

#### 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	Tilia cordata	Flower	Dry
	<ul><li>Littleleaf linden</li></ul>			
	► Small-leaf European			
	linden			
	Small-leaf lime			
	<ul><li>Small-leaf lime tree</li></ul>			
	Small-leaf linden			
	► Tilia			
Tilia x europaea	<ul><li>European Lime tree</li></ul>	Tilia x europaea		
	<ul><li>European linden</li></ul>			
	▶ Lime			
	► Lime tree			
	► Linden			
	► Tilia			
Tilia platyphyllos	<ul><li>Big-leaf linden</li></ul>	Tilia platyphyllos		
	<ul><li>Broadleaf lime</li></ul>			
	<ul><li>Large-leaf lime</li></ul>			
	<ul><li>Large-leaf linden</li></ul>			
	► Linden			
	► Tilia			

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 webbased 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).

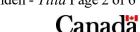
#### Note

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 <sup>1</sup>	2-4 years	0.2	2
	5-9 years	0.4	3
	10-11 years	0.8	6
Adolescents <sup>1</sup>	12-14 years	0.8	6
	15-17 years	1.5	12
Adults <sup>2</sup>	18 years and older	1.5	12

<sup>&</sup>lt;sup>1</sup>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.

## Direction(s) for use

No statement required.

## **Duration(s) of use**

No statement required.

### **Risk information**

### Caution(s) and warning(s)

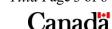
Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.

## **Contraindication(s)**

No statement required.

# **Known adverse reaction(s)**

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



<sup>&</sup>lt;sup>2</sup>Adult dose supported by the following references: Hoffmann 2003, Blumenthal et al. 2000, Bradley 1992, Felter and Lloyd 1983.



## 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

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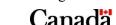
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McIntyre A. Herbal Treatment of Children - Western and Ayurvedic Perspectives. Toronto (ON): Elsevier Limited; 2005.

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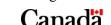
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