NATURAL HEALTH PRODUCT

ECHINACEA PALLIDA

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 pallida_ (Nutt.) Nutt. (Asteraceae) (USDA 2012; Upton 2010)

Common name(s):

► _Echinacea pallida_ (Upton 2010; McGuffin et al. 2000)
► pale echinacea (USDA 2012; ITIS 2010)
► pale purple coneflower (ITIS 2010; Upton 2010; McGuffin et al. 2000)

Source material(s):

Root (Blumenthal 2003; Dorn et al. 1997)

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 (Giaccoia et al. 2008; EMEA/CHMP 2006).
- **Children 3-5 years**: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giaccoia 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 (Blumenthal et al. 2000; Moerman 1998).
- Supportive therapy in the treatment of upper respiratory tract infections (e.g., common colds) (EMA 2009; Dorn et al. 1997).
- Helps to relieve the symptoms and shorten the duration of upper respiratory tract infections (e.g., common cold) (Dorn et al. 1997).

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

**Dose(s):**

**Table 1  Daily dose expressed as quantity dried equivalent of *Echinacea pallida* root**

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Quantity dried equivalent (root) (g/day)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children¹</td>
<td>2-4 y</td>
<td>0.06</td>
<td>0.5</td>
</tr>
<tr>
<td>Children and adolescents¹</td>
<td>5-9 y</td>
<td>0.09</td>
<td>0.8</td>
</tr>
<tr>
<td>Adolescents¹</td>
<td>10-14 y</td>
<td>0.18</td>
<td>1.5</td>
</tr>
<tr>
<td>Adolescents and adults¹²³</td>
<td>≥ 15 y</td>
<td>0.36</td>
<td>3.0</td>
</tr>
</tbody>
</table>

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

²Adult dose supported by the following references: EMA 2009; Blumenthal 2003; Blumenthal et al. 2000; Blumenthal et al. 1998; Dorn et al. 1997.

³Includes pregnant and breastfeeding women

**Directions for use**

Start treatment at first signs of common cold (EMA 2009).

**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. 1998).

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; EMA 2009; 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 et al. 2006).

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

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 2 below.

Table 2  Echinacea pallida monographs published in the British (BP), European (Ph.Eur.) and
United States (USP) Pharmacopoeias

<table>
<thead>
<tr>
<th>Pharmacopoeia</th>
<th>Monograph</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP</td>
<td>Echinacea Pallida Root</td>
</tr>
<tr>
<td>Ph.Eur.</td>
<td>Pale Coneflower Root: Echinacea pallidae radix</td>
</tr>
<tr>
<td>USP</td>
<td><em>Echinacea pallida</em>&lt;br&gt;Powdered <em>Echinacea pallida</em>&lt;br&gt;Powdered <em>Echinacea pallida</em> Extract</td>
</tr>
</tbody>
</table>

**References cited:**


USDA 2012: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germlasm Resources Information Network (GRIN) [Internet]. Beltsville (MD): National Germlasm Resources Laboratory. [Echinacea pallida.: Last updated
References reviewed:


Appendix 1  Examples of dosage preparations, frequencies of use and directions for use

For adults only

Dried root

0.9-1 g, 3 times per day (Blumenthal 2003)

Decoction

1 g dried root, 3 times per day (Blumenthal et al. 2000)

Directions for use:
Place dried root in 150 ml of cold water, bring to a boil and simmer for 10 minutes (Blumenthal et al. 2000). Drink between meals (Blumenthal 2003).

Tincture

▶ 0.9 g dried equivalent, per day
   (1:5, 50% ethanol) (EMA 2009; Blumenthal et al. 1998)
▶ 0.9 g dried equivalent, per day (Dorn et al. 1997)

Dry extract

(4-8:1), extraction solvent: ethanol 50% (v/v) (EMA 2009)

Posology (EMA 2009):
1) 3 times daily 1 tablet containing 30 mg dry extract (4-8:1)
2) 4 times daily 2 tablets containing 12 mg dry extract (4-8:1)
3) 5 times daily 25 drops containing 100% tincture (1:5)

Duration of use:
The therapy should start at first signs of common cold.
If the symptoms persist longer than 10 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.