EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Urtica dioica* L.; *Urtica urens* L., folium

Final

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BG (bălgarski): CS (čeština): DA (dansk): DE (Deutsch): Brennesselblätter EL (elliniká): EN (English): nettle leaf ES (espanol): ET (eesti keel): FI (suomi): FR (français): Ortie (feuille d') HU (magyar): Csalánlevél IT (italiano):	LT (lietuvių kalba): LV (latviešu valoda): MT (malti): NL (nederlands): PL (polski): PT (português): RO (română): SK (slovenčina): SL (slovenščina): SV (svenska): brännässleblad *IS (íslenska)*: *NO (norsk)*:

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., folium

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. or a mixtures of the two species, folium (nettle leaf) i) Herbal substance cut dried leaves ii) Herbal preparations a) Comminuted herbal substance b) Liquid extract (DER 1:5), extraction solvent ethanol 96% (V/V):water:wine 16.5% (V/V) (1.65:1.35:7) c) Dry extract (DER 4.7-6:1), extraction solvent water d) Dry extract (DER 5-10:1), extraction solvent water e) Dry extract (DER 8-10:1), extraction solvent ethanol 50% (V/V)

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal substance or comminuted herbal substance as herbal tea for oral use. Herbal preparations in solid or liquid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

1 The material complies with the Ph. Eur. monograph (ref.: 01/2008:1897, corrected 6.0).

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

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product for relief of minor articular pain. Indication 2) 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 product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adolescents, Adults and Elderly* i) Herbal substance 2-4 g as single dose for preparation of an herbal tea, 3-6 times daily. The daily dosage is equivalent to 8-12 g of herbal substance. ii) Herbal preparations a) Comminuted herbal substance: 2-4 g as single dose for preparation of a herbal tea, 3-6 times daily. The daily dosage is equivalent to 8-12 g of herbal substance. b) Liquid extract (1:5): 30-40 oral drops as a single dose, 3-4 times daily. c) Dry extract (4.7-6:1): 750 mg as a single dose, 2-3 times daily. d) Dry extract (5-10:1): 450 mg as a single dose, 3 times daily. e) Dry extract (8-10:1): 540 mg as a single

Well-established use	Traditional use
	dose, 2 times daily. 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) Not to be used for more than 4 weeks. Indication 2) Not to be used for more than 2-4 weeks. If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s). Condition where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	When articular pain is accompanied by swelling of joint, redness or fever a doctor should be consulted. The use in children under 12 years of age has not been established due to lack of adequate data. If minor 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 professional should be consulted. For tinctures and liquid extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the

Well-established use	Traditional use
	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. 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.

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
	Mild gastrointestinal complaints (e.g. nausea, vomiting, diarrhoea) and skin reactions (e.g. itching, exanthema, hives) 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. 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

14 January 2010