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

DRAFT

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

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| DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP) | September 2006 October 2006 January 2007 March 2007 |
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| KEYWORDS | Herbal medicinal products; HMPC; Community herbal monographs; well-established medicinal use; traditional use; <i>Echinacea purpurea</i> (L.) Moench; Echinaceae purpureae herba; purple coneflower herb |
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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> |
|--|---|
| With regard to the marketing authorisation application of Article 10(a) of directive 2001/83/EC, as amended | With regard to the registration application of Article 16d(1) of directive 2001/83/EC, as amended |
| <i>Echinacea purpurea</i> (L.) Moench, herba recens (purple coneflower herb) | <i>Echinacea purpurea</i> (L.) Moench, herba recens (purple coneflower herb) |
| i) Herbal substance Fresh flowering aerial parts | i) Herbal substance Fresh flowering aerial parts |
| ii) Herbal preparations <ul style="list-style-type: none"> - expressed juice. - dried expressed juice. | ii) Herbal preparations <ul style="list-style-type: none"> - expressed juice - dried expressed juice. |

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

| <u>Well-established use</u> | <u>Traditional use</u> |
|--|---|
| Herbal medicinal product for the treatment of early symptoms of common cold. | Traditional herbal medicinal product for treatment of small superficial wounds. |

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 (> 12 years of age) or dried expressed juice equivalent to 8 to 18 g of the herbal substance, 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>Start the therapy at first signs of common cold. Do not use the medicinal product for more than 10 days.</p> <p>If the symptoms worsen during the use of the product or persist for more than 10 days, a physician 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>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>Topical use</p> |

4.3. Contraindications

| <u>Well-established use</u> | <u>Traditional use</u> |
|---|---|
| <p>Children under 1 year of age because the immune system is not fully developed.</p> <p>Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family. Echinacea must not be used in cases of progressive systemic disorders (tuberculosis, sarcoidosis) and autoimmune diseases (e.g.collagenoses, multiple sclerosis), immunodeficiencies (e.g.:HIV infection; AIDS), immunosuppression (e.g.: oncological cytostatic therapy; history of organ or bone marrow transplant), haematologic systemic diseases of the white blood cell system (e.g.: agranulocytosis, leukemias) allergic diathesis (e.g.: urticaria, atopic dermatitis, asthma)</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>Patients with serious infections or high fever should consult their doctor before using Echinacea.</p> <p>There is a possible risk of anaphylactic reactions in atopic patients. Atopic patients should consult their doctor before using Echinacea.</p> <p>Patients should be aware that because of the intake of products containing Echinacea species autoimmune diseases can be triggered.</p> <p>The use in children between 1 and 12 years of age is not recommended because efficacy has not been sufficiently documented although specific risks other than those mentioned in sections 4.3, 4.6 and 4.8 in children over 4 years of age are not documented.</p> | <p>If purulent discharge, erythema, oedema and fever occurs during the use of the medicinal products, a doctor or a qualified health care practitioner should be consulted.</p> |

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

| <u>Well-established use</u> | <u>Traditional use</u> |
|--|------------------------|
| <p>Not to be used concomitantly with immunosuppressant medications such as cyclosporin and methotrexate.</p> | <p>None reported.</p> |

4.6. Pregnancy and lactation

| <u>Well-established use</u> | <u>Traditional use</u> |
|--|--|
| <p>Data on a limited number (100) 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. The potential risk for humans is unknown.</p> <p>In the absence of sufficient data, the use in pregnancy and lactation is not recommended.</p> | <p>There are no reports of undesirable or damaging effects during pregnancy or lactation when used at the recommended dosage.</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> |
|--|--|
| <p>No studies on the effects on the ability to drive and use machines have been performed.</p> | <p>No studies on the effects on the ability to drive and use machines have been performed.</p> |

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.</p> <p>Echinacea can trigger allergic reactions in atopic patients. 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.</p> <p>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>Echinacea can trigger allergic reactions in atopic patients.</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, repeated-dose toxicity 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 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 March 2007