The European Agency for the Evaluation of Medicinal Products
*Evaluation of Medicines for Human Use*

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# WORKING PARTY ON HERBAL MEDICINAL PRODUCTS

# DRAFT PROPOSAL FOR A CORE-DATA FOR NETTLE ROOT

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| **DISCUSSION IN THE HMPWP** | February, July 2003 |
| **RELEASE FOR CONSULTATION** | July 2003 |
| **DEADLINE FOR COMMENTS** | October 2003 |
| **ANTICIPATED RE-DISCUSSION IN THE HMPWP** | November 2003 |

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# Draft Proposal for a Core-data on Nettle root

The Working Party on Herbal Medicinal Products proposes the following core-data for *Urticae radix*.

## 1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1) Nettle root[1]

2) Herbal preparations
Composition described in bibliography data provided by ESCOP

a) Infusion
b) Extracts
Dried extracts with 20% methanol (7-14 : 1)
Dried extracts with 70% methanol (12-16 : 1)

Liquid extracts with 16% methanol (1 : 1)
Liquid extracts with 45% methanol (1 : 1)
Liquid extracts with 40% methanol (1 : 5)

## 3. PHARMACEUTICAL FORM

The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

None accepted on the basis of bibliographic data[2].

### 4. 2. Posology and method of administration

**Dosage**

Described in bibliographic data provided by ESCOP

Elderly, adults and children over 12 years of age daily:

Drug as infusion: 4-6 g

[1] The herbal drug complies with Deutsches Arzneibuch 2002
[2] Decision by majority

Dried extracts with 20% methanol (7-14 : 1) 600 - 1200 mg
Dried extracts with 70% methanol (12-16 : 1) 540 - 1080 mg

Liquid extracts with 16% methanol (1 : 1) 6 ml
Liquid extracts with 45% methanol (1 : 1) 4.5 - 7.5 ml
Liquid extracts with 40% methanol (1 : 5) 15 ml

**Method of administration**

Oral use

**Duration of use**

Not applicable.

**4.3. Contraindications**

Patients with known hypersensitivity to Nettle should not use Nettle root preparations.

**4.4. Special warnings and precautions for use**

Not applicable.

**4.5 Interaction with other medicinal products and other forms of interaction**

None reported.

**4.6. Pregnancy and lactation**

Not applicable.

**4.7. Effects on ability to drive and use machines**

None known.

**4.8. Undesirable effects**

Gastrointestinal complaints (nausea, heartburn, diarrhoea).

Rare cases of allergic skin reactions.

**4.9. Overdose**

None reported.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1. Pharmacodynamic properties

The use of Nettle root preparations is not sufficiantly supported by results of clinical studies, pharmacological studies and/or evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities.

### 5.2. Pharmacokinetic properties

No data available.

### 5.3. Preclinical safety data

No data available.

## 6. DATE OF COMPILATION

July 2003