NATURAL HEALTH PRODUCT

ECHINACEA PURPUREA

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes

Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant’s discretion.

The solidus (/) indicates that the terms are synonyms or that the statements are synonymous. Either term or statement may be selected by the applicant.

Date: July 18, 2017

Proper name(s):

_Echinacea purpurea_ L. Moench (Asteraceae) (USDA 2012)

Common name(s):

► Echinacea (Blumenthal et al. 2000; McGuffin et al. 1997)
► Purple coneflower (McGuffin et al. 2000)

Source material(s):

Herb top and/or root (Barnes et al. 2007; ESCOP 2003)

Route(s) of administration:

Oral

Dosage form(s):

This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Dosage forms by age group:
- **Children 2 years:** The acceptable dosage forms are limited to emulsion/suspension and solution/drops (Giacofa et al. 2008; EMEA/CHMP 2006).
- **Children 3-5 years:** The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giacofa et al. 2008; EMEA/CHMP 2006).
- **Children 6-12 years, Adolescents 13-17 years, and Adults ≥ 18 years:** The acceptable dosage forms include, but are not limited to capsules, chewables (e.g., gummies, tablets), liquids, powders, strips or tablets.

**Use(s) or Purpose(s):**

- Traditionally used in Herbal Medicine to help relieve cold symptoms (Moerman 1998; Grieve 1971; Remington and Wood 1918).
- (Traditionally) used in Herbal Medicine to help fight off infections, especially of the upper respiratory tract (Hoffmann 2003; Mills and Bone 2000; Grieve 1971; Remington and Wood 1918).
- Helps to relieve the symptoms (Goel et al. 2004; Schulten et al. 2001; Brinkeborn et al. 1999; Hoheisel et al. 1997; Bräunig et al. 1992) and shorten the duration (Goel et al. 2004; Schulten et al. 2001; Hoheisel et al. 1997; Bräunig et al. 1992) of upper respiratory tract infections.

**Note**

A claim for traditional use must include the term “Herbal Medicine”.

**Dose(s):**

**Table 1** Dose information expressed as “quantity dried equivalent” of *Echinacea purpurea* herb top presented as dose per day

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Quantity dried equivalent (herb top) (g/day)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children 1</td>
<td></td>
<td>0.4</td>
<td>1.0</td>
</tr>
<tr>
<td>Children and adolescents 1</td>
<td></td>
<td>0.6</td>
<td>1.5</td>
</tr>
<tr>
<td>Adolescents 1</td>
<td></td>
<td>1.3</td>
<td>3.0</td>
</tr>
<tr>
<td>Adolescents and adults 1,2,3</td>
<td>≥ 15 y</td>
<td>2.5</td>
<td>6.0</td>
</tr>
</tbody>
</table>

1 Children and adolescent doses were calculated as a proportion of the adult dose (JC 2012). The use of *Echinacea purpurea* herb top in children is supported by the following references: McIntyre 2005; Bove 2001; Schilcher 1997.

2 Adult dose supported by the following reference: Mills and Bone 2000

3 Includes pregnant and breastfeeding women

**Table 2** Dose information for the pressed juice of *Echinacea purpurea* herb top presented as dose per day
<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Pressed juice (herb top) (ml/day)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children¹</td>
<td>2-4 y</td>
<td>0.7</td>
<td>1.7</td>
</tr>
<tr>
<td>Children and adolescents¹</td>
<td>5-9 y</td>
<td>1.0</td>
<td>2.5</td>
</tr>
<tr>
<td>Adolescents¹</td>
<td>10-14 y</td>
<td>2.0</td>
<td>5.0</td>
</tr>
<tr>
<td>Adolescents and adults ¹,²,³</td>
<td>≥ 15 y</td>
<td>3.9</td>
<td>10.0</td>
</tr>
</tbody>
</table>

¹Children and adolescent doses were calculated as a proportion of the adult dose (JC 2012). The use of *Echinacea purpurea* herb top in children is supported by the following references: McIntyre 2005; Bove 2001; Schilcher 1997.

²Adult dose supported by the following references: Schulten et al. 2001; Hoheisel et al. 1997

³Includes pregnant and breastfeeding women

Table 3 Dose information expressed as “quantity dried equivalent” of *Echinacea purpurea* root presented as dose per day

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Quantity dried equivalent (root) (g/day)</th>
<th>Minimum</th>
<th>Minimum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children¹</td>
<td>2-4 y</td>
<td>0.15</td>
<td>0.8</td>
</tr>
<tr>
<td>Children and adolescents¹</td>
<td>5-9 y</td>
<td>0.23</td>
<td>1.1</td>
</tr>
<tr>
<td>Adolescents¹</td>
<td>10-14 y</td>
<td>0.45</td>
<td>2.3</td>
</tr>
<tr>
<td>Adolescents and adults ¹,²,³</td>
<td>≥ 15 y</td>
<td>0.90</td>
<td>4.5</td>
</tr>
</tbody>
</table>

