Thyme - Buccal

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THYME - THYMUS VULGARIS - Buccal 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 - 49 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 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 on the label. Date March 28, 2025 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Preparation(s) Thymus vulgaris Common thyme Conehead thyme English thyme French thyme Garden thyme Thyme Thymus vulgaris Flowering herb top Leaf Dry References: Proper name: USDA 2024; Common names: Gardner and McGuffin 2013; Wiersma and León 1999; Source information: Hoffmann 2003; Blumenthal et al. 2000; WHO 1999. Route of Administration Buccal (Mills and Bone 2005; Blumenthal et al. 2000) Dosage Form(s) Acceptable dosage forms when used according to the requirements indicated in this monograph: Gargle; Loose; Mouthwash; Powder (Bradley 2006; Mills and Bone 2005; Hoffman 2003; BHP 1983). Use(s) or Purpose(s) (Traditionally) used in Herbal Medicine to help relieve minor mucous membrane inflammations of the mouth and throat (such as laryngitis and tonsillitis) (McIntyre 2005; Mills and Bone 2005; Hoffmann 2003; WHO 1999; Bove 1996). Notes For multi-ingredient products: To prevent the product from being represented as a “traditional medicine”, any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Thyme is traditionally used in Herbal Medicine to help relieve minor mucous membrane inflammations of the mouth and throat). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required. Dose(s) Subpopulation(s) Children 6-11 years, Adolescents 12-17 years, Adults 18 years and older (McIntyre 2005; Berardi et al. 2002; Bove 1996) Quantity(ies) Note: On the PLA form, quantities can be expressed as percentage weight by weight (% w/w), percentage weight by volume (% w/v) or percentage volume by volume (% v/v), depending on the product formulation. On the product label, quantities can also be expressed in other equivalent concentration units (e.g., mg/mL). Loose/Powder dosage forms Methods of preparation: Dry, Powdered 100% dried leaf and/or flowering herb top (Mills and Bone 2005; Bove 2001). Note: Powdered and dried leaves and/or flowering herb tops must be prepared as an infusion by the consumer prior to use (see direction for use) and must provide an equivalent of 30 to 50 milligrams dried leaves and/or flowering herb tops per 1 milliliter of finished product. Gargle/Mouthwash dosage forms Methods of preparation: Non-Standardized Liquid Extracts (Decoction, Decoction concentrate, Infusion, Infusion concentrate, Tincture) 10 - 100% dried leaf and/or flowering herb top extract preparation in the finished product (Mills and Bone 2005; Bove 2001). Note: The extract ratio must be between 1:2 and 1:20. The formulation must be prepared in a way which is equivalent to a quantity of 30 to 50 milligrams crude dried leaves and/or flowering herb tops per 1 milliliter of finished product. For example, for a tincture prepared with a 1:5 w/w ratio, the concentration of tincture in the finished product should be 15 to 25% (30 - 50 mg crude dried leaves and/or flowering herb tops * 5 w/w (dilution) = 150 - 250 mg liquid extract in 1 mL finished product = 15 - 25% w/v extract preparation in the finished product). Methods of preparation: Non-Standardized Dry Extracts (extract dry) 0.5 - 2.5% dried leaf and/or flowering herb top extract preparation in the finished product (Mills and Bone 2005; Bove 2001). Notes: The extract ratio must be between 2:1 and 10:1. The formulation must be prepared in a way which is equivalent to a quantity of 30 to 50 milligrams crude dried leaves and/or flowering herb tops for 1 milliliter of finished product. For example, for a dry extract prepared with a 4:1 w/w ratio, the concentration of dry extract in the finished product must be 0.75 to 1.25% (30 - 50 mg crude dried leaves and/or flowering herb tops / 4 w/w (concentration) = 7.5 - 12.5 mg dry extract in 1 mL finished product = 0.75 - 1.25% w/w extract preparation in the finished product). The minimum quantity of

0.5% still applies for more concentrated extracts, (e.g., a product containing 0.5% of a dry extract contains 5 mg dry extract in 1 gram finished product; 5 mg of a 10:1 w/w dry extract is equivalent to 50 mg crude dried leaves and/or flowering herb tops). Solvents allowed for this method of preparation are ethanol and/or water. Direction(s) for use Loose/Powder dosage forms Place [insert volume to be measured by consumer in order to obtain 4 to 6 grams dried leaves and/or flowering herb top, e.g., 1 teaspoon] of product in ½ cup (125 mL) of boiling water, infuse for 10 minutes and strain. Let cool. Use 1 tablespoon (15 mL) as a mouthwash/gargle, 3 times a day (Keukenmeester et al. 2012; Bradley 2006; BHP 1983). Gargle/Mouthwash dosage forms Use 1 tablespoon (15 mL) as a mouthwash/gargle, 3 times a day (Keukenmeester et al. 2012; Bradley 2006; BHP 1983). All products Do not swallow (Berardi et al. 2002). Supervise children when they use this product. Duration(s) of use No statement required. Risk Information Caution(s) and warning(s) Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or last (for) more than 7 days. 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations . 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. Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. 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. ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. 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Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch 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. 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. 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

RISK INFORMATION

Caution(s) and warning(s) Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or last (for) more than 7 days. 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 Must be established in accordance with the requirements described in theNatural Health Products Regulations.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations.

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. Example of Product Facts: Consult the Guidance Document,Labelling of Natural Health Productsfor more details.

REFERENCES

Route of Administration Buccal (Mills and Bone 2005; Blumenthal et al. 2000)

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Thymus vulgaris	Common thymeConehead thymeEnglish thymeFrench thymeGarden thymeThyme	Flowering herb topLeaf		Dry