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*Evaluation of Medicines for Human Use*

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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)**

**DRAFT**

# COMMUNITY HERBAL MONOGRAPH ON *ARCTIUM LAPPA* L., RADIX

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| **DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)** | November 2009<br>January 2010 |
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| **REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)** | |
| **ADOPTION BY HMPC** | |

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| **KEYWORDS** | Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Arctium lappa* L.; Arctii radix; burdock root |

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# COMMUNITY HERBAL MONOGRAPH ON *ARCTIUM LAPPA* L., RADIX

## 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 registration application of Article 16d(1) of Directive 2001/83/EC as amended<br><br>*Arctium lappa* L. radix<br>(burdock root)<br><br>i) Herbal substance<br>Not applicable.<br><br>ii) Herbal preparations<br>- Comminuted herbal substance<br>- Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V<br>- Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 45% V/V |

## 3. PHARMACEUTICAL FORM

| Well-established use | Traditional use |
|---|---|
| | Herbal preparation in solid or liquid dosage forms or as herbal tea for oral use.<br><br>The pharmaceutical form should be described by the European Pharmacopoeia full standard term. |

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

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

| Well-established use | Traditional use |
|---|---|
| | a) Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints.<br><br>b) Traditional herbal medicinal product used in temporary loss of appetite.<br><br>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**<br><br>*Adults and elderly*<br><br>- Comminuted herbal substance:<br>3-6 g as an infusion, 3 times daily.<br>- Liquid extract: 25 to 50 drops, 3 times daily.<br>- Tincture: 50 drops, 3 times daily.<br><br>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').<br><br>**Duration of use**<br><br>If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.<br><br>**Method of administration**<br><br>Oral use.<br><br>For preparations other than tea: to ensure an increase of the amount of urine, adequate fluid intake is required during treatment. |

### 4.3. Contraindications

| Well-established use | Traditional use |
|---|---|
| | Hypersensitivity to the active substance(s). |

### 4.4. Special warnings and precautions for use

| Well-established use | Traditional use |
|---|---|
| | The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.<br><br>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.<br><br>If complaints of symptoms such as fever, dysuria, spasms or blood in the urine occur during the use of the medicinal product, a doctor or a qualified health care professional should be consulted.<br>Concomitant treatment with synthetic diuretics is not recommended.<br><br>For tinctures 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 |
|---|---|
| | 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 |
|---|---|
| | One case has been reported. 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 |
|---|---|
| | 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.<br><br>Adequate tests on reproductive toxcity genotoxicity and carcinogenicity have not been performed. |

## 6. PHARMACEUTICAL PARTICULARS

| Well-established use | Traditional use |
|---|---|
| | Not applicable. |

## 7. DATE OF COMPILATION/LAST REVISION

14 January 2010