

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)
Echinacea pallida	► Echinacea	Echinacea pallida	Root	Dried
	► Echinacea pallida			
	► Pale echinacea			
	► Pale-flower echinacea			
	► Pale purple-coneflower			
	► Purple cone flower			

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 (Giacoia 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 (Giacoia 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)



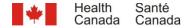


Table 2. Dose information for Echinacea pallida root per day

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

¹ 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.

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.



² Adult 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.



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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