



## NATURAL HEALTH PRODUCT

### FLAXSEED- *LINUM USITATISSIMUM*

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

September 25, 2018

#### 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)
<i>Linum usitatissimum</i>	<ul style="list-style-type: none"> <li>▶ Flax</li> <li>▶ Flaxseed</li> <li>▶ Linseed</li> </ul>	<i>Linum usitatissimum</i>	Seed

References: Proper name: USDA 2018; Common name: Sweetman 2007, McGuffin et al. 2000; Source material: Blumenthal et al. 2000.

#### 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)

- ▶ Source of essential fatty acids for the maintenance of good health (IOM 2006).
- ▶ Source of omega-3 fatty acids for the maintenance of good health (IOM 2006).
- ▶ Source of alpha-linolenic acid (ALA) for the maintenance of good health (IOM 2006).
- ▶ Source of omega-6 fatty acids for the maintenance of good health (IOM 2006).
- ▶ Source of linoleic acid (LA) for the maintenance of good health (IOM 2006).
- ▶ (Used in Herbal Medicine as a) bulk-forming laxative (Blumenthal et al. 2000; BHP 1996).
- ▶ (Used in Herbal Medicine to) promote(s) bowel movement by increasing bulk volume and water content (Pray 2006; ESCOP 2003; Gennaro 2000; McGuffin et al. 1997).
- ▶ (Used in Herbal Medicine to) provide(s) gentle relief of constipation and/or irregularity (EMEA 2006; Pray 2006; ESCOP 2003; Gennaro 2000).
- ▶ (Used in Herbal Medicine to) help(s) reduce blood lipid levels in adults (Patade et al. 2008; Lucas et al. 2002; Jenkins et al. 1999; Cunnane et al. 1993).
- ▶ Source of/ Provides antioxidants (Kinniry et al. 2006; Rajesha et al. 2006; Prasad 2005; Prasad 1997).

The following combined use(s) or purpose(s) is/are also acceptable:

- ▶ (Used in Herbal Medicine as a) bulk-forming laxative to promote bowel movements and to provide gentle relief of constipation and/or irregularity (EMEA 2006; Pray 2006; ESCOP 2003; Gennaro 2000; McGuffin et al. 1997).

### Dose(s)

### Subpopulation(s)

As specified below.

### Quantity(ies)

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

Table 2. Dose information of Flaxseed presented as dose per day and single dose, based on uses or purposes, subpopulations.

Uses or Purposes	Subpopulations <sup>1,2,3</sup>		Seed (g)/day		Seed (g)/single dose
			Min.	Max.	Max. single dose
Source of essential fatty acids, omega-3 fatty acids, and/or ALA	Children	6-11 years	0.18	15	7.5
	Adolescents	12-17 years	0.36	45	22.5
	Adults	18 years and older	0.36	45	22.5
Source of omega-6 fatty acids and/or LA	Children	6-11 years	7	15	7.5
	Adolescents	12-17 years	14	45	22.5
	Adults	18 years and older	14	45	22.5
Laxative	Children	6-11 years	4.5	15	7.5
	Adolescents	12-17 years	10	45	22.5
	Adults	18 years and older	10	45	22.5
Provides antioxidants	Children	6-11 years	>0	15	7.5
	Adolescents	12-17 years	>0	45	22.5
	Adults	18 years and older	>0	45	22.5
Reduces blood lipid levels	Adolescents	12-17 years	30	45	22.5
	Adults	18 years and older	30	45	22.5

<sup>1</sup> Children and adolescent doses were calculated as a proportion of the adult dose (ESCOP 2003; Boon 2000). The use of Flaxseed in children and adolescents is supported by the following references: ESCOP 2003; Bove 2001; Boon 2000; Schilcher 1997.

<sup>2</sup> Adult dose supported by the following references: Patade et al. 2008; EMEA 2006; IOM 2006; ESCOP 2003; Lucas et al. 2002; Jenkins et al. 1999; Cunnane et al. 1993.

<sup>3</sup> Includes pregnant and breastfeeding women (Mills et al. 2006; ESCOP 2003).

Methods of preparation: Standardized extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

If potencies are declared, the only acceptable potencies are as follows:

- ▶ 20-30 % ALA (CGC 2008; HC 2008; Cunnane 1993)
- ▶ 5-7 % LA (HC 2008)

## Direction(s) for use

### *Products providing 5 g or more of flaxseed per day*

- ▶ For each dose, drink (or mix with) at least 150 ml of liquid (EMEA 2006; ESCOP 2003).
- ▶ Take 2 hours before or after taking other medications (Sweetman 2007; EMEA 2006).

### *Laxative products*

- ▶ Optional: Take during the day (not immediately prior to bedtime) (EMEA 2006).
- ▶ Effects observed 12-24 hours after first dose, and may take 2-3 days (EMEA 2006; ESCOP 2003).

### *Optional (for products with a dosage range)*

Minimum daily dose may be increased, up to the maximum daily dose, until desired effect is obtained.

## Duration(s) of use

No statement required.

## Risk information

:

## Caution(s) and warning(s)

### *Products providing 5 g or more of flaxseed per day*

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician immediately if you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product (EMEA 2006).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are experiencing a sudden change in bowel habits that has persisted for more than 2 weeks, undiagnosed rectal bleeding, or have failed to defaecate following the use of a laxative product (EMEA 2006).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have symptoms such as abdominal pain, nausea, vomiting or fever (as these could be signs of other serious conditions) (EMEA 2006; ESCOP 2003; Brinker 2010).

- ▶ Consult a health care practitioner prior to use if you have diabetes or difficulty swallowing (EMEA 2006; ESCOP 2003).

### *Laxative*

Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or if laxative effect does not occur within seven days (Pray 2006; Repchinsky 2002).

### **Contraindication(s)**

No statement required.

### **Known adverse reaction(s)**

#### *All products*

Stop use if hypersensitivity/allergy occurs (EMEA 2006; León et al. 2003).

#### *Products providing 5 g or more of flaxseed per day*

May cause temporary gas and bloating (EMEA 2006).

### **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 condition(s)**

#### *All products, except those encapsulated*

Refrigerate after opening (Nykter et al. 2006; Lukaszewicz et al. 2003).

### **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.

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