use	Traditional use
	Indication 2) Traditional herbal medicinal product used for symptomatic treatment of minor inflammations in the mouth or the throat. Indication 3) 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. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration[4]

Well-established use	Traditional use
	Posology *Adolescents, adults and elderly* Indication 1) 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. Daily dose: 4.5-8 g Indication 2) 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. Daily dose: 6-7.5 g Indication 3) Single dose: Herbal tea: 3 g of the comminuted herbal substance in 200 mL of water as a decoction 2 times daily. Daily dose: 6 g

[4] 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
	Indication 1), 2) and 3) The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1) and 2) 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. Indication 3) 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. **Method of administration** Indication 1) and 3) Oral use Indication 2) Oromucosal use

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s). Indication 3) Conditions where reduced fluid intake is recommended (e.g. severe cardiac diseases).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Indication 1), 2) and 3) The use in children under 12 years of age has not been established due to lack of adequate data. Indication 1), 2) If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Well-established use	Traditional use
	Indication 3) 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. To ensure an increase of the amount of urine, adequate fluid intake is required during treatment.

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
	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.

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

5 April 2016