

Lemon Balm

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LEMON BALM - MELISSA OFFICINALIS 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 - 45 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 April 26, 2024 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 material(s) Source material(s) Part(s) Preparation Melissa officinalis Balm Bee balm Lemon balm Melissa Melissa officinalis Herb top Dry References: Proper name: USDA 2023; Common names: USDA 2023; Source information: EMA 2014. 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. Use(s) or Purpose(s) (Traditionally) used in Herbal Medicine to help relieve restlessness and/or nervousness (which helps to promote sleep) (nervine/calimative) (EMA 2014; ESCOP 2009; Bradley 2006; Barnes et al. 2002; Blumenthal et al. 2000). (Traditionally) used in Herbal Medicine to help relieve symptoms of mild digestive disturbances/dyspepsia/indigestion (such as upset stomach, bloating and flatulence) (EMA 2014). Notes The above claims can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g. Traditionally used in Herbal Medicine to help relieve restlessness or nervousness and to help relieve digestive disturbances). 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. Lemon balm is traditionally used in Herbal Medicine to help relieve digestive disturbances). 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) Adolescents 12 to 17 years and Adults 18 years and older (EMA 2014) Quantity(ies) Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract*, Tincture, Fluid extract, Decoction, Infusion) 0.4 - 13.5 grams of dried herb top, per day (EMA 2014) *Note: Solvents allowed for the method of preparation "Dry extract" as part of this monograph are ethanol and/or water only. Direction(s) for use No statement required. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (EMA 2014). When using this product exercise caution if you drive or use machinery as you may experience drowsiness (EMA 2014). Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. 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 Barnes J, Anderson LA, Philipson JD. Herbal Medicines: A Guide for Healthcare Professionals, 2nd edition. London (GB): The Pharmaceutical Press; 2002. 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, 13 th edition. Washington (DC): American Pharmaceutical Association; 2002.

Blumenthal M, Goldberg A, Brinckmann J. Herbal Medicine: Expanded Commission E Monographs. American Botanical Council; 2000. Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (GB): British Herbal Medicine Association; 2006. DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM. Pharmacotherapy: A Pathophysiological Approach, 5 th edition. New York (NY): McGraw-Hill Co. Inc.; 2002 EMA 2014. European Medicines Agency. Melissae folium.. London (UK): EMA Committee on Herbal Medicinal Products (HMPC), 16 June2014. [Accessed 2023 October 27]. Available at: <https://www.ema.europa.eu/en/medicines/herbal/melissae-folium> ESCOP 2009: European Scientific Cooperative on Phytotherapy. ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition, Supplement 2009. Exeter (GB): European Scientific Cooperative on Phytotherapy in collaboration with Thieme. USDA 2023: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2023 September 11]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> Report a problem on this page Date modified: 2019-03-01

DOSAGE FORM(S)

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

RISK INFORMATION

Caution(s) and warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (EMA 2014).When using this product exercise caution if you drive or use machinery as you may experience drowsiness (EMA 2014).Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. 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 CONDITION(S)

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.

Proper name(s)	Common name(s)	Source material(s)		
Source material(s)	Part(s)	Preparation		
Melissa officinalis	BalmBee balmLemon balmMelissa	Melissa officinalis	Herb top	Dry