Echinacea pallida

Source: https://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq?atid=echinacea.pallida⟨=eng

Extracted: 2025-08-26T06:32:26.083661

ECHINACEA - ECHINACEA PALLIDA Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 84.6 KB) 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 Pale echinacea Pale-flower echinacea Pale purple-coneflower Purple cone flower Echinacea pallida 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. 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. 2 Adult dose supported by the following references: EMA 2009; Blumenthal 2003; Blumenthal et al. 2000; Blumenthal et al. 1998; Dorn et al. 1997. 3 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; 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. References Cited Blumenthal M, editor. 2003. The ABC Clinical Guide to Herbs. Austin (TX): American Botanical Council. Blumenthal M, Goldberg A, Brinckmann J. 2000. Herbal Medicine: Expanded Commission E Monographs. Newton (MA): Integrative Medicine Communications. Blumenthal M, Busse WR, Goldberg A, Gruenwald J, Hall T, Riggins CW, Rister RS, editors. 1998. The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines. Austin (TX): American Botanical Council. Bove M. 2001. An Encyclopedia of Natural Healing for Children and Infants, 2 nd edition. New York (NY): McGraw-Hill. Bradley PR, editor. 2006. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (GB): British Herbal Medicine Association. Brinker F. Herb Contraindications and Drug Interactions, 4 th edition. Sandy (OR): Eclectic Medical Publications; 2010. Dorn M, Knick E, Lewith G. 1997. Placebo-controlled, double-blind study of Echinacea pallidae radix in upper respiratory tract infections. Complementary Therapies in Medicine 5(1): 40-42. EMA 2009: EMA/HMPC/332350/2008 Community herbal monograph on ECHINACEA PALLIDA (NUTT.) NUTT., RADIX, Final. 16 July 2009. London (GB): European Medicines Agency: Committee on Herbal Medicinal Products (HMPC). [Accessed 2018 September 27]. Available from: http://www.ema.europa.eu EMEA/CHMP 2006: European Medicines Agency: Pre-authorization Evaluation of Medicines for Human Use. Committee for Medicinal Products for Human Use. Reflection Paper: Formulations of choice for the paediatric population. Adopted September 2006. EMEA/CHMP/PEG/194810/2005. [Accessed 2018 September 27]. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003782.pdf ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2 nd edition. Exeter (GB): European Scientific Cooperative on Phytotherapy and Thieme. Giacoia GP, Taylor-Zapata P, Mattison D. Eunice Kennedy Shriver National Institute of Child Health and Human Development Pediatric Formulation Initiative: selected reports from working groups. Clinical Therapeutics 2008; 30(11):2097-2101. ITIS 2018: Integrated Taxonomic Information System. Taxon Based on Biological Information System [Internet]. Canadian Biodiversity Information Facility, Government of Canada. [Accessed 2018 September 27]. Available from: https://www.itis.gov/servlet/SingleRpt/SingleRpt?search_topic=TSN&search_value=37279#null JC 2018: Justice Canada. Natural Health Products Regulations [Internet]. Ottawa (ON): Justice Canada. [Accessed 2018 September 27]. Available from: http://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/page-11.html?txthl=dosage McGuffin M, Kartesz JJ, Leung AY, Tucker AO, editors. 2000. Herbs of Commence, 2 nd edition. Silver Spring (MD): American Herbal Products Association. McGuffin M, Hobbs C, Upton R, Goldberg A, editors. 1997. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press. Mills E, Dugoua J, Perri D, Koren G. 2006. Herbal Medicines in Pregnancy and Lactation : An Evidence-Based Approach. London (GB): Taylor and Francis Medical. Moerman DE. 1998. Native American Ethnobotany. Portland (OR): Timber Press. Schilcher H. 1997. Phytotherapy in Paediatrics: Handbook for Physicians and Pharmacists. Stuttgart (DE): medpharm Scientific Publishers. Upton R, editor. 2010. American Herbal Pharmacopoeia and Therapeutic Compendium: Echinacea pallida Root (Echinacea pallida (Nutt.) Nutt.) - Standards of Analysis, Quality Control, and Therapeutics. Santa Cruz (CA): American Herbal Pharmacopoeia. USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [Internet].Beltsville (MD): National Germplasm Resources Laboratory. [Accessed 2018 September 27]. Available from: http://www.ars-grin.gov/cgi- bin/npgs/html/tax_search.pl References Reviewed Barnes J, Anderson LA, Gibbons S, Phillipson JD. 2005. Echinacea species (Echinacea angustifolia (DC.) Hell., Echinacea pallida (Nutt.) Nutt., Echinacea purpurea (L.) Moench: a review of their chemistry, pharmacology and clinical properties. Journal of Pharmacy and Pharmacology 57(8):929-954. Barnes J, Anderson LA, Phillipson JD. 2007. Herbal Medicines, 3 rd edition. London (GB): The Pharmaceutical Press. BHP 1983: British Herbal Pharmacopoeia. Bournemouth (GB): British Herbal Medicine Association. Bielory L. 2004. Complementary and alternative interventions in asthma, allergy, and immunology. Annals of Allergy, Asthma & Immunology 93(1):S45-S54. Boon H, Smith M, editors. 2004. The Complete Natural Medicine Guide to the 50 Most Common Medicinal Herbs, 2 nd edition. Toronto (ON): Robert Rose Inc. Bradley PR, editor. 1992. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 1. Bournemouth (GB): British Herbal Medicine Association. Chicca A, Pellati F, Adinolfi B, Matthias A, Massarelli I, Benvenuti S, Martinotti E, Bianucci AM, Bone K, Lehmann R, Nieri P. 2008. Cytotoxicity activity of polyacetylenes and polyenes isolated from roots of Echinacea pallida. British Journal of Pharmacology 153(5):879-885. EMEA 2000: The European Agency for the Evaluation of Medicinal Products. Committee for Veterinary Medicinal Products: Echinacea (use in veterinary homeopathy) Summary Report [Internet]. London (GB): EMEA; 2000. [Accessed 2013 January 30]. Available from: http://www.emea.europa.eu/pdfs/vet/mrls/068799en.pdf Gallo M, Sarkar M, Au W, Pietrzak K, Comas B, Smith

