



NATURAL HEALTH PRODUCT

ECHINACEA ANGUSTIFOLIA

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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date: July 18, 2017

Proper name(s):

Echinacea angustifolia DC. (Asteraceae) (USDA 2012)

Common name(s):

- ▶ Echinacea (McGuffin et al. 2000; McGuffin et al. 1997; Bradley 1992)
- ▶ Narrow-leaf Echinacea (McGuffin et al. 2000; McGuffin et al. 1997; Bradley 1992)
- ▶ Narrow-leaf purple coneflower (McGuffin et al. 2000; McGuffin et al. 1997; Bradley 1992)

Source material(s):

Root and rhizome (Barnes et al. 2007; Grieve 1971 [1931])

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 (Giacoaia et al. 2008; EMEA/CHMP 2006).
- **Children 3-5 years:** The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giacoaia 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 the symptoms of upper respiratory tract infections (Barnes et al. 2007; Blumenthal et al. 2000; Ellingwood 1983 [1919]; Felter and Lloyd 1983 [1898]; Grieve 1971 [1931]).
- ▶ Traditionally used in Herbal Medicine to help relieve sore throats (Blumenthal et al. 2000; Moerman 1998).

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 angustifolia* root and rhizome presented as dose per day

Subpopulation		Quantity dried equivalent (g/day)	
		Minimum	Maximum
Children ¹	2-4 y	0.17	0.5
Children and adolescents ¹	5-9 y	0.25	0.8
Adolescents ¹	10-14 y	0.5	1.5
Adolescents and adults ^{1,2,3}	≥ 15 y	1.0	3.0

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

² Adult dose supported by the following references: Barnes et al. 2007; Blumenthal et al. 2000; Bradley 1992

³ Includes pregnant and breastfeeding women

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 (Brinker 2001).



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 and/or HIV infection, consult a health care practitioner prior to use (Brinker 2010; 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)

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 angustifolia* monographs published in the European (Ph. Eur.) and United States (USP) Pharmacopoeias

Pharmacopoeia	Monograph
Ph.Eur.	Narrow-leaved Coneflower Root
USP	<i>Echinacea angustifolia</i> Powdered <i>Echinacea angustifolia</i> Powdered <i>Echinacea angustifolia</i> Extract



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

Dried root and rhizome

- ▶ 1-3 g, per day (Barnes et al. 2007)
- ▶ 1 g, 3 times per day (Bradley 1992)

Infusion

1 g dried root and rhizome, several times per day (not to exceed 3 g per day) (Blumenthal et al. 2000)

Directions for use:

Pour 150 ml of boiling water on dried root and rhizome and steep for at least 10 minutes. Drink between meals (Blumenthal et al. 2000).

Decoction

1 g dried root and rhizome, 3 times per day (Bradley 1992)

Directions for use:

Place dried root and rhizome in 150 ml water, bring to a boil, and simmer for 10 minutes (Blumenthal et al. 2000).

Fluidextract

0.5-1 g dried equivalent, 3 times per day
(1:1, 45% alcohol, 0.5-1 ml) (Bradley 1992)

Tincture

0.4-1 g dried equivalent, 3 times per day
(1:5, 45% alcohol, 2-5 ml) (Bradley 1992)