EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 November 2015
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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Epilobium angustifolium* L. and/or *Epilobium parviflorum* Schreb., herba

Final

Discussion in Working Party on European Union monographs and European Union list (MLWP)	November 2014 January 2015
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	10 March 2015
Start of public consultation	9 April 2015
End of consultation (deadline for comments[1]).	15 July 2015
Rediscussion in MLWP	September 2015
Adoption by HMPC	24 November 2015

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Epilobium angustifolium* L. and/or *Epilobium parviflorum* Schreb., herba; Epilobii herba; Willow herb

BG (bălgarski): Теснолистна върбовка, стрък	LT (lietuvių kalba): Ožkarožių žolė
CS (čeština): vrbovková nať	LV (latviešu valoda): Ugunspuķu laksts
DA (dansk): Dueurt	MT (malti): ħaxixa tal-Epilobju
DE (Deutsch): Weidenröschenkraut	NL (nederlands): Wilgeroosje, kruid
EL (elliniká): Πόα επιλοβίου	PL (polski): ziele wierzbówki kiprzycy
EN (English): Willow herb	PT (português): Epilobium-angustifolium, partes aéreas
ES (espanol): Epilobio, partes aéreas de	RO (română): iarbă de pufuliță
ET (eesti keel): pajulilleürt	SK (slovenčina): Vňať vŕbovky
FI (suomi): horsma, verso	SL (slovenščina): zel vrbovca
FR (français): Epilobe (parties aériennes d')	SV (svenska): Dunört, ört
HR (hrvatski): zelen vrbolike	*IS (íslenska)*:
HU (magyar): Kisvirágú füzike virágos hajtás	*NO (norsk): Geitrams*
IT (italiano): Epilobio parti aeree	

[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'.

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Community herbal monograph on *Epilobium angustifolium* L. and/or *Epilobium parviflorum* Schreb., herba

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Epilobium angustifolium* L. and/or *Epilobium parviflorum* Schreb., herba (Willow 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. 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 for the relief of lower urinary tract symptoms related to benign prostatic hyperplasia after serious conditions have been excluded by a medical doctor. The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

[2] The declaration of the active substance for an individual finished product should be in accordance with relevant herbal quality guidance.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adults and elderly* Single dose Herbal tea: 1.5-2.0 g of the comminuted herbal substance in 250 ml of boiling water as a herbal infusion 2 times daily. There is no relevant use in children and adolescents under 18 years of age. **Duration of use** Long-term use is possible (see section 4.4 'Special warnings and precautions for use'). **Method of administration** Oral use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	If complaints worsen or if symptoms such as fever, spasms or blood in the urine, painful urination, or urinary retention occur during the use of the medicinal product, a doctor should be consulted.

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

Well-established use	Traditional use
	None reported.

[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).

4.6. Fertility, pregnancy and lactation

Well-established use	Traditional use
	No fertility data available. The use in pregnancy and lactation is not relevant due to the indication.

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

24 November 2015