Thyme - Oral

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THYME - THYMUS VULGARIS - Oral 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 - 54 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 July 1, 2019 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 Thymus vulgaris Common thyme Conehead thyme English thyme French thyme Garden thyme Thyme Thymus vulgaris Flowering herb top Leaf Dried References: Proper name: USDA 2019; Common names: McGuffin et al. 2000, Wiersma and Léon 1999; Source materials: Hoffmann 2003, Blumenthal et al. 2000, WHO 1999. Route of Administration Oral (Mills and Bone 2005; Blumenthal et al. 2000) 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 1-2 years: The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giacoia et al. 2008; EMA/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; EMA/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 as an expectorant to help relieve the symptoms of bronchitis and mucus buildup of the (upper) respiratory tract (anti-catarrh) (EMA 2014; Bradley 2006; Mills and Bone 2005; ESCOP 2003; Hoffmann 2003). Traditionally used in Herbal Medicine to help relieve coughs (spasmolytic) (EMA 2014; Bradley 2006; Mills and Bone 2005; Blumenthal et al. 2000). Traditionally used in Herbal Medicine to help relieve indigestion/flatulent dyspepsia and colic (carminative) (Bradley 2006; Mills and Bone 2005; Hoffmann 2003). The following combined use(s) or purpose(s) is/are also acceptable: Traditionally used in Herbal Medicine to help relieve coughs (spasmolytic), the symptoms of bronchitis and mucus buildup of the (upper) respiratory tract (anti-catarrh) (EMA 2014; Bradley 2006; Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000). Note Claims for traditional use must include the term "Herbal Medicine", "Traditional Chinese Medicine", or "Ayurveda". Dose(s) Subpopulation(s) Children 1 to 11 years, Adolescents 12 to 17 years and Adults 18 years and older (EMA 2014; ESCOP 2003) Quantity(ies) Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion) 1 - 8.4 grams of dried leaf and/or flowering herb top, per day (Bradley 2006; Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000) Direction(s) for use No statement required. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) Consult a healthcare 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 are pregnant. 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 Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 13th edition. Washington (DC): American Pharmaceutical Association; 2002. Blumenthal M, Goldberg A, Brinkmann J, editors. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications; 2000. Bove, M. An Encyclopedia of Natural Healing for Children and Infants. 2nd edition.

New York (NY): McGraw-Hill Publishing, Incorporated; 2001. Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (UK): British Herbal Medicine Association; 2006. EMA 2014. European Medicines Agency. Community Monograph on Thymus vulgaris L. and Thymus zygis L., Herba. London (UK): EMA Committee on Herbal Medicinal Products (HMPC), February 06 2014. [Accessed 2019 May 23]. Available from: https://www.ema.europa.eu/en/documents/herbal-monograph/final-community-herbal-monograph-thymus-vulgaris-l-thymus-zygis-l-herba_en.pdf EMA/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. EMA/CHMP/PEG/194810/2005. [Accessed on 2019 May 23]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-formulations-choice-paediatric-population_en.pdf ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. Exeter (UK): European Scientific Cooperative on Phytotherapy and Thieme; 2003. 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. Hoffmann D. Medical Herbalism. Rochester (VT): Healing Arts Press; 2003. McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. Herbs of Commerce, 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000. McIntyre A. Herbal Treatment of Children - Western and Ayurvedic Perspectives. Toronto (ON): Elsevier Limited; 2005. Mills S, Bone K. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone; 2005. USDA 2019: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). Thymus vulgaris L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2019 May 23]. Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx WHO 1999: World Health Organization. WHO Monographs on Selected Medicinal Plants, Volume 1. Geneva (CHE): World Health Organization; 1999. Wiersema J, Léon B. World Economic Plants: A Standard Reference. Boco Raton (FL): CRC Press LLC; 1999. References Reviewed Basch E, Ulbricht C, Hammerness P, Bevins A, Sollars D. Thyme (Thymus vulgaris L.), thymol. Journal of Herbal Pharmacotherapy 2004;4(1):49-67. Brinker F. Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications; 2001. Brinker F. The Toxicity of Botanical Medicines. Sandy (OR): Eclectic Medical Publications; 2000. BHP 1983: British Herbal Pharmacopoeia. Cowling (UK): British Herbal Medical Association; 1983. Gruenwald J, Graubaum HJ, Busch R. Evaluation of the non-inferiority of a fixed combination of thyme fluid- and primrose root extract in comparison to a fixed combination of thyme fluid extract and primrose root tincture in patients with acute bronchitis. A single-blind, randomized, bi-centric clinical trial. Arzneimittel-Forschung 2006;56(8):574-581. Gruenwald J, Graubaum HJ, Busch R. Efficacy and tolerability of a fixed combination of thyme and primrose root in patients with acute bronchitis. A double-blind, randomized, placebo- controlled clinical trial. Arzneimittel-Forschung 2005;55(11):669-676. Kemmerich B, Eberhardt R, Stammer H. Efficacy and tolerability of a fluid extract combination of thyme herb and ivy leaves and matched placebo in adults suffering from acute bronchitis with productive cough. A prospective, double-blind, placebo-controlled clinical trial. Arzneimittel-Forschung 2006;56(9):652-660. McGuffin M, Hobbs C, Upton R, Goldberg A, editors. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press; 1997. Mills S, Bone K. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone; 2000. Schilcher, H. Phytotherapy in Paediatrics. Handbook for Physicians and Pharmacists. Stuttgart (D): Medpharm Scientific Publishers; 1997. Wichtl M, editor. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, 3rd edition. Stuttgart (D): Medpharm GmbH Scientific Publishers; 2004. 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)

Acceptable dosage forms by age group: Children 1-2 years:The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giacoia et al. 2008; EMA/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; EMA/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 healthcare 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 are pregnant. 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 (Mills and Bone 2005; Blumenthal et al. 2000)

Proper name(s)	Common name(s)	Source material(s)		
Proper name(s)	Part(s)	Preparation		
Thymus vulgaris	Common thymeConehead thymeEnglish thymeFrench thymeGarden thyme	Thymus vulgaris	Flowering herb topLeaf	Dried