M, Jaeger TV, Einarson A, Koren G. 2000. Pregnancy outcome following gestational exposure to echinacea: a prospective controlled study. Archives of Internal Medicine 160(20):3141-3143. Huntley A, Coon JT, Ernst E. 2005. The safety of herbal medicinal products derived from echinacea species. Drug Safety 28(5):387-400. Islam J, Carter R. 2005. Use of Echinacea in upper respiratory tract infection. Southern Medical Journal 98(3): 311-318. Melchart D, Linde K, Worku F, Sarkady L, Holzmann M, Jurcic K, Wagner H. 1995. Results of five randomized studies on the immunomodulatory activity of preparations of Echinacea. Journal of Alternative and Complementary Medicine 1(2): 145-160. Miller LG. 1998. Herbal medicinals: selected clinical considerations focusing on known or potential drug-herb interactions. Archives of Internal Medicine 158(20):2200-2211. Mills S. 1985. The Dictionary of Modern Herbalism. Wellingborough (GB): Thorsons Publishers Ltd. Mills S, Bone K. 2005. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone. Mills S, Bone K. 2000. Principles and Practice of Phytotherapy: Modern Herbal Medicine. Toronto (ON): Churchill Livingstone. Newall CA, Anderson LA, Phillipson JD. 1996. Herbal Medicines: A Guide for Health-Care Professionals. London (GB): The Pharmaceutical Press. Perri D, Dugoua JJ, Mills E, Koren G. 2006. Safety and efficacy of echinacea (Echinacea angustifolia, E. purpurea and E. pallida) during pregnancy and lactation. The Canadian Journal of Clinical Pharmacology 13(3):e262-e267. Speroni E, Govoni P, Guizzardi S, Renzulli C, Guerra MC. 2002. Anti-inflammatory and cicatrizing activity of Echinacea pallida Nutt. root extract. Journal of Ethnopharmacology 79(2): 265-272. WHO 1999: World Health Organization. WHO Monographs on Selected Medicinal Plants: Radix Echinaceae [Internet]. Geneva (CH): World Health Organization; 2007. [Accessed 2013 January 30]. Available from: http://whqlibdoc.who.int/publications/1999/9241545178.pdf Wichtl M, editor. 2004. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, 3 rd edition. Stuttgart (DE): Medpharm GmbH Scientific Publishers. Wiersema JH, León B, editors. 1999. World Economic Plants: A Standard Reference. Boca Raton (FL): CRC Press LLC. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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.

DOSAGE FORM(S)

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.

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; 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.

STORAGE CONDITION(S)

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.

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source material(s)		
Proper name(s)	Part(s)	Preparation(s)		
Echinacea pallida	EchinaceaEchinacea pallidaPale echinacea	Echinacea pallidaPale purple coneflower	Root	Dried

pulation(s)	Dried root (gram/day)								
n	Maximum								
1	2-4 years	0.06	0.5						
ents1	12-14 years	0.18	1.5	15-17 years	0.36	3.0	Adults2,3	18 years and older	0
ents1	12-14 years	0.18	1.5						