22 January 2025
EMA/HMPC/322646/2023
Committee on Herbal Medicinal Products (HMPC)

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

Final – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	January 2010 March 2011 July 2011
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	13 September 2011
Start of public consultation	15 October 2011
End of consultation (deadline for comments)	15 February 2012
Re-discussion in MLWP	March 2012
Adoption by HMPC Monograph (EMA/HMPC/461160/2008) Assessment Report (EMA/HMPC/461156/2008) List of References (EMA/HMPC/461158/2008) Overview of comments received during the public consultation (EMA/HMPC/203843/2012) HMPC Opinion (EMA/HMPC/627569/2012)	24 September 2012
First revision	
Discussion in HMPC	January 2022 May 2022
Adopted by HMPC for release for consultation	29 May 2024
Start of public consultation	15 June 2024
End of consultation (deadline for comments)[1]	15 September 2024
Re-discussion in HMPC	November 2024 January 2025
Adoption by HMPC	22 January 2025

[1] No comments were received during the period of public consultation. Therefore, the final monograph is published together with the final assessment report and list of references, without an 'overview of comments received during the public consultation'.

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Keywords	Committee on Herbal Medicinal Products; HMPC; European Union herbal monographs; herbal medicinal products; traditional herbal medicinal products; traditional use; *Urtica dioica* L.; *Urtica urens* L.; Urticae radix; Nettle root

BG (bălgarski): Коприва, корен	LT (lietuvių kalba): Dilgėlių šaknys
CS (čeština): kopřivový kořen	LV (latviešu valoda): Nātru sakne
DA (dansk): Brændenælderod	MT (malti): għerq il-Ħurrieq
DE (Deutsch): Brennnesselwurzel	NL (nederlands): Brandnetelwortel
EL (elliniká): κνιδης ριζα	PL (polski): Korzeń pokrzywy
EN (English): Nettle root	PT (português): urtiga, raiz
ES (espanol): ortiga, raíz de	RO (română): rădăcină de urzică
ET (eesti keel): nõgesejuur	SK (slovenčina): pŕhľavový koreň
FI (suomi): nokkonen, juuri	SL (slovenščina): korenina koprive
FR (français): ortie (racine d')	SV (svenska): brännässelrot
HR (hrvatski): koprivina korijen	IS (íslenska):
HU (magyar): csalángyökér	NO (norsk): neslerot
IT (italiano): Ortica radice	

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

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[2, 3]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC *Urtica dioica* L. and Urtica *urens* L., radix (nettle root) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Dry extract (DER 7-14:1), extraction solvent methanol 20% V/V c) Dry extract (DER 5.4-8.3:1), extraction solvent ethanol 20% V/V d) Dry extract (DER 12-16:1), extraction solvent ethanol 70% V/V e) Liquid extract (DER 1:1), extraction solvent ethanol 30% V/V f) Dry extract (7-9:1), extraction solvent ethanol 60% V/V g) Dry extract (5.4-6.6:1), extraction solvent ethanol 80% V/V

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

[3] The material complies with the European Pharmacopoeia monograph 01/2022:2538

3. Pharmaceutical form

Well-established use	Traditional use
	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.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product for the relief of lower urinary tract symptoms related to benign prostatic hyperplasia after serious conditions have been excluded by a medical doctor. 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[4]

Well-established use	Traditional use
	Posology *Adults, elderly men* a) 2 g of comminuted herbal substance in 150 ml of water as a herbal infusion, 2-3 times daily b) Dry extract (DER 7-14:1), extraction solvent methanol 20% V/V SD=150-160 mg, 3 times daily DD=450-480 mg for the first 3 months: SD=300 mg twice daily DD=600 mg Or

[4] 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
	SD=460 mg, once daily DD=460 mg c) Dry extract (DER 5.4-8.3:1), extraction solvent ethanol 20% V/V SD=240 mg, 3 times daily DD=720 mg d) Dry extract (DER 12-16:1), extraction solvent ethanol 70% V/V SD: 150.5-189 mg, twice daily DD: 301-378 mg e) Liquid extract (DER 1:1), extraction solvent ethanol 30% V/V SD= 40 drops, 3 times daily or 30 drops, 4 times daily DD=120 drops f) Dry extract (7-9:1), extraction solvent ethanol 60% V/V SD=250 mg, twice daily DD=500 mg g) Dry extract (5.4-6.6:1), extraction solvent ethanol 80% V/V SD=240 mg, 3 times daily DD=720 mg at the beginning of treatment: 480 mg twice daily There is no relevant use in children and adolescents under 18 years of age. **Duration of use** Long-term use is possible (see section 4.4 'Special warnings and precautions for use'). **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
	If complaints worsen or if symptoms such as fever, spasms or blood in the urine, painful urination, or urinary retention occur during the use of the medicinal product, a doctor should be consulted. For 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
	Pregnancy and lactation: not relevant. No fertility data 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, heartburn, feeling of fullness, flatulence, diarrhoea. The frequency is not known. Immune system disorders: allergic reactions (pruritus, rash, urticaria). The frequency is not known.

Well-established use	Traditional use
	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. Adequate tests on genotoxicity have not been performed. Tests on reproductive toxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

22 January 2025