30 May 2017
EMA/HMPC/424583/2016
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Echinacea purpurea* (L.) Moench, radix

Final

Initial assessment	
Discussion in Working Party on European Union monographs and list (MLWP)	January 2009 May 2009 July 2009
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	16 July 2009
End of consultation (deadline for comments)	15 December 2009
Re-discussion in MLWP	January 2010 March 2010
Adoption by HMPC Monograph (EMA/HMPC/577784/2008) AR (EMA/HMPC/577786/2008) List of references (EMA/HMPC/577790/2008) Overview of comments received during public consultation (EMA/HMPC/7084/2010) HMPC Opinion (EMA/HMPC/153975/2010)	11 March 2010
First systematic review	
Discussion in Working Party on European Union monographs and list (MLWP)	July 2016 September 2016
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	22 November 2016
End of consultation (deadline for comments[1])	15 March 2017
Re-discussion in MLWP	March 2017
Adoption by HMPC	30 May 2017

[1] No comments were received during the period of public consultation. Therefore the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'

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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Echinacea purpurea* (L.) Moench, radix; Echinaceae purpureae radix; purple coneflower root

BG (bulgarski): Пурпурна ехинацея, корен	LT (lietuvių kalba): Rausvažiedžių ežiuolių šaknys
CS (čeština): kořen třapatky nachové	LV (latviešu valoda): Sarkanās ehinacejas saknes
DA (dansk): Purpur solhatrod	MT (Malti): gherq ta' l-echinacea vjola
DE (Deutsch): Purpursonnenhutwurzel	NL (Nederlands): Paarse Zonnehoed
EL (elliniká): εχινάκεας πορφυράς ρίζα	PL (polski): Korzeń jeżówki purpurowej
EN (English): purple coneflower root	PT (português): Equinácea purpúrea, raiz
ES (español): Equinácea purpúrea, raíz de	RO (română): rădăcină de echinacea/pălăria soarelui
ET (eesti keel): punase siilkübara juur	SK (slovenčina): koreň echinacey purpurovej
FI (suomi): kaunopunahattu, juuri	SL (slovenščina): korenina škrlatne ehinaceje
FR (français): echinacée pourpre (racine d')	SV (svenska): röd solhatt, rot
HR (hrvatski): korijen purpurne rudbekije	IS (íslenska):
HU (magyar): bíbor kasvirág virágos gyökér	NO (norsk): rød solhatt, rot
IT (italiano): Echinacea purpurea radice	

European Union herbal monograph on *Echinacea purpurea* (L.) Moench, radix

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition[2,3]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC *Echinacea purpurea* (L.) Moench, radix (purple coneflower root) i) Herbal substance Not applicable ii) Herbal preparations a) Dry extract (DER 5.5-7.5:1), extraction solvent ethanol 45% (V/V) b) Dry extract (DER 4:1); extraction solvent water

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal preparations in solid 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
	Indication 1) Traditional herbal medicinal product for the relief of symptoms of common cold.

[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[3] The material complies with the Ph. Eur. monograph (ref.: 1824).

Well-established use	Traditional use
	Indication 2) Traditional herbal medicinal product used for the relief of spots and pimples due to mild acne. The product is a traditional herbal medicinal 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
	Posology Indication 1) **a) Dry extract (DER 5.5-7.5:1)** *Adolescents, adults and elderly* Single dose: 40 mg of extract every second hour Daily dose: 360 mg (40 mg, 9 times daily) Indication 2) **b) Dry extract (DER 4:1)** *Adults and elderly* Single dose: 50-100 mg of extract Daily dose: 150-300 mg of extract *Adolescents* Single dose: 50 mg of extract Daily dose: 100 mg of extract The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1) The therapy should start at the first signs of common cold. 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.

Well-established use	Traditional use
	Indication 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. **Method of administration** Indication 1) Oral and oromucosal use Indication 2) Oral use

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
	The use is not recommended in cases of progressive systemic disorders, autoimmune diseases, immunodeficiencies, immunosuppression and diseases of the white blood cell system. 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. There is a possible risk of allergic reactions in sensitive individuals. Those patients should consult their doctor before using *Echinacea*. There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult their doctor before using *Echinacea*. The use in children under 12 years of age has not been established due to lack of adequate data.

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

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

30 May 2017