Health Canada Santé Canada

NATURAL HEALTH PRODUCT

LINDEN – *TILIA*

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 March 31, 2023

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)
Tilia cordata	▶ Linden ▶ Littleleaf linden ▶ Small-leaf European linden ▶ Small-leaf lime ▶ Small-leaf lime tree ▶ Small-leaf linden ▶ Tilia	*Tilia cordata*	Flower	Dry
Tilia x europaea	▶ European Lime tree ▶ European linden ▶ Lime ▶ Lime tree ▶ Linden ▶ Tilia	*Tilia x europaea*		
Tilia platyphyllos	▶ Big-leaf linden ▶ Broadleaf lime ▶ Large-leaf lime ▶ Large-leaf linden ▶ Linden ▶ Tilia	*Tilia platyphyllos*		

References: Proper names: USDA 2019; Common names: McGuffin et al. 2000, Wiersema and León 1999; Source information: Bradley 1992, Felter and Lloyd 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 by age group:

Children 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 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 (nervine/calmative) (Wichtl 2004; Hoffmann 2003; Bradley 1992; Felter and Lloyd 1983).
- (Traditionally) used in Herbal Medicine to help relieve coughs, mucous buildup (catarrh) and irritation of the throat due to cold. (Wichtl 2004; Blumenthal et al. 2000; Bradley 1992; Felter and Lloyd 1983).

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

Dose(s)

Subpopulation(s)

As specified below.

Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Table 2. Dose information for the total amount of dried flower presented as grams per day

Subpopulation(s)		Dried flower (grams/day)	
		Minimum	Maximum
Children[1]	2-4 years	0.2	2
	5-9 years	0.4	3
	10-11 years	0.8	6
Adolescents[1]	12-14 years	0.8	6
	15-17 years	1.5	12
Adults[2]	18 years and older	1.5	12

[1]Children and adolescent doses were calculated as a fraction of the adult dose (JC 2019). The use of linden in children and adolescents is supported by the following references: McIntyre 2005, Schilcher 1997, Bove 1996.
[2]Adult dose supported by the following references: Hoffmann 2003, Blumenthal et al. 2000, Bradley 1992, Felter and Lloyd 1983.

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.

Contraindication(s)

No statement required.

Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs (Mills and Bone 2005; De Smet 1993).

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* (NHPR).

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

BHP 1996: British Herbal Pharmacopoeia. Bournemouth (UK): British Herbal Medicine Association; 1996.

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. New Canaan (CT): Keats Publishing, Incorporated; 1996.

Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 1. Bournemouth (UK): British Herbal Medicine Association; 1992.

De Smet PAGM, Keller K, Hansel R, Chandler RF, editors. Adverse Effects of Herbal Drugs, Volume 2. Berlin (DE): Springer-Verlag; 1993.

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 2019 June 27]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-formulations-choice-paediatric-population_en.pdf

Felter HW, Lloyd JU. King's American Dispensatory, Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original].

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.

JC 2019: Justice Canada. *Food and Drug Regulations*. (C.01.021). Ottawa (ON): Justice Canada; 2019. [Accessed2019 June 27]. Available from: https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/FullText.html

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.

Schilcher H. Phytotherapy in Paediatrics: Handbook for Physicians and Pharmacists. Stuttgart (D): Medpharm Scientific Publishers; 1997.

USDA 2019: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). *Tilia* x *europaea* L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2019 June 27]. Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx

Wichtl M, editor. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, 3rd edition. Stuttgart (D): Medpharm GmbH Scientific Publishers; 2004.

Wiersema J, León B. World Economic Plants: A Standard Reference. Boca Raton (FL): CRC Press LLC; 1999.

References reviewed

Barnes J, Anderson LA, Philipson JD. Herbal Medicines, 3rd edition. London (UK): The Pharmaceutical Press; 2007.

Hutchens AR. Indian Herbology of North America. Boston (MA): Shambhala Publications, Inc.; 1991.

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.