EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2010
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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Arctium lappa* L., radix

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	November 2009 January 2010
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Arctium lappa* L.; Arctii radix; burdock root

BG (bălgarski): репей, корен	LT (lietuvių kalba):
CS (čeština): lopuchový kořen	LV (latviešu valoda): Dadža saknes
DA (dansk): Burrerod	MT (malti):
DE (Deutsch): Klettenwurzel	NL (nederlands): Klitwortel
EL (elliniká): Ρίζα αρκτίου	PL (polski): Korzeń łopianu
EN (English): Burdock root	PT (português): Bardana, raiz
ES (espanol): Bardana, raíz de	RO (română): rădăcină de brusture
ET (eesti keel): takjajuur	SK (slovenčina): Lopúchový koreň
FI (suomi):	SL (slovenščina): korenina navadnega repinca
FR (français):	SV (svenska): Stor kardborre, rot
HU (magyar): Közönséges bojtorján gyökér	*IS (íslenska)*:
IT (italiano): Bardana radice	*NO (norsk):* Storborrerot

[1] Changes introduced in substance names in EU languages and section 4.2

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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[2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Arctium lappa* L., radix[3] (burdock root) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V d) Soft extract[4], extraction solvent water e) Tincture (ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 45% V/V f) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 25% V/V

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

2 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
3 Dried, total or cut roots of *Arctium lappa* L. (=*A. major* Gaertn.), *A. minus* (Hill) Bernh., *A. tomentosum* Mill. (*Asteraceae*) and from related species, hybrids or mixtures thereof. The root is collected in the autumn of the first year or in the spring of the second year. The material complies with DAC 2008 "Klettenwurzel – Bardanae radix"
4 Codex Francais 1949

Well-established use	Traditional use
	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 to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary tract complaints. Indication 2) Traditional herbal medicinal product used in temporary loss of appetite. Indication 3) Traditional herbal medicinal product used in treatment of seborrhoeic skin conditions. 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 *Adults and Elderly* a) Comminuted herbal substance: single dose: 2-6 g as an infusion, 3 times daily. b) Powdered herbal substance: single dose 350 mg, 3 to 5 times daily. c) Liquid extract: 2-8 ml, 3 times daily. d) Soft extract: single dose 0.2 g, daily dose 1-2 g. e) Tincture (45% V/V): 8-12 ml, 3 times daily. f) Tincture (25% V/V): 8-12 ml, 3 times daily. The use in children and adolescents under 18 years of age is not recommended (see section

Well-established use	Traditional use
	4.4 'Special warnings and precautions for use').
	Duration of use
	Indication 1) and 2)
	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.
	Indication 3)
	If the symptoms persist longer than 4 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.
	Method of administration
	Oral use.
	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 or to plants of the *Asteraceae* family.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Indication 1), 2) and 3)
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.
	If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.
	Indication 1)
	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. Concomitant treatment with synthetic diuretics is

Well-established use	Traditional use
	not recommended. For preparations 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
	Anaphylactic shock has been reported. 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 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. Adequate 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

16 September 2010