

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 label at the applicant’s discretion.
- The solidus (/) indicates that either term and/or statement may be selected on the label.

Date

December 19, 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)
<i>Tilia cordata</i>	<ul style="list-style-type: none"> • Linden • Littleleaf linden • Small-leaf European linden • Small-leaf lime • Small-leaf lime tree • Small-leaf linden • Tilia 	<i>Tilia cordata</i>	Flower	Dry
<i>Tilia x europaea</i>	<ul style="list-style-type: none"> • European Lime tree • European linden • Lime • Lime tree • Linden • Tilia 	<i>Tilia x europaea</i>		
<i>Tilia platyphyllos</i>	<ul style="list-style-type: none"> • Big-leaf linden • Broadleaf lime • Large-leaf lime • Large-leaf linden • Linden • Tilia 	<i>Tilia platyphyllos</i>		

References: Proper names: USDA 2024; Common names: Gardner and McGuffin 2013, 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 (Giacoa 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 (Giacoa 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/calmativ) (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).

Notes

- The above uses 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, coughs, mucous buildup and irritation of the throat due to cold).
- **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., Linden is traditionally used in Herbal Medicine to help relieve restlessness and/or nervousness).
 - 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)

As specified below.

Quantity(ies)

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

Table 2. Dose information (grams) for the total amount of dried flower per day

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

¹Children 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.

²Adult dose supported by the following references: Hoffmann 2003, Blumenthal et al. 2000, Bradley 1992, Felter and Lloyd 1983.

***Note:** Solvents allowed for the method of preparation “Non-Standardized Extracts (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 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*.

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.

Product Facts
Medicinal ingredients in each capsule <i>Tilia cordata</i> (Linden) X:1 extract XX mg Equivalent to YY g of dried flower <i>Tilia x europaea</i> (Tilia – flower) XX mg
Uses • Traditionally used in Herbal Medicine to help relieve restlessness and/or nervousness.
Warnings
If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame Stop use if allergy occurs. Ask a health care practitioner if symptoms persist or worsen.
Directions Adults 18 years and older: • Take X capsule(s), X time(s) per day.
Other information (Add storage information)
Non-medicinal ingredients List all NMIs
Questions? (Call) 1-XXX-XXX-XXXX

¹This section can be removed from the table if the product contains no allergen or aspartame.

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. [Accessed 2024 November 20]. 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].

Gardner Z, McGuffin M, editors. American Herbal Products Association's Botanical Safety Handbook. 2nd edition. Boca Ration (FL): Taylor and Francis Group; 2013.

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. [Accessed 2024 November 20]. Available from: https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/FullText.html

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 2024: United States Department of Agriculture, Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) – Global. U.S. National Plant Germplasm System. [Accessed 2024 November 14]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch>

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.

Mills S, Bone K. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone; 2000.