

Echinacea purpurea

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ECHINACEA - ECHINACEA PURPUREA 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 - 137 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 Echinacea purpurea Eastern purple-coneflower Echinacea Purple coneflower Echinacea purpurea Herb top Dried Juice Root Herb top and root Dried References: Proper name: USDA 2018; Common names: Blumenthal et al. 2000, McGuffin et al. 2000, 1997; Source materials: Barnes et al. 2007, ESCOP 2003. 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 (Giaccoia 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 (Giaccoia 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 (Moerman 1998; Grieve 1971; Remington and Wood 1918). Traditionally used in Herbal Medicine to help relieve symptoms of upper respiratory tract infections (Moerman 1998; Grieve 1971; Remington and Wood 1918). (Traditionally) used in Herbal Medicine to help fight off infections, especially of the upper respiratory tract (Hoffmann 2003; Mills and Bone 2000; Grieve 1971; Remington and Wood 1918). Supportive therapy in the treatment of upper respiratory tract infections (e.g. common colds) (Goel et al. 2004; Schulten et al. 2001; Brinkeborn et al. 1999; Hoheisel et al. 1997; Bräunig et al. 1992). Helps to relieve the symptoms and shorten the duration of upper respiratory tract infections (Goel et al. 2004; Schulten et al. 2001; Brinkeborn et al. 1999; Hoheisel et al. 1997; Bräunig et al. 1992). 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 (Goel et al. 2004; Schulten et al. 2001; Brinkeborn et al. 1999; Moerman 1998; Hoheisel et al. 1997; Bräunig et al. 1992; Grieve 1971; Remington and Wood 1918). 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) HERB TOP Table 2. Dose information for Echinacea purpurea herb top per day Subpopulation(s) Dried herb top (gram/day) Minimum Maximum Children 1 2-4 years 0.4 1.0 5-9 years 0.6 1.5 10-11 years 1.3 3.0 Adolescents 1 12-14 years 1.3 3.0 15-17 years 2.5 6.0 Adults 2,3 18 years and older 2.5 6.0 1 Children and adolescent doses were calculated as a proportion of the adult dose (JC 2018). The use of Echinacea purpurea herb top in children is supported by the following references: McIntyre 2005; Bove 2001; Schilcher 1997. 2 Adult dose supported by the following reference: Mills and Bone 2000. 3 Includes pregnant and breastfeeding women. ROOT Table 3. Dose information for Echinacea purpurea root per day Subpopulation(s) Dried root (gram/day) Minimum Maximum Children 1 2-4 years 0.15 0.8 5-9 years 0.23 1.1 10-11 years 0.45 2.3 Adolescents 1 12-14 years 0.45 2.3 15-17 years 0.90 4.5 Adults 2,3 18 years and older 0.90 4.5 1 Children and adolescent doses were calculated as a proportion of the adult dose (JC 2012). The use of Echinacea purpurea root in children is supported by the following references: McIntyre 2005; Bove 2001; Schilcher 1997 2 Adult dose supported by the following references: Mills and Bone 2000; Bräunig et al. 1992 3 Includes pregnant and breastfeeding women HERB TOP and ROOT Table 4. Dose information for Echinacea purpurea root per day Subpopulation(s) Dried herb top and root (gram/day) Minimum Maximum Children 1 2-4

