EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 November 2015
EMA/HMPC/48704/2014 *Corr* [1]
Committee on Herbal Medicinal Products (HMPC)

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

Final

Initial assessment	
Discussion in Working Party on European Union monographs and list (MLWP)	September 2006 October 2006 January 2007 March 2007
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	8 March 2007
End of consultation (deadline for comments)	15 June 2007
Re-discussion in MLWP	October 2007 January 2008 March 2008
Adoption by HMPC Monograph (EMEA/HMPC/104945/2006) AR (EMEA/HMPC/104918/2006) List of references (EMEA/HMPC/111536/2007) Overview of comments received during the public consultation (EMEA/HMPC/475463/2007) HMPC Opinion (EMEA/HMPC/355881/2008)	6 March 2008
First systematic review	
Discussion in MLWP	September 2013 November 2013 January 2014 March 2014 May 2014 July 2014 September 2014
Adoption by HMPC	24 November 2014

[1] Minor correction of single dose (section 4.2; well-established use part)

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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; well-established medicinal use; traditional use; *Echinacea purpurea* (L.) Moench, herba; Echinaceae purpureae herba; purple coneflower herb

BG (bulgarski): Пурпурна ехинацея, стрък CS (čeština): čerstvá nať třapatky nachové DA (dansk): Purpursolhat, frisk urt DE (Deutsch): Purpur-Sonnenhut-Kraut EL (elliniká): Πόα Εχινάκεας της πορφυράς EN (English): purple coneflower herb ES (español): Equinácea purpúrea, partes aéreas incluidas sumidades floridas ET (eesti keel): punase siilkübara ürt FI (suomi): kaunopunahattu, verso FR (français): Echinacée pourpre (parties aériennes fraîches d') HR (hrvatski): zelen purpurne rudbekije HU (magyar): Bíbor kasvirág virágos hajtás IT (italiano): Echinacea purpurea parti aeree fiorite	LT (lietuvių kalba): rausvažiedžių ežiuolių žolė LV (latviešu valoda): Sarkanās ehinacejas laksti MT (Malti): Echinacea Vjola NL (Nederlands): Paarse Zonnehoed PL (polski): Ziele jeżówki puprpurowej PT (português): Equinácea purpúrea, parte aérea florida RO (română): iarbã proaspãtã de Echinacea, pãlãria soarelui SK (slovenčina): Vňať echinacey purpurovej SL (slovenščina): zel škrlatne ehinaceje SV (svenska): röd solhatt, ört *IS (íslenska)*: Sólhattur *NO (norsk):* Rød solhatt

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

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 marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended *Echinacea purpurea* (L.) Moench, herba recens (purple coneflower herb) i) Herbal substance Not applicable ii) Herbal preparations - expressed juice (DER 1.5-2.5:1) - dried juice corresponding to the expressed juice above	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Echinacea purpurea* (L.) Moench, herba recens (purple coneflower herb) i) Herbal substance Not applicable ii) Herbal preparations - expressed juice - dried expressed juice

3. Pharmaceutical form

Well-established use	**Traditional use**
Herbal preparations in solid or liquid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.	Herbal preparations in semi-solid or liquid dosage forms for cutaneous 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**
Herbal medicinal product for the short-term prevention and treatment of common cold.	Traditional herbal medicinal product for treatment of small superficial wounds. The product is a traditional herbal medicinal

[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
[3] Detailed specifications for the herbal substance shall be given by references to bibliographic sources in absence of a monograph in the European Pharmacopoeia, a national pharmacopoeia or national codex currently used officially in a Member State.

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

4.2. Posology and method of administration

Well-established use	Traditional use
Posology *Adolescents, adults and elderly* Single dose: 1.5-4.5 ml expressed juice Daily dose: 6-9 ml expressed juice. Doses of dried expressed juice should correspond to the posologies of the expressed juice. The use in children under 12 year of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** For prevention and treatment, do not use the medicinal product for more than 10 days. For treatment, start the therapy at first signs of common cold. If the symptoms persist for more than 10 days, a doctor or a pharmacist should be consulted. **Method of administration** Oral use	**Posology** *Adolescents, adults and elderly* 10 to 20 g /100 g of expressed juice or equivalent amount of dried expressed juice. Small amount of ointment is applied on the affected area 2-3 times a day. The use in children under 12 years of age is not recommended (see 4.4. 'Special warnings and precautions for use'). **Duration of use** Not to be used for more than 1 week. If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Cutaneous use

4.3. Contraindications

Well-established use	Traditional use
Hypersensitivity to the active substance and to other plants of the *Asteraceae (Compositae)* family.	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 product, a doctor or a pharmacist should be consulted. There is a possible risk of severe hypersensitivity reactions in atopic patients. Atopic patients should consult their doctor before using Echinacea. The use is not recommended in children below 12 years of age due to insufficient data. 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.	If signs of skin infection are observed, medical advice should be sought. The use in children below 12 years of age is not recommended because a safe use has not been sufficiently documented.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	**Traditional use**
None reported.	None reported.

4.6. Fertility, pregnancy and lactation

Well-established use	**Traditional use**
Limited data (several hundreds of exposed pregnancies) indicate no adverse effects of Echinacea on pregnancy or on the health of the foetus/newborn child. No other relevant epidemiological data are available. In the absence of sufficient data, the use in pregnancy and lactation is not recommended unless advised by a doctor. No fertility data available.	There are no data on use during pregnancy or lactation. Products containing *Echinacea* should not be applied to the breast of breastfeeding women. No fertility data available.

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
No studies on the effects on the ability to drive and use machines have been performed.	No studies on the effects on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
Hypersensitive reactions in the form of rash, urticaria, itching, swelling of the face may occur. Cases of severe hypersensitivity reactions, such as Stevens-Johnson Syndrome, angioedema of the skin, Quincke oedema, bronchospasm with airway obstruction, asthma and anaphylactic shock have been reported. The frequency is not known. Echinacea can trigger allergic reactions in atopic patients. Association with autoimmune diseases cannot be excluded. If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.	Hypersensitive reactions (local rash, contact dermatitis, eczema and angioedema of the lips) 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.	No case of overdose has been reported.

5. Pharmacological properties

5.1. Pharmacodynamic properties

Well-established use	Traditional use
Pharmacotherapeutic group: Other cold preparations Proposed ATC code: R05X The mechanism of action is not known.	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
No data available.	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
*Echinaceae purpurea*e herba expressed juice showed no toxicity in single-dose toxicity (rodents), repeated-dose toxicity (4 weeks, rodents) and *in vitro* and *in vivo* genotoxicity studies. Tests on reproductive toxicity and carcinogenicity have not been performed.	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. *Echinaceae purpureae* herba expressed juice showed no toxicity in single-dose toxicity (rodents), repeated-dose toxicity (4 weeks, rodents) and *in vitro* and *in vivo* genotoxicity studies. Tests on reproductive toxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

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

7. Date of compilation/last revision

24 November 2014