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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

FINAL

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

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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 A) Comminuted herbal substance B) Powdered herbal substance C) Expressed juice (1:0.5-1.1) from fresh herb[2] D) Expressed juice (1.36-1.96:1) from fresh herb E) Liquid extract (1:1), extraction solvent: ethanol 25% (V/V) F) Liquid extract (1:1.8-2.2), extraction solvent: ethanol 30% (V/V) G) Tincture (1:5), extraction solvent: ethanol 45% (V/V) H) Dry extract (5-10:1), extraction solvent: water

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

[2] According to the method in Urticae herba monograph of Hagers Handbuch 1998

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Herbal substance or herbal preparation in solid or liquid dosage forms or 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
	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 c) Traditional herbal medicinal product used in seborrhoeic skin conditions 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 *Indication a) and b)* *Adolescents over 12 years of age, adults, elderly* A) Dried cut or fragmented or comminuted herbal substance: 2-4 g as single dose up to 3 times daily as infusion. B) Powdered herbal substance: 380-570 mg as single dose up to 3-4 times daily. C) Expressed juice (1:0.5-1.1) from fresh herb: 10-15 ml as a single dose up to 3 times daily.

	E) Expressed juice from fresh herb (1.36-1.96:1): 3.5 ml as a single dose up to 3-4 times daily D) Liquid extract (1:1), extraction solvent: ethanol 25% (V/V) 3-4 ml as single dose up to 3 times daily. E) Liquid extract (1:1.8-2.2), extraction solvent: ethanol 30% (V/V): 100 drops as single dose up to 4 times daily. F) Tincture (1:5), extraction solvent: ethanol 45% (V/V): 2-6 ml as single dose up to 3 times daily. G) Dry extract (5-10:1), extraction solvent: water corresponding to 2-4 g of herbal substance as a single dose up to 3 times daily. Indication c) *Adolescents over 12 years of age, adults, elderly* 275 mg powdered herbal substance as single dose up to 3-4 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 a) and c) The herbal substance is traditionally used over a period of two up to four weeks. If symptoms persist within one week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication b) Not to be taken for more than 4 weeks. If symptoms persist within one month during the use of the medicinal product 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 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
	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 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 practitioner 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
	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, and diarrhoea) and allergic 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 and carcinogenicity have not been performed. Adequate tests on genotoxicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

4 September 2008