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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

COMMUNITY LIST ENTRY ON ECHINACEA PURPUREA (L.) MOENCH, HERBA RECENS

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	May 2007
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	8 May 2007
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 June 2007
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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

KEYWORDS	Herbal medicinal products; HMPC; Community list of herbal substance(s), preparation(s) and combinations thereof for use in traditional herbal medicinal products; traditional use; <i>Echinacea purpurea</i> (L.) Moench;
	Echinaceae purpureae herba; purple coneflower herb

ENTRY TO COMMUNITY LIST OF HERBAL SUBSTANCES, PREPARATIONS AND COMBINATIONS THEREOF FOR USE IN TRADITIONAL HERBAL MEDICINAL PRODUCTS: ECHINACEA PURPUREA (L.) MOENCH, HERBA RECENS

Scientific name of the plant

Echinacea purpurea (L.) Moench

Botanical family

Asteraceae (Compositae)

Common name in all EU official languages

ES (espanol): Equinácea purpúrea, partes aéreas HU (magyar): piros kasvirág

incluidas sumidades floridas MT (Malti):

BG (bălgarski): NL (Nederlands):

CS (čeština): čerstvá nať třapatky nachové PL (polski): jezówka purpurowa, swiezy sok.

DA (dansk): PT (português):

DE (Deutsch): Purpursonnenhutkraut RO (română): iarbã proaspãtã de Echinacea,

ET (eesti keel): punane siilkübar pãlāria soarelui

EL (elliniká): Πόα Εχινάκειας SK (slovenčina): echinacea purpurová, čerstvá vňať EN (English): Purple Coneflower Herb SL (slovenščina): škrlatna ehinaceja, sveža zel FR (français): parties aériennes fraîches FI (suomi): kaunopunahattu, tuore verso

içais). parties acriemies fraiches

d'échinacée pourpre SV (svenska):

IT (italiano):

LV (latviešu valoda): IS (íslenska): Sólhattur LT (lietuvių kalba): NO (norsk): Rød solhatt, rot

Herbal preparation(s)

Expressed juice and dried expressed juice from fresh flowering aerial parts

European Pharmacopoeia monograph reference

N/A

Indication(s)

Traditional herbal medicinal product for treatment of small superficial wounds.

The product is a traditional herbal medicinal product for use in a specified indication exclusively based on long-standing use

Type of tradition

European

Specified strength

See Specified posology.

Specified posology

Adolescents over the age of 12 years, adults, elderly

10 to 20 g /100 g of expressed juice or equivalent amount of dried expressed juice

Route of administration

Topical use

Duration of use or any restrictions on the duration of use

Do not use the medicinal product 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.

Any other information necessary for the safe use

Contraindications

Hypersensitivity to the active substance or to plants of the Asteraceae (Compositae) family.

Special warnings and precautions for use

If purulent discharge, erythema, oedema and fever occurs during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Interactions with other medicinal products and other forms of interaction

None reported.

Pregnancy and lactation

There are no reports of undesirable or damaging effects during pregnancy or lactation when used at the recommended dosage.

Products containing Echinacea should not be applied to the breast of breastfeeding women.

Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

Undesirable effects

Hypersensitive reactions (local rash, contact dermatitis, eczema and angioedema of the lips) may occur. Echinacea can trigger allergic reactions in atopic patients.

The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

Overdose

No case of overdose has been reported.

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience [If necessary]

Not applicable.

Pharmaceutical particulars [If necessary]

Not applicable.