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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *URTICA DIOICA* L., *URTICA URENS* L., FOLIUM

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ADOPTION BY HMPC	

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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Urtica dioica* L.; *Urtica urens* L.; Urticae folium; nettle leaf

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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 marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended	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 mixture of the two species, folium (nettle leaf) i) Herbal substance whole or cut dried leaves ii) Herbal preparations A) liquid extract (1:5) prepared with 96% ethanol: water: wine 16.5% (V/V) (1.65:1.35:7) B) dry extract (4.7-6:1), extraction solvent: water C) dry extract (5-10:1), extraction solvent: water D) dry extract (8-10:1), extraction solvent: ethanol 50% (V/V)

3. PHARMACEUTICAL FORM

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

[1] The material complies with the Eur. Ph. monograph (ref. 01/2008:1897)
[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
	a) Traditional herbal medicinal product for relief of minor articular pain. b) 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 over 12 years of age, adults, elderly* i) Herbal substance 2-4g whole or cut dried leaves for preparation of tea as single dose up to 3-6 times daily. The daily dosage is equivalent to 8-12 g of herbal substance. Pour one cup of boiling water over 2-4 teaspoonfuls (approximately 2-4 g) nettle leaves. Steep for about 10 minutes and then pass through a tea strainer. ii) Herbal preparations A) 30-40 oral drops of liquid extract (1:5) prepared with 96% ethanol: water: wine 16.5% (V/V) (1.65:1.35:7) as a single dose up to 3-4 times daily B) 750 mg dry extract (4.7-6:1), extraction solvent: water as a single dose up to 2-3 times daily (equivalent with 2-3x 4 g herbal substance) C) 450 mg dry extract (5-10:1), extraction solvent: water as a single dose up to 3 times daily (equivalent with 3x 3.4 g herbal substance) D) 536 mg dry extract (8-10:1), extraction solvent: ethanol 50% (V/V) as a single dose up to 2 times daily (equivalent with 2x 4.8 g herbal substance)

	The use is not recommended in children under 12 years of age (see section 4.4. Special warnings and precautions for use). **Duration of use** For indication a) 4 weeks For indication b) 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. 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
	Where articular pain accompanied by swelling of joint, redness or fever are present, a doctor should be consulted. The use is not recommended in children under 12 years of age because of the lack of adequate experience. 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 liquid 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. 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 allergic reactions (e.g. itching, exanthema, hives) may occur. The frequency is not known.

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.	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

8 May 2008