NATURAL HEALTH PRODUCT

LINDEN, LARGE-LEAF – *TILIA PLATYPHYLLOS*

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 18, 2017

**Proper name(s):**

*Tilia platyphyllos* Scop. (Tiliaceae) (USDA 2008)

**Common name(s):**

- Linden (McGuffin et al. 2000; Wiersema and León 1999)
- Large-leaf linden (McGuffin et al. 2000; Wiersema and León 1999)
- Large-leaf lime (McGuffin et al. 2000; Wiersema and León 1999)
- Tilia (McGuffin et al. 2000; Wiersema and León 1999)

**Source material(s):**

Flower (Bradley 1992; Felter and Lloyd 1983 [1898])

**Route(s) of administration:**

Oral

**Dosage form(s):**

This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.
Dosage forms by age group:

- **Children 2 years**: The acceptable dosage forms are limited to emulsion/suspension and solution/drops (Giaccoia et al. 2008; EMEA/CHMP 2006).

- **Children 3-5 years**: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giaccoia et al. 2008; EMEA/CHMP 2006).

- **Children 6-12 years, Adolescents 13-17 years, and Adults ≥ 18 years**: The acceptable dosage forms include, but are not limited to capsules, chewables (e.g., gummies, tablets), liquids, powders, strips or tablets.

**Use(s) or Purpose(s):**

- Traditionally used in Herbal Medicine as a nervine to help relieve nervousness (Wichtl 2004; Hoffmann 2003; Bradley 1992) and restlessness (Bradley 1992; Felter and Lloyd 1983[1898]).

- Traditionally used in Herbal Medicine to help relieve coughs and irritation of the throat in colds and catarrh of the respiratory tract (Wichtl 2004; Blumenthal et al. 2000; Bradley 1992; Felter and Lloyd 1983[1898]).

**Dose(s):**

Table 1: Dose information for linden flower presented as dose per day

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Linden flower (g/day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Minimum</td>
</tr>
<tr>
<td>Children¹</td>
<td>2-4 y</td>
</tr>
<tr>
<td>Children and adolescents¹</td>
<td>5-9 y</td>
</tr>
<tr>
<td>Adolescents¹</td>
<td>10-14 y</td>
</tr>
<tr>
<td>Adolescents and adults¹,²,³</td>
<td>≥ 15 y</td>
</tr>
</tbody>
</table>

¹ Children and adolescent doses were calculated as a fraction of the adult dose (JC 2008). 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[1898].
³ Includes pregnant and breastfeeding women

See Appendix 1 for examples of appropriate dosage preparations, frequencies of use and directions for use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

**Duration of use:**

No statement required.
Risk information:

Caution(s) and warning(s):
Consult a health care practitioner if symptoms persist or worsen.

Contraindication(s):
No statement required.

Known adverse reaction(s):
Hypersensitivity and/or an allergy are known to occur; in which case, discontinue use (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.

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:


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


References reviewed:


Appendix 1: Examples of appropriate dosage preparations, frequencies of use and directions for use

Dried flower: 2-4 g, per day (Blumenthal et al. 2000)

Infusion:
- 1.8 g dried flower, 3 times per day (Hoffmann 2003)
- 1.8-2 g dried flower, 1-2 times per day (Blumenthal et al. 2000)
- 2-4 g dried flower, 3 times per day (Bradley 1992)
- 2-2.6 g (30 or 40 grains) dried flower, per day (Felter and Lloyd 1983 [1898])

**Directions for use:** Pour 150 ml to 473 ml (1 pint) of boiling water over dried flowers and infuse for 10-15 minutes (Hoffmann 2003; Blumenthal et al. 2000; Felter and Lloyd 1983 [1898]).

1.8 g = 1 tsp. (Wichtl 2004)

Fluidextract:
- 2 g dried equivalent, 1-2 times per day
  (1:1, 2 ml) (Blumenthal et al. 2000)
- 2-4 g dried equivalent, 3 times per day
  (1:1, 25% alcohol, 2-4 ml) (Bradley 1992)

Tincture:
- 0.5-1 g dried equivalent, 3 times per day
  (1:5, 40% alcohol, 2.5-5 ml) (Hoffmann 2003)
- 2 g dried equivalent, 1-2 times per day
  (1:5, 10 ml) (Blumenthal et al. 2000)
- 0.8-2 g dried equivalent, 3 times per day
  (1:5, 25% alcohol, 4-10 ml) (Bradley 1992)