EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 September 2012
EMA/HMPC/461160/2008
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Urtica dioica* L., *Urtica urens* L., their hybrids or their mixtures, radix

Discussion in Working Party on Community monographs and Community list (MLWP)	January 2010 March 2011 July 2011
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	13 September 2011
End of consultation (deadline for comments).	15 February 2012
Rediscussion in Working Party on Community monographs and Community list (MLWP)	March 2012
Adoption by Committee on Herbal Medicinal Products (HMPC)	24 September 2012

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Urtica dioica* L., *Urtica urens* L., their hybrids or their mixtures, radix

BG (bălgarski): Коприва, корен	LT (lietuvių kalba):
CS (čeština): kopřivový kořen	LV (latviešu valoda): Nātru saknes
DA (dansk): Brændenælderod	MT (malti): Għerq il-Ħurrieq
DE (Deutsch): Brennnesselwurzel	NL (nederlands): Brandnetelwortel
EL (elliniká): ρίζα κνίδης	PL (polski): Korzeń pokrzywy
EN (English): Nettle Root	PT (português): Urtiga, raiz
ES (espanol): Ortiga, raíz de	RO (română): rădăcină de urzică
ET (eesti keel): nõgesejuur	SK (slovenčina): Pŕhľavový koreň
FI (suomi): nokkonen, juuri	SL (slovenščina): korenina koprive
FR (français): Ortie (racine d')	SV (svenska): Brännässelrot
HU (magyar): csalángyökér	*IS (íslenska)*:
IT (italiano): Ortica radice	*NO (norsk):* Neslerot

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Community herbal monograph on *Urtica dioica* L., *Urtica urens* L., their hybrids or their mixtures, radix

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 *Urtica dioica* L., *Urtica urens* L., their hybrids or mixtures, radix (nettle root) Nettle root consists of the whole, cut or powdered dried root and rhizomes of *Urtica dioica* L. *Urtica urens* L., their hybrids or mixtures of these.[1] i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Dry extract (DER 7.1-14.3:1), extraction solvent methanol 20% V/V c) Dry extract (DER 6.7-8.3:1), extraction solvent ethanol 20% V/V d) Dry extract (DER 12-16:1), extraction solvent ethanol 70% V/V e) Liquid extract (DER 1:1), extraction solvent ethanol 30% V/V

3. Pharmaceutical form

Well-established use	**Traditional use**
	Comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use.

[1] The material complies with the German Pharmacopoeia monograph (DAB 10, Nachtrag 1993)
[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance

Well-established use	Traditional 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.

4.2. Posology and method of administration[3]

Well-established use	**Traditional use**
	Posology *Adults, elderly* Single dose a) Herbal tea: 1.5 g of the comminuted herbal substance as a decoction 3-4 times daily b) Dry extract, extraction solvent methanol 20% V/V 160 mg 3 times daily or 460 mg once a day c) Dry extract, extraction solvent ethanol 20% V/V 240 mg 3 times daily d) Dry extract, extraction solvent ethanol 70% V/V 150-190 mg twice a day e) Liquid extract

[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**
	Maximum 5 ml daily divided into 3 or 4 single doses 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. For extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

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**
	Not relevant.

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**
	Gastro-intestinal complaints such as nausea, heartburn, feeling of fullness, flatulence, diarrhoea may occur. The frequency is not known. Allergic reactions i.e. pruritus, rash, urticaria may occur. The frequency is not known. If other adverse reactions not mentioned above 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.

Well-established use	Traditional use
	Adequate 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 September 2012