European Pennyroyal

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EUROPEAN PENNYROYAL - MENTHA PULEGIUM 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 - 51 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 August 5, 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 Mentha pulegium European pennyroyal Lurk-in-the-Ditch Mosquito plant Pennyroyal Pudding Grass Pulegium Run-by-the-Ground Squaw Balm Squawmint Tickweed Mentha pulegium Herb top Dried References: Proper name: USDA 2019; Common names: McGuffin et al. 2000; Source material: BHP 1983. 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 for any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document. Use(s) or Purpose(s) (Traditionally) used in Herbal Medicine to aid digestion (stomachic) (Mills and Bone 2005; Hoffman 2003; Williamson et al. 1988; BHP 1983; Grieve 1971). (Traditionally) used in Herbal Medicine to help relieve indigestion/flatulent dyspepsia (carminative) (Mills and Bone 2005; Hoffman 2003; Williamson et al. 1988; BHP 1983). (Traditionally) used in Herbal Medicine to help relieve intestinal colic (anti-spasmodic) (Mills and Bone 2005; Hoffman 2003; Williamson et al. 1988; BHP 1983; Grieve 1971). The following combined use(s) or purpose(s) is/are also acceptable: (Traditionally) used in Herbal Medicine to help relieve indigestion/flatulent dyspepsia (carminative) and intestinal colic (anti-spasmodic) (Mills and Bone 2005; Hoffman 2003; Williamson et al. 1988; BHP 1983; Grieve 1971). Note Claims for traditional use must include the term "Herbal Medicine", "Traditional Chinese Medicine", or "Ayurveda". Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract, Fluid extract, Decoction, Infusion) 3 - 12 grams of dried herb top, per day; Not to exceed 4 grams of dried herb top per single dose (Mills and Bone 2005; Williamson et al. 1988; BHP 1983; Grieve 1971) Method of preparation: Tincture 0.6 - 1.2 grams of dried herb top, per day (Mills and Bone 2005; Hoffman 2003) Direction(s) for use No statement required. Duration(s) of Use No statement required. 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 liver or kidney problems (Brinker 2000; McGuffin et al. 1997). Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking acetaminophen (Brinker 2000). Contraindication(s) Do not use this product if you are pregnant or breastfeeding (Brinker 2010). 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 Barnes J, Anderson LA, Philipson JD. Herbal Medicines, 3 rd edition. London (GB): The Pharmaceutical Press; 2007. BHP 1983: British Herbal Pharmacopoeia. Cowling (GB): British Herbal Medical Association; 1983. Brinker F. Herbal Contraindications and Drug Interactions, 4 th edition. [Internet]. Sandy (OR): Eclectic Medical Publications; 2010. [Accessed 2019 June 17]. Available from: https://www.eclecticherb.com/herb-contraindications-drug-interactions Brinker F. The Toxicology of Botanical Medicines, 3 rd edition. Sandy (OR): Eclectic Medical Publications; 2000. Grieve M. A Modern Herbal, Volume 1. New York (NY): Dover Publications; 1971 [Reprint of 1931 Harcourt, Brace & Company publication]. Hoffmann D. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts

Press; 2003. McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. Herbs of Commerce, 2 nd edition. Silver Spring (MD): American Herbal Products Association; 2000. 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. 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). [Internet]. Mentha pulegium L. Lamiaceae. Beltsville (MD): National Germplasm Resources Laboratory. [Accessed 2019 June 17]. Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx Williamson EM, Evans FJ, Wren RC. Potter's New Cyclopaedia of Botanical Drugs and Preparations. Saffron Walden (GB): C.W. Daniel Company Limited; 1988. References Reviewed Bakerink JA, Gospe SM Jr, Dimand RJ, Eldridge MW. Multiple organ failure after ingestion of pennyroyal oil from herbal tea in two infants. Pediatrics 1996;98(5):944-947. Brinker F. Herb Contraindications and Drug Interactions, 3 rd edition, including extensive appendices addressing common problematic conditions, medications and nutritional supplements, and influences on Phase I, II & III metabolism with new appendix on botanicals as complementary adjuncts with drugs. Sandy (OR): Eclectic Medical Publications; 2001. Buechel DW, Haverlah VC, Gardner ME. Pennyroyal oil ingestion: report of a case. The Journal of the American Osteopathic Association 1983;82(10):793-794. Burkhard PR, Burkhardt K, Haenggeli CA, Landis T. Plant-induced seizures: reappearance of an old problem. Journal of Neurology 1999;246(8):667-670. Duke JA, Bogenschutz-Godwin MJ, duCellier J, Duke PK. Handbook of Medicinal Herbs, 2 nd edition. Boca Raton (FL): CRC Press; 2002. Felter HW, Lloyd JU. King's American Dispensatory, Volume 2, 18 th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original]. Gruenwald J. Brendler T, Jaenicke C, editors. PDR for Herbal Medicines, 2 nd edition. Montvale (NJ): Medical Economics Co.: 1998. Sullivan JB Jr, Rumack BH, Thomas H Jr, Peterson RG, Bryson P. Pennyroval oil poisoning and hepatotoxicity. Journal of the American Medical Association 1979;242(26):2873-2874. Thomassen D, Slattery JT, Nelson SD. Menthofuran-dependent and independent aspects of pulegone hepatotoxicity: roles of glutathione. The Journal of Pharmacology and Experimental Therapeutics 1990;253(2):567-572. Tisserand R. Balacs T. Essential oil safety. Edinburgh (GB): Churchill Livingstone; 1995. Vallance WB. Pennyroyal poisoning: A fatal case. Lancet 1955;269(6895):850-851. 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 for any age category listed in this monograph for the specified route of administration are listed 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 liver or kidney problems (Brinker 2000; McGuffin et al. 1997). Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking acetaminophen (Brinker 2000). Contraindication(s) Do not use this product if you are pregnant or breastfeeding (Brinker 2010). 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			
Mentha pulegium	European pennyroyalLurk-in-the-DitchMosq	uilloolephtmat Penhenginungal Pudding Gra	skil@ubetojpmR	un Dorijed he	-GroundSqu