29 May 2024
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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Urtica dioica* L.; *Urtica urens* L., herba

Draft – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	January 2007 July 2007 September 2007
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Adoption by HMPC Monograph (EMEA/HMPC/170261/2006) Assessment Report (EMEA/HMPC/168380/2006) List of References (EMEA/HMPC/366106/2007) Overview of comments received during the public consultation (EMEA/HMPC/4251/2008) HMPC Opinion (EMEA/HMPC/187995/2008)	04 September 2008
First systematic review	
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Urtica dioica* L.; *Urtica urens* L.; Urticae herba; nettle herb

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

BG (bulgarski): Коприва, стрък	LT (lietuvių kalba): Dilgėlių žolė
CS (čeština): kopřivová nať	LV (latviešu valoda): Nātru laksts
DA (dansk): Brændenælde	MT (Malti): werqa tal-ħurrieq
DE (Deutsch): Brennnesselkraut	NL (Nederlands): Brandnetel
EL (elliniká): κνίδης πόα	PL (polski): Ziele pokrzywy
EN (English): Nettle herb	PT (português): urtiga
ES (español): ortiga, partes aéreas de	RO (română): iarbă de urzică
ET (eesti keel): nõgeseürt	SK (slovenčina): vňať pŕhľavy
FI (suomi): nokkonen, verso	SL (slovenščina): zel koprive
FR (français): ortie (parties aériennes d')	SV (svenska): brännässla, ört
HR (hrvatski): koprivina zelen	IS (íslenska):
HU (magyar): csalán hajtás	NO (norsk): nesle
IT (italiano): Ortica parti aeree	

European Union herbal monograph on *Urtica dioica* L.; *Urtica urens* L., herba

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 *Urtica dioica* L.; *Urtica urens* L., herba (nettle herb) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Expressed juice (1:0.5-1.1) from fresh herb d) Expressed juice (1:1) from fresh herb, stabilized and adjusted with ethanol 96% (V/V) e) Expressed juice (1.36-1.96:1) from fresh herb f) Liquid extract (1:1), extraction solvent: ethanol 25% (V/V) g) Liquid extract (1:1.8-2.2), extraction solvent: ethanol 30% (V/V) h) Tincture (1:5), extraction solvent: ethanol 45% (V/V) i) 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] Detailed specifications for the herbal substance shall be given by references to bibliographic sources in absence of a monograph in the European Pharmacopoeia, a national pharmacopoeia or national codex currently used officially in a Member State

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal substance or comminuted herbal substance for infusion or herbal preparations in liquid dosage forms 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
	Indication 1) Traditional herbal medicinal product used for the relief of symptoms associated with minor urinary complaints in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine. Indication 2) Traditional herbal medicinal product for the relief of minor articular pain. Indication 3) Traditional herbal medicinal product used in seborrhoeic skin conditions. The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology Indication 1) *Adults, elderly* a) Herbal tea SD=1.5 g of the comminuted herbal substance in 150 ml of boiling water as

[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
	infusion, 3-4 times daily DD=4.5-6 g *Adolescents over 12 years of age, adults, elderly* b) Powdered herbal substance SD=380-570 mg, 3-4 times daily DD=1140-2280 mg c) Expressed juice (1:0.5-1.1) from fresh herb SD=10-15 ml, 3 times daily DD=30-45 ml d) Expressed juice (1:1) from fresh herb, stabilized and adjusted with ethanol 96% (V/V) SD=2.5-5 ml, 3 times daily DD=7.5-15 ml e) Expressed juice from fresh herb (1.36-1.96:1) SD=3.5 ml, 4 times daily DD=14 ml g) Liquid extract (1:1.8-2.2), extraction solvent: ethanol 30% (V/V) SD=100 drops, 4 times daily DD=400 drops i) Dry extract (5-10:1), extraction solvent: water SD=300-450 mg, 3-4 times daily DD=1200-1350 mg Indication 2) *Adults, elderly* a) Herbal tea SD=3-6 g of the comminuted herbal substance in 200 ml boiling water as a herbal infusion, 3 times daily DD= 9-18 g c) Expressed juice (1:0.5-1.1) from fresh herb SD=10-15 ml, 3 times daily DD=30-45 ml d) Expressed juice (1:1) from fresh herb, stabilized and adjusted with ethanol 96% (V/V)

Well-established use	Traditional use
	SD= 2.5-5 ml, 3 times daily DD= 7.5-15 ml f) Liquid extract (1:1), extraction solvent: ethanol 25% (V/V) SD=2-4 ml, up to 3 times daily DD=2-12 ml h) Tincture (1:5), extraction solvent: ethanol 45% (V/V) SD=2-6 ml, up to 3 times daily DD=2-18 ml i) Dry extract (5-10:1), extraction solvent: water SD=300-450 mg, 3-4 times daily DD=1200-1350 mg <u>Indication 3)</u> *Adolescents, adults, elderly* b) Powdered herbal substance SD=275 mg, 3 times daily DD=825 mg Indication 1): Preparation a) The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Preparations b), c), d), e), g), i) The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Indication 2): The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Indication 3): 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) If symptoms persist longer than two weeks during the use of the medicinal product, a doctor or a qualified health care practitioner

Well-established use	Traditional use
	should be consulted. Indications 2) and 3) If symptoms persist longer than four weeks 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.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Indication 1) Preparation a) The use in children and adolescents under 18 years of age has not been established due to the lack of adequate data. Preparations b), c), d), e), g), i) The use in children under 12 years of age has not been established due to the lack of adequate data. Because adequate fluid intake is required during treatment, *Urtica dioica* L. and *Urtica urens* L., *herba* are not recommended for patients with conditions where reduced fluid intake is advised. 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. Indication 2) The use in children and adolescents under 18 years of age has not been established due to the lack of adequate data. Articular pain accompanied by swelling of joints, redness and fever should be examined by a

Well-established use	Traditional use
	doctor. Indication 3) The use in children under 12 years of age has not been established due to the lack of adequate data, Indications 1), 2) and 3) If the symptoms worsen during the use of the 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. Fertility, 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. No fertility data are available.

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
	Gastrointestinal disorders: Nausea, vomiting and diarrhoea. The frequency is not known.

Well-established use	Traditional use
	Skin and subcutaneous tissue disorders: allergic pruritus, rash and urticaria. 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.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, 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

29 May 2024