European Medicines Agency
Evaluation of Medicines for Human Use

London, 4 September 2008
Doc. Ref. EMEA/HMPC/332350/2008

COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY HERBAL MONOGRAPH ON *ECHINACEA PALLIDA* NUTT., RADIX

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	July 2008 September 2008
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	4 September 2008
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 January 2009
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

Comments should be provided using this template to hmpc.secretariat@emea.europa.eu
Fax: +44 20 75 23 70 51

KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; Echinaceae pallidae radix; *Echinacea pallida* Nutt.; pale coneflower root

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

COMMUNITY HERBAL MONOGRAPH ON *ECHINACEA PALLIDA* 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 as amended *Echinacea pallida* Nutt., radix (pale coneflower root) i) Herbal substance Not applicable. ii) Herbal preparations - dry extract (4-8:1), extraction solvent: ethanol 50% (V/V) - liquid extract (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.

[1] The material complies with the Ph. Eur. monograph (ref.: 01/2008:1822)
[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
	Traditional herbal medicinal product for supportive treatment of common cold. The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adolescents over 12 years of age, adults, elderly* Oromucosal use: 1) 3 times daily 1 tablet containing 30 mg dry extract (4-8:1) Oral use: 2) 4 times daily 2 tablets containing 12 mg dry extract (4-8:1) 3) 5 times daily 25 drops containing 100% liquid extract (1:5) The use in children under 12 years of age is contraindicated (see section 4.3. 'Contraindications'). **Duration of use** Not to be used for more than 10 days. The therapy should start at first signs of common cold. If the symptoms persist for more than 10 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral and oromucosal use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family. Echinacea must not be used in cases of progressive systemic disorders, autoimmune diseases, immunodeficiencies, immunosuppression and diseases of the white blood cell system. Children under 12 years of age.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	If the symptoms worsen or high fever occurs during the use of the medical product, a doctor should be consulted. There is a possible risk of allergic reactions in sensitive individuals. Those patients should consult their doctor before using *Echinacea*.

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
	Safety during pregnancy and lactation has not been established. 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 effects on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	Hypersensitive reactions (skin reactions) have been reported. The frequency is not known.

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

4 September 2008