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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. AND *URTICA URENS* L., HERBA

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

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COMMUNITY HERBAL MONOGRAPH ON
***URTICA DIOICA* L. AND *URTICA URENS* L., HERBA**

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[1]

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., their hybrids or mixtures, herba (nettle herb) i) Herbal substance Dried cut or fragmented aerial parts of the plant collected or harvested during the flowering period ii) Herbal preparations Comminuted herbal substance Expressed juice from the fresh herb[2], Urticae herbae succus (1:1)[3] Liquid extract with 25% ethanol 1:1 Tincture with 45% ethanol 1:5

3. PHARMACEUTICAL FORM

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

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

[2] Fresh nettle herb is pressed cold or for example with hot steam after plasmolysis and after it is autoclaved for the purpose of preservation. The ratio of fresh herb and the expressed juice is 1:0.5, 1:1 (Hagers Handbuch 1998)

[3] Prepared according to the following Polish traditional method: the fresh material is stabilized with boiling ethanol steam in temperature 75-78ºC under a low pressure (0.2-0.25 MPa) and this stabilized material is macerated with condensate and ethanol during 5-7 days. After this operation, the macerated material is pressed to obtain a liquid extract, which further underly standardization. The product prepared according to this method is named “stabilized juice”).

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	a) Traditional herbal medicinal product to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints. b) Traditional herbal medicinal product for relief of minor articular pain. 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* Single dose Dried cut or fragmented herbal substance: 2-4 g as single dose up to 3 times daily as infusion. Expressed juice[2]: 5-10 ml as a single dose up to 3 times daily. Urticae herbae succus (1:1)[3]: 2.5-5 ml as a single dose, up to 3 times daily. Liquid extract: 3-4 ml as single dose up to 3 times daily. Tincture: 2-6 ml as single dose up to 3 times daily. The use is not recommended in children under 12 years of age (see also 4.4. Special warnings and precautions for use).

	Duration of use Indication a) If symptoms persist or do not improve within one week, a doctor or a qualified health care practitioner should be consulted. Indication b) If symptoms persist or do not improve within one month, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use. Indication a) For extracts, ensure appropriate fluid intake.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to nettle herb. 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
	Patients suffering from diabetes or hypertension should consult their doctor before using nettle herb preparations. The product is not intended to be used in case of acute arthritis as this condition requires medical advice. The use is not recommended in children under 12 years of age because of the lack of available experience. If complaints or 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 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
	Concomitant treatment with synthetic diuretics is not recommended. For preparations other than herbal teas: Patients under anticoagulant therapy should consult their doctor because of the vitamin K content of nettle herb.

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.

7. DATE OF COMPILATION/LAST REVISION

7 September 2007