

NATURAL HEALTH PRODUCT

LEMON BALM – *MELISSA OFFICINALIS*

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(s)
<i>Melissa officinalis</i>	<ul style="list-style-type: none"> ▶ Balm ▶ Bee balm ▶ Lemon balm ▶ Melissa 	<i>Melissa officinalis</i>	Herb top	Dried

References: Proper name: USDA 2019; Common names: USDA 2019; Source material: 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 the age category listed in this monograph 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 a sleep aid (during times of mental stress) (EMA 2014).
- ▶ Traditionally used in Herbal Medicine to help relieve digestive disturbances (such as dyspepsia) (EMA 2014).

Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

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)

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

Sleep aid

Consult a health care practitioner/health care provider/health care professional/doctor/physician if sleeplessness persists continuously for more than 4 weeks (chronic insomnia) (Berardi et al. 2002; Dipiro et al. 2002).



All uses

- ▶ 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 are pregnant or breastfeeding (EMA 2014).
- ▶ Avoid taking with alcohol or products that cause drowsiness (EMA 2014).

Contraindication(s)

No statement required.

Known adverse reaction(s)

Some people may experience drowsiness. Exercise caution if operating heavy machinery, driving a motor vehicle or involved in activities requiring mental alertness (EMA 2014).

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.

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM. Pharmacotherapy: A Pathophysiological Approach, 5th 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 June 2014. [Accessed 2019 May 9]. Available at: <https://www.ema.europa.eu/en/medicines/herbal/melissae-folium>

USDA 2019: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). *Melissa officinalis* L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2019 May 9]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx>