



## NATURAL HEALTH PRODUCT

### FLAXSEED OIL

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 labels at the applicants' 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 Oil</li> <li>▶ Flaxseed Oil</li> <li>▶ Linseed Oil</li> </ul>	<i>Linum usitatissimum</i>	Seed

References: Proper name: USDA 2018; Common names: Ph. Eur. 2008, Sweetman 2007, Hoffman 2003, Hendler and Rorvik 2001; Source material: Sweetman 2007.

#### 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 (Giacoaia et al. 2008; EMEA/CHMP 2006).

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

**Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older:** The acceptable dosage forms for this age category and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

### **Use(s) or Purpose(s)**

- ▶ Source of essential fatty acids (alpha-linolenic acid (ALA) and linoleic acid (LA)) 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).

### **Dose(s)**

#### **Subpopulation(s)**

As specified below.

#### **Quantity(ies)**

Methods of preparation: Non-standardized fixed oil

Table 2. Dose information for Linseed oil presented as dose per day, based on uses or purposes and subpopulations.

Uses or Purposes	Subpopulations <sup>1,2,3</sup>		Oil g/day		Oil ml/day	
			Min.	Max.	Min.	Max.
Source of essential fatty acids, omega-3 fatty acids, and/or ALA	Children	2-4 years	0.04	5.33	0.17	5.67
		5-9 years	0.06	8	0.25	8.50
		10-11 years	0.12	16	0.5	17
	Adolescents	12-14 years	0.12	16	0.5	17
		15-17 years	0.23	32	1	34
	Adults	18 years and older	0.23	32	1	34
Source of omega-6 fatty acids and/or LA	Children	2-4 years	1.28	5.33	1.33	5.67
		5-9 years	1.93	8	2	8.50
		10-11 years	3.85	16	4	17
	Adolescents	12-14 years	3.85	16	4	17
		15-17 years	7.70	32	8	34
	Adults	18 years and older	7.70	32	8	34

<sup>1</sup> Children and adolescent doses were calculated as a proportion of the adult dose (JC 2018). The use of Flaxseed oil in children and adolescents is supported by Bove 2001.

<sup>2</sup> Adult dose supported by the following references: IOM 2006; Schwab et al. 2006; Nordström et al. 1995; Kelley et al. 1993; Fischer et al. 1984.

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

Method of preparation: Standardized fixed oil

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

- ▶ 35-65 % ALA (CGC 2008; HC 2008; Ph. Eur. 2008; Hoffmann 2003)
- ▶ 11-24 % LA (HC 2008; Ph. Eur. 2008; Hoffmann 2003)

The following potency is considered as additional information and can be included on the label:

- ▶ 11-35% oleic acid (Ph. Eur. 2008)

### Direction(s) for use

No statement required.



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

No statement required.

### **Risk information**

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

No statement required.

#### **Contraindication(s)**

No statement required.

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

No statement required.

### **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.
- ▶ For products indicating one or more of the optional potencies listed in the dose section, an assay must be performed in order to confirm the potency(ies).



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