



EMEA/HMPC/453709/2007EN  
EMEA/HMPC/M/H/0022

OPINION OF THE COMMITTEE ON HERBAL MEDICINAL PRODUCTS ON A  
COMMUNITY HERBAL MONOGRAPH ON  
*ECHINACEA PURPUREA* (L.) MOENCH., HERBA

**This document was valid from 6 March 2008 until November 2014.  
It is now superseded by a [new version](#) adopted by the HMPC on  
24 November 2014 and published on the EMA website.**

1. The HMPC, in accordance with Article 16h(3) of Directive 2001/83/EC, as amended, and as set out in the appended assessment report, establishes by a majority of 19 out of 24 votes a Community herbal monograph on *Echinacea purpurea* (L.) Moench, herba which is set out in Annex I.


The divergent positions are appended to this opinion.

The Icelandic and the Norwegian HMPC members agree with the above-mentioned recommendation of the HMPC.

This opinion is forwarded to Member States, to Iceland and Norway, together with its Annex I and appendices.

The Community herbal monograph and assessment report will be published on the EMEA website.

London, 6 March 2008

 I. Chinou

On behalf of the HMPC  
Prof. Ioanna Chinou, Vice-chair

**ANNEX I: COMMUNITY HERBAL MONOGRAPH (EMEA/HMPC/104945/2006)**

Superseded

**APPENDIX I: ASSESSMENT REPORT (EMEA/HMPC/104918/2006)**

Superseded

**APPENDIX II: DIVERGENT POSITIONS**

Superseded

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reasons:

I do not agree with the HMPC's opinion for the following reasons:

The evidence does not support the position of Echinacea herb as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC.

The data presented as evidence for the indication of *short-term prevention and treatment of common cold* are not conclusive and do not demonstrate that the use of Echinacea in such indication is well-established.

With regard to the indication, the interpretation and clinical relevance of *short-term prevention* (which is in the posology section limited to not more than 10 days) is unclear.

The currently available data could however give ground for the plausibility of traditional use indications for Echinacea in conditions of common cold. A monograph in which appropriate conditions of use are specified (such as posology, contra-indications and special warnings) could ensure a safe use of Echinacea in the traditional use legal framework.

London, 14 March 2008.

The member of the of the HMPC mentioned below did not agree with the HMPC's opinion for the following reasons:

I disagree with the indication 'for the short-term prevention of common cold' proposed under well established use of expressed juice and dried expressed juice of *Echinaceae purpurea* (L.) Moench, herb in the Community herbal monograph

I consider that the clinical data presented do not support the above mentioned indication.

In addition, the recommend duration of use (10 days) does not reflect the duration of the clinical studies supporting this indication.

London, 6 March 2008

Superseded

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reasons:

I consider that the available data are not sufficient to grant the "well-established use" indication in the Community herbal monograph on *Echinacea purpurea* (L.) Moench., herba.

London, 12 March 2008

Superseded

The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reasons:

I do not agree with the HMPC opinion on the Community monograph for *Echinacea Purpurea* L., Herba Recens.

The data provided is insufficient to support a well-established use indication for Echinacea as a "Herbal medicinal product for the short-term prevention and treatment of common cold."

The clinical trials presented are of inadequate quality and the results inconsistent. *Echinacea purpurea* herb has not been scientifically proven to have recognised efficacy in accordance with the requirements of Article 10a and Annex 1 of Directive 2001/83/EC, as amended.

The data presented could however support the plausibility of a traditional-use indication of Echinacea in a Community monograph with the appropriate conditions of use (posology, contraindications and special warnings) provided.

London, 6 March 2008



The member of the HMPC mentioned below did not agree with the HMPC's opinion for the following reasons:

I do not support the HMPC's opinion on the information given under Well-established use for the following reasons:

The evidence does not support the proposed indication of Echinacea herb as having well-established medicinal use and recognised efficacy as required by Article 10a of Directive 2001/83/EC, in particular the data presented as evidence for the indication of *short-term prevention and treatment of common cold* are not conclusive.

In this respect, the proposed indication (WEU) for the short-term prevention and treatment of common cold, is confusing both for the combination "short-term prevention" and for the combination "prevention and treatment" which makes no sense from the viewpoint of medical practice. Moreover, also the related information given under Duration of use: "for prevention and treatment, do not use the product for more than 10 days" together with: "for treatment, start the therapy at first signs of common cold" do not provide a clear advice how to use the product for this indication.

London, 6 March 2008