



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 label 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 on the label.

Date

April 25, 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)
<i>Linum usitatissimum</i>	- Flax Oil - Flaxseed Oil - Linseed Oil	<i>Linum usitatissimum</i>	Seed

References: Proper name: USDA 2024; Common names: Brayfield and Cadart 2024, Ph. Eur. 2023, Hoffman 2003, Hendler and Rorvik 2001; Source information: Brayfield and Cadart 2024.

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; EMA/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; 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)

All products

- 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).

Note: The above uses can be combined on the product label (e.g., Source of omega-3 and omega-6 fatty acids for the maintenance of good health).

Dose(s)

Subpopulation