



## NATURAL HEALTH PRODUCT

### ECHINACEA – *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 and/or statements are synonymous. Either term or statement may be selected by the applicant.

#### Date

December 18, 2018

#### Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
<i>Echinacea pallida</i>	<ul style="list-style-type: none"> <li>▶ Echinacea</li> <li>▶ Echinacea pallida</li> <li>▶ Pale echinacea</li> <li>▶ Pale-flower echinacea</li> <li>▶ Pale purple-coneflower</li> <li>▶ Purple cone flower</li> </ul>	<i>Echinacea pallida</i>	Root	Dried

References: Proper name: USDA 2018, Upton 2010; Common names: ITIS 2018, USDA 2018, Upton 2010, McGuffin et al. 2000; Source material: Blumenthal 2003, Dorn et al. 1997.

#### Route of administration

Oral

#### Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.



### Acceptable dosage forms by age group:

**Children 2 years:** The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giacoaia et al. 2008; EMEA/CHMP 2006).

**Children 3-5 years:** The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/liquid preparations (Giacoaia et al. 2008; EMEA/CHMP 2006).

**Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older:** The acceptable dosage forms for this age category and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

### Use(s) or Purpose(s)

- ▶ Traditionally used in Herbal Medicine to help relieve cold symptoms (Blumenthal et al. 2000; Moerman 1998).
- ▶ Traditionally used in Herbal Medicine to help relieve symptoms of upper respiratory tract infections (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).

The following combined use(s) or purpose(s) is/are also acceptable:

Traditionally used in Herbal Medicine to help relieve symptoms of colds and upper respiratory tract infections (EMA 2009; Blumenthal et al. 2000; Moerman 1998; Dorn et al. 1997).

### Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

### Dose(s)

#### Subpopulation(s)

As specified below.

#### Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)



Table 2. Dose information for *Echinacea pallida* root per day

Subpopulation(s)		Dried root (gram/day)	
		Minimum	Maximum
Children <sup>1</sup>	2-4 years	0.06	0.5
	5-9 years	0.09	0.8
	10-11 years	0.18	1.5
Adolescents <sup>1</sup>	12-14 years	0.18	1.5
	15-17 years	0.36	3.0
Adults <sup>2,3</sup>	18 years and older	0.36	3.0

<sup>1</sup> Children and adolescent doses were calculated as a proportion of the adult dose (JC 2018). The use of *Echinacea pallida* in children is supported by the following references: Bove 2001; Schilcher 1997.

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

<sup>3</sup> Includes pregnant and breastfeeding women.

### Direction(s) for use

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

### Duration(s) of use

Consult a health care practitioner /health care provider/health care professional/doctor/physician for use beyond 8 weeks (ESCOP 2003; Blumenthal et al. 1998).

### Risk information

#### Caution(s) and warning(s)

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a progressive systemic disease such as tuberculosis, collagenosis, multiple sclerosis, AIDS and/or HIV infection or an auto-immune disorder (Brinker 2010; EMA 2009; Brinker 2010; McGuffin et al. 1997).
- ▶ Consult a health care practitioner /health care provider/health care professional/doctor/physician prior to use if you are taking medications to suppress the immune system (immunosuppressive medications) (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.

### **Storage conditions**

No statement required.

### **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.

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