¹Children and adolescent doses were calculated as a proportion of the adult dose (JC 2012). The use of *Echinacea purpurea* root in children is supported by the following references: McIntyre 2005; Bove 2001; Schilcher 1997

²Adult dose supported by the following references: Mills and Bone 2000; Bräunig et al. 1992

³Includes pregnant and breastfeeding women

Table 4 Dose information expressed as “quantity dried equivalent” of *Echinacea purpurea* preparations containing both herb top and root presented as dose per day

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Quantity dried equivalent (herb top and root) (g/day)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children¹</td>
<td>2-4 y</td>
<td>0.5</td>
<td>0.9</td>
</tr>
<tr>
<td>Children and adolescents¹</td>
<td>5-9 y</td>
<td>0.8</td>
<td>1.4</td>
</tr>
<tr>
<td>Adolescents¹</td>
<td>10-14 y</td>
<td>1.5</td>
<td>2.8</td>
</tr>
<tr>
<td>Adolescents and adults ¹,²,³</td>
<td>≥ 15 y</td>
<td>3.0</td>
<td>5.5</td>
</tr>
</tbody>
</table>

¹Children and adolescent doses were calculated as a proportion of the adult dose (JC 2012). The use of *Echinacea purpurea* in children is supported by the following references: McIntyre 2005; Bove 2001; Schilcher 1997

²Adult dose supported by the following reference: Mills and Bone 2000

³Includes pregnant and breastfeeding women

Directions for use

Take at the first sign of infection (Goel et al. 2004; Schulten et al. 2001; Brinkeborn et al. 1999; Hoheisel et al. 1997).

Note

Refer to Appendix 1 for examples of dosage preparations and directions for use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.
Duration of use:

For use beyond 8 weeks, consult a health care practitioner (ESCOP 2003; Blumenthal et al. 2000).

Risk information:

Caution(s) and warning(s)

- If symptoms persist or worsen, consult a health care practitioner.
- If you have a progressive systemic disease such as tuberculosis, collagenosis, multiple sclerosis, AIDS, or HIV infection, consult a health care practitioner prior to use (Brinker 2010; Brinker 2001; McGuffin et al. 1997).
- If you have an auto-immune disorder, consult a health care practitioner prior to use (Brinker 2010; McGuffin et al. 1997).
- If you are taking immunosuppressants, consult a health care practitioner prior to use (Brinker 2010; Mills and Bone 2005).

Contraindication(s)

No statement required.

Known adverse reaction(s)

Preparations containing herb top:
Rare cases of severe allergic reactions have been known to occur; use caution if you are allergic to plants of the Daisy family. (MHRA 2012; EMA 2010; Kligler 2003; WHO 1999).

Non-medicinal ingredients:

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Specifications:

- The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- The medicinal ingredient must comply with the requirements outlined in the NHPID.
- The medicinal ingredient may comply with the specifications outlined in the pharmacopoeial monographs listed in Table 5 below.

Table 5  
Echinacea purpurea monographs published in the European (Ph.Eur.) and United
### States (USP) Pharmacopoeias

<table>
<thead>
<tr>
<th>Pharmacopia</th>
<th>Monograph</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ph.Eur.</td>
<td>Purple Coneflower Herb&lt;br&gt;Purple Coneflower Root</td>
</tr>
<tr>
<td>USP</td>
<td>Echinacea purpurea Aerial Parts&lt;br&gt;Echinacea purpurea Root&lt;br&gt;Powdered Echinacea purpurea&lt;br&gt;Powdered Echinacea purpurea Extract</td>
</tr>
</tbody>
</table>

### References cited:


Livingstone.


References reviewed:


Bielory L. 2002. Adverse reactions to complementary and alternative medicine: ragweed’s cousin, the coneflower (echinacea), is “a problem more than a sneeze”. Annals of Allergy, Asthma & Immunology 88(1):7-9.


Felter HW, Lloyd JU. 1983. King’s American Dispensatory, Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; [Reprint of 1898 original].


Appendix 1  Examples of appropriate dosage preparations, frequencies of use and directions for use (for adults only)

Herb top

Dried herb top

2.5-6 g, per day (Mills and Bone 2000)

Pressed juice

- 5 ml, 2 times per day (22% alcohol) (Schulten et al. 2001)
- 1.3 ml (20 drops), per dose (22% alcohol) (Hoheisel et al. 1997)

Direction for use:
Take each dose in a half glass of water every two hours for the first day, followed by three times per day until symptoms disappear [not to exceed 10 ml, per day] (Hoheisel et al. 1997).

Root

Dried root:
1.5-4.5 g, per day (Mills and Bone 2000)

Tincture:
- 1.5-4.5 g dried equivalent, per day (1:2, 3-9 ml) (Mills and Bone 2000)
- 1.5-4.5 g dried equivalent, per day (1:5, 7.5-22.5 ml) (Mills and Bone 2000)
- 0.9 g dried equivalent, per day (1:5, 55% ethanol) (Bräunig et al. 1992)

Preparations containing herb top and root

Fluidextract:
3-5.5 g dried equivalent, per day (1:1, 3-5.5 ml) (Mills and Bone 2000)