



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Echinacea pallida* (Nutt.) Nutt., radix

Final

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	July 2008 September 2008
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	04 September 2008
End of consultation (deadline for comments)	15 January 2009
Re-discussion in MLWP	May 2009 July 2009
Adoption by HMPC Monograph (EMEA/HMPC/332350/2008) AR (EMEA/HMPC/332358/2008) List of references (EMEA/HMPC/332366/2008) HMPC Opinion (EMEA/HMPC/375219/2009)	16 July 2009
First systematic review	
Discussion in Working Party on European Union monographs and list (MLWP)	November 2016 November 2017 March 2018
Adoption by HMPC	05 June 2018

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Echinacea pallida</i> (Nutt.) Nutt; pale coneflower root
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BG (bulgarski): Бледа ехинацея, корен	LT (lietuvių kalba): Blyškiųjų ežiulių šaknys
CS (čeština): kořen třapatky bleďé	LV (latviešu valoda): Bālās ehinacejas saknes
DA (dansk): Bleg solhatrod	MT (Malti): gherq ta' l-echinacea
DE (Deutsch): Blasser-Sonnenhut-Wurzel	NL (Nederlands): bleekbladige zonnehoeed / egelzonnehoeed, wortel
EL (elliniká): εχινάκεας ωχράς ριζα	PL (polski): Korzeń jeżówki bladej
EN (English): pale coneflower root	PT (português): equinácia pálida, raiz
ES (español): equinácea pálida, raíz de	RO (română): rădăcină de echinacea/pălăria soarelui
ET (eesti keel): kahkjase siilkübara juur	SK (slovenčina): koreň echinacey bledej
FI (suomi): rohtopäivänhattu, juuri	SL (slovenščina): korenina blede ehinaceje
FR (français): echinacée pâle (racine d')	SV (svenska): läkerudbeckia, rot
HR (hrvatski): korijen svijetlocvjetne rudbekije	IS (íslenska):
HU (magyar): halvány kasvirág gyökér	NO (norsk): blek solhatt, rot
IT (italiano): Echinacea pallida radice	

European Union herbal monograph on *Echinacea pallida* (Nutt.) Nutt., 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 <i>Echinacea pallida</i> (Nutt.) Nutt., radix, (pale coneflower root) i) Herbal substance Not applicable ii) Herbal preparations a) dry extract (DER 4-8:1), extraction solvent: ethanol 50% V/V b) tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 50% V/V

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in solid or liquid dosage forms for oral and oromucosal use. 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 symptoms of common cold. The product is a traditional herbal medicinal

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 Ph. Eur. monograph (ref.: 1822).

Well-established use	Traditional use
	product for use in the specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, adults and elderly</i></p> <p>a) Dry extract</p> <p>Single dose: 24-30 mg of extract</p> <p>Daily dose: 90-96 mg of extract</p> <p>b) Tincture</p> <p>Single dose: 25 drops containing 100% tincture</p> <p>Daily dose: 125 drops containing 100% tincture</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 the 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>a) oral and oromucosal use</p> <p>b) oral use</p>

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use is not recommended in cases of progressive systemic disorders, autoimmune diseases, immunodeficiencies, immunosuppression and diseases of the white blood cell system.</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> <p>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.</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.

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. 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

05 June 2018