



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2012
EMA/HMPC/688216/2008
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Echinacea angustifolia* DC., radix

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	January 2009 May 2009 November 2009
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	12 November 2009
Release of draft public statement for public consultation postponed	2010
Discussion in MLWP	January 2011 March 2011
Adoption of draft monograph by HMPC for release for consultation	31 March 2011
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 August 2011
Redisussion in MLWP	September 2011 January 2012
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Echinacea angustifolia</i> DC., radix; Echinaceae angustifoliae radix; narrow-leaved coneflower root

BG (bălgarski): Дълголистна ехинасея, корен CS (čeština): Kořen třapatky úzkolisté DA (dansk): Smalbladet solhatrod DE (Deutsch): Schmalblättriger-Sonnenhut-Wurzel EL (elliniká): Εχινάκεια στενοφύλλου ρίζα EN (English): Narrow-leaved coneflower root ES (español): Equinácea oficial, raíz de ET (eesti keel): Ahtalehise siilkübara juur FI (suomi): Kaitapäivänhattu, juuri FR (français): Echinacée à feuilles étroites (racine d') HU (magyar): Keskenylevelű kasvirág gyökér IT (italiano): Echinacea angustifolia radice	LT (lietuvių kalba): LV (latviešu valoda): Šaurlapu ehinacejas saknes MT (malti): Gherq ta' l-Echinacea NL (nederlands): Rode Zonnehoed PL (polski): Korzeń jeżówki wąskolistnej PT (português): Equinácia angustifolia, raiz RO (română): SK (slovenčina): Koreň echinacey úzkolistej SL (slovenščina): Korenina ozkolistne ehinaceje SV (svenska): Liten läkerudbeckiarot IS (íslenska): NO (norsk): Smalbladet solhatt, rot
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Community herbal monograph on *Echinacea angustifolia* DC., 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
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Echinacea angustifolia</i> DC., radix (narrow-leaved coneflower root)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Powdered herbal substance</p> <p>c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 45% V/V</p> <p>d) Liquid extract (DER 1:1), extraction solvent: ethanol 45% V/V</p>

3. Pharmaceutical form

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

¹ The material complies with the Ph. Eur. monograph (ref.: 01/2008:1821 corrected 6.0)

² 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
	<p>Traditional herbal medicinal product for supportive treatment of common cold.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.</p>

4.2. Posology and method of administration

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, adults and elderly</i></p> <p>Single dose</p> <p>Herbal tea:</p> <p>1 g of the comminuted herbal substance in 150 ml of boiling water as an infusion 3 times daily. Time of infusion: at least 10 minutes</p> <p>1 g of the comminuted herbal substance in 150 ml of water as a decoction 3 times daily. Time of decoction: 10 minutes</p> <p>Powdered herbal substance: 500 mg, up to 3 times daily.</p> <p>Tincture: 1-2 ml, three times daily.</p> <p>Liquid extract: 0.25 -1 ml, three times daily.</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>The therapy should start at first signs of common cold.</p> <p>If the symptoms persist longer than 10 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral use.</p>

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s) and to other plants of the Asteraceae (Compositae) family.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>Not recommended in cases of progressive systemic diseases such as tuberculosis, diseases of the white blood cells system, collagenoses, multiple sclerosis, AIDS, HIV infections and other immune diseases.</p> <p>If the symptoms worsen or high fever occurs during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>There is a possible risk of allergic reactions in sensitive individuals. Those patients should consult their doctor before using <i>Echinacea</i>.</p> <p>There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult their doctor before using <i>Echinacea</i>.</p> <p>The use in children under 12 years of age has not been established due to lack of adequate data.</p>

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
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p>

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
	Hypersensitivity reactions (skin reactions) may occur. 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. 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

27 March 2012