29 May 2024
EMA/HMPC/322646/2023
Committee on Herbal Medicinal Products (HMPC)

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

Draft – Revision 1

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| **Initial assessment** | |
| Discussion in Working Party on European Union monographs and European Union list (MLWP) | January 2010<br>March 2011<br>July 2011 |
| Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation | 13 September 2011 |
| End of consultation (deadline for comments) | 15 February 2012 |
| Rediscussion in MLWP | March 2012 |
| Adoption by HMPC<br>Monograph (EMA/HMPC/461160/2008)<br>Assessment Report (EMA/HMPC/461156/2008)<br>List of References (EMA/HMPC/461158/2008)<br>Overview of comments received during the public consultation (EMA/HMPC/203843/2012)<br>HMPC Opinion (EMA/HMPC/627569/2012) | 24 September 2012 |
| **First systematic review** | |
| Discussion in HMPC | January 2022<br>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). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu | 15 September 2024 |


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| Keywords | Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Urtica dioica* L.; *Urtica urens* L.; Urticae radix; nettle root |



**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
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|---|---|
| BG (bălgarski): Коприва, корен | LT (lietuvių kalba): Dilgėlių šaknys |
| CS (čeština): kopřivový kořen | LV (latviešu valoda): Nātru saknes |
| DA (dansk): Brændenælderod | MT (malti): Għerq il-Ħurrieq |
| DE (Deutsch): Brennnesselwurzel | NL (nederlands): Brandnetelwortel |
| EL (elliniká): ριζα κνιδης | 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): Príhľavový koreň |
| FI (suomi): nokkonen, juuri | SL (slovenščina): korenina koprive |
| FR (français): Ortie (racine d') | SV (svenska): Brännässelrot |
| HU (magyar): csalángyökér | *IS (íslenska)*: |
| IT (italiano): Ortica radice | *NO (norsk):* Neslerot |

# 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[1, 2]

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

## 3. Pharmaceutical form

| Well-established use | Traditional use |
|---|---|

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

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

| Well-established use | Traditional use |
|---|---|
| | Comminuted herbal substance as herbal tea for oral use.<br><br>Herbal preparations in solid or liquid dosage forms for oral use.<br><br>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.<br><br>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**<br><br>*Adults, elderly men*<br><br>a) 2 g of comminuted herbal substance in 150 ml of water as a herbal infusion, 2-3 times daily<br><br>b) Dry extract (DER 7-14:1), extraction solvent methanol 20% V/V<br>SD=150-160 mg, 3 times daily<br>DD=450-480 mg<br>at the beginning of treatment, for the first 3 months, 300 mg twice daily<br>or<br>SD=460 mg, once daily<br>DD=460 mg<br><br>c) Dry extract (DER 5.4-8.3:1), extraction solvent ethanol 20% V/V |

[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 |
|---|---|
| | SD=240 mg, 3 times daily<br>DD=720 mg<br><br>d) Dry extract (DER 12-16:1), extraction solvent ethanol 70% V/V<br>SD: 150.5-189 mg, twice daily<br>DD: 301-378 mg<br><br>e) Liquid extract (DER 1:1), extraction solvent ethanol 30% V/V<br>SD= 40 drops, 3 times daily or 30 drops, 4 times daily<br>DD=120 drops<br><br>f) Dry extract (7-9:1), extraction solvent ethanol 60% V/V<br>SD=250 mg, twice daily<br>DD=500 mg<br><br>g) Dry extract (5.4-6.6:1), extraction solvent ethanol 80% V/V<br>SD=240 mg, 3 times daily<br>DD=720 mg<br>at the beginning of treatment, 480 mg twice daily<br><br>There is no relevant use in children and adolescents under 18 years of age.<br><br>**Duration of use**<br><br>Long-term use is possible (see section 4.4 'Special warnings and precautions for use').<br><br>**Method of administration**<br><br>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 |

| Well-established use | Traditional use |
|---|---|
| | consulted.<br><br>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.<br><br>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.<br><br>Immune system disorders: Allergic reactions (pruritus, rash, urticaria). The frequency is not known.<br><br>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 |
|---|---|

| 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.<br>Adequate tests on genotoxicity have not been performed.<br>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

29 May 2024