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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

FINAL

**COMMUNITY HERBAL MONOGRAPH ON
ECHINACEA PURPUREA (L.) MOENCH, HERBA RECENS**

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	September 2006 October 2006 January 2007 March 2007
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Changes introduced in sections 3 and 4.2

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**COMMUNITY 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 COMPOSITION¹

<u>Well-established use</u>	<u>Traditional use</u>
<p>With regard to the marketing authorisation application of Article 10(a) of directive 2001/83/EC, as amended</p> <p><i>Echinacea purpurea</i> (L.) Moench, herba recens (purple coneflower herb)</p> <p>i) Herbal substance Not applicable</p> <p>ii) Herbal preparations</p> <ul style="list-style-type: none"> - expressed juice. - dried expressed juice. 	<p>With regard to the registration application of Article 16d(1) of directive 2001/83/EC, as amended</p> <p><i>Echinacea purpurea</i> (L.) Moench, herba recens (purple coneflower herb)</p> <p>i) Herbal substance Not applicable</p> <p>ii) Herbal preparations</p> <ul style="list-style-type: none"> - expressed juice - dried expressed juice.

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
<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>	<p>Herbal preparations in semi-solid or liquid dosage form for cutaneous use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u>
<p>Herbal medicinal product for the short-term prevention and treatment of common cold.</p>	<p>Traditional herbal medicinal product for treatment of small superficial wounds.</p>

¹ The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u>
<p>Posology</p> <p><i>Adolescents over the age of 12 years, adults, elderly</i> Expressed juice 6 – 9 ml per day or equivalent amount of dried expressed juice, divided in 2 to 4 doses.</p> <p>Paediatric population The use in children below 1 year of age is contraindicated (see 4.3. Contraindications)</p> <p>The use in children between 1 and 12 years of age is not recommended (see 4.4. Special warnings and precautions for use).</p> <p>Duration of use</p> <p>For prevention and treatment, do not use the medicinal product for more than 10 days.</p> <p>For treatment, start the therapy at first signs of common cold.</p> <p>If the symptoms persist for more than 10 days, a doctor or a pharmacist should be consulted.</p> <p>Method of administration</p> <p>Oral use</p>	<p>Posology</p> <p><i>Adolescents over the age of 12 years, adults, elderly</i> 10 to 20 g /100 g of expressed juice or equivalent amount of dried expressed juice</p> <p>Small amount of ointment is applied on the affected area 2-3 times a day.</p> <p>The use in children below 12 years of age is not recommended (see 4.4. Special warnings and precautions for use).</p> <p>Duration of use</p> <p>Do not use the medicinal product for more than 1 week.</p> <p>If the symptoms persist 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>Cutaneous use</p>

4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u>
<p>Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family.</p> <p>Because of its immunostimulating activity, Echinacea must not be used in cases of progressive systemic disorders, autoimmune diseases, immunodeficiencies, immunosuppression and diseases of the white blood cell system.</p> <p>Children under 1 year of age.</p>	<p>Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family.</p>

4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u>
<p>If the symptoms worsen or high fever occurs during the use of the product, a physician or a pharmacist should be consulted.</p> <p>There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult their doctor before using Echinacea.</p> <p>The use in children is not recommended because efficacy has not been sufficiently documented although specific risk in children over 1 year of age is not documented.</p>	<p>If signs of skin infection are observed, medical advice should be sought.</p> <p>The use in children below 12 years of age is not recommended because a safe use has not been sufficiently documented.</p>

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

<u>Well-established use</u>	<u>Traditional use</u>
None reported.	None reported.

4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u>
<p>Limited data (several hundreds of exposed pregnancies) indicate no adverse effects of Echinacea on pregnancy or on the health of the foetus/newborn child. Data concerning the immune system of the newborn child are not available. To date, no other relevant epidemiological data are available.</p> <p>In the absence of sufficient data, the use in pregnancy and lactation is not recommended unless advised by a doctor.</p>	<p>There are no data on use during pregnancy or lactation.</p> <p>No concern has arisen about any malformation in humans.</p> <p>Products containing Echinacea should not be applied to the breast of breastfeeding women.</p>

4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u>
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

<u>Well-established use</u>	<u>Traditional use</u>
<p>Hypersensitive reactions (rash, urticaria, Stevens-Johnson Syndrome, angioedema of the skin, Quincke edema, bronchospasm with obstruction, asthma and anaphylactic shock) may occur. Echinacea can trigger allergic reactions in atopic patients.</p> <p>Association with autoimmune diseases (encephalitis disseminata, erythema nodosum, immunothrombocytopenia, Evans Syndrome, Sjögren syndrome with renal tubular dysfunction) has been reported.</p> <p>Leucopenia may occur in long-term use (more than 8 weeks).</p> <p>The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a pharmacist should be consulted.</p>	<p>Hypersensitive reactions (local rash, contact dermatitis, eczema and angioedema of the lips) may occur.</p> <p>The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u>
No case of overdose has been reported.	No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u>
<p>Pharmacotherapeutic group: ATC-code: L03AW05 immunomodulators of plant origin R07AX other preparations for respiratory system</p> <p><i>Echinacea purpurea</i> stimulates nonspecific immune system (phagocytosis by macrophages, natural killer cells activity).</p>	<p>Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.</p>

5.2. Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u>
No data available.	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u>
<p><i>Echinacea purpurea</i> showed no toxicity in single-dose toxicity (rodents), repeated-dose toxicity (rodents) and genotoxicity studies.</p> <p>Tests on reproductive toxicity and on carcinogenicity have not been performed.</p>	<p>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.</p> <p><i>Echinacea purpurea</i> showed no toxicity in single-dose toxicity, repeated-dose toxicity and genotoxicity studies.</p> <p>Tests on local tolerance, reproductive toxicity and on carcinogenicity have not been performed.</p>

6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u>
Not applicable.	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

8 May 2008