years 0.5 0.9 5-9 years 0.8 1.4 10-11 years 1.5 2.8 Adolescents 1 12-14 years 1.5 2.8 15-17 years 3.0 5.5 Adults 2,3 18 years and older 3.0 5.5 1 Children and adolescent doses were calculated as a proportion of the adult dose (JC 2012). The use of *Echinacea purpurea* in children is supported by the following references: McIntyre 2005; Bove 2001; Schilcher 1997. 2 Adult dose supported by the following reference: Mills and Bone 2000. 3 Includes pregnant and breastfeeding women. Method of preparation: Juice HERB TOP Table 5. Dose information for the juice of *Echinacea purpurea* herb top per day Subpopulation(s) Juice of herb top (milliliter/day) Minimum Maximum Children 1 2-4 years 0.7 1.7 5-9 years 1.0 2.5 10-11 years 2.0 5.0 Adolescents 1 12-14 years 2.0 5.0 15-17 years 3.9 10.0 Adults 2,3 18 years and older 3.9 10.0 1 Children and adolescent doses were calculated as a proportion of the adult dose (JC 2018). The use of *Echinacea purpurea* herb top in children is supported by the following references: McIntyre 2005; Bove 2001; Schilcher 1997. 2 Adult dose supported by the following references: Schulten et al. 2001; Hoheisel et al. 1997. 3 Includes pregnant and breastfeeding women. Direction(s) for use Take at the first sign of infection (Goel et al. 2004; Schulten et al. 2001; Brinkeborn et al. 1999; Hoheisel et al. 1997). Duration(s) of Use Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 8 weeks (ESCAP 2003; Blumenthal et al. 2000). 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 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 and Bone 2005). Contraindication(s) No statement required. Known adverse reaction(s) Preparations containing herb top Stop use if hypersensitivity/allergy occurs (MHRA 2018; EMA 2010; Kligler 2003; WHO 1999). 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 Barnes J, Anderson LA, Philipson JD. Herbal Medicines, 3 rd edition. London (UK): The Pharmaceutical Press; 2007. Blumenthal M, Goldberg A, Brinkmann J, editors. 2000. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications. Bove M. 2001. An Encyclopedia of Natural Healing for Children and Infants. New Canaan (CT): Keats Publishing, Incorporated. Bräunig B, Dorn M, Limburg, Knick E, Bausendorf. 1992. *Echinacea purpurea* radix: zur Stärkung der körpereigenen Abwehr bei grippalen Infekten. Zeitschrift für Phytotherapie 13:713. Brinkeborn RM, Shah DV, Degenring FH. 1999. 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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)

Acceptable dosage forms by age group: Children 2 years:The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giacchia 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 (Giacchia 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.

DOSE(S)

2Adult dose supported by the following reference: Mills and Bone 2000. 3Includes pregnant and breastfeeding women. ROOT Table 3. Dose information forEchinacea purpurearoot per daySubpopulation(s)Dried root (gram/day)MinimumMaximumChildren12-4 years0.150.85-9 years0.231.110-11 years0.452.3Adolescents112-14 years0.452.315-17 years0.904.5Adults2,318 years and older0.904.5

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 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 and Bone 2005). Contraindication(s) No statement required. Known adverse reaction(s) Preparations containing herb top Stop use if hypersensitivity/allergy occurs (MHRA 2018; EMA 2010; Kligler 2003; WHO 1999).

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		
Echinacea purpurea	Eastern purple-coneflowerEchinaceaPurple coneflower	Echinacea purpurea	Herb top	DriedJuice
RootHerb top and root	Dried			

Population(s)	Dried herb top (gram/day)							
	Maximum							
	2-4 years	0.4	1.0					
Children 12-14 years	12-14 years	1.3	3.0	15-17 years	2.5	6.0	Adults 2,3	18 years and older
Children 1	12-14 years	1.3	3.0					

Population(s)	Dried root (gram/day)							
Children	Maximum							
Children 1	2-4 years	0.15	0.8					

ents1	12-14 years	0.45	2.3	15-17 years	0.90	4.5	Adults2,3	18 years and older	0
ents1	12-14 years	0.45	2.3						

ulation(s)	Dried herb top and root (gram/day)								
	Maximum								
	2-4 years	0.5	0.9						
nts1	12-14 years	1.5	2.8	15-17 years	3.0	5.5	Adults2,3	18 years and older	
nts1	12-14 years	1.5	2.8						

ulation(s)	Juice of herb top (milliliter/day)								
	Maximum								
	2-4 years	0.7	1.7						
s1	12-14 years	2.0	5.0	15-17 years	3.9	10.0	Adults2,3	18 years and older	
s1	12-14 years	2.0	5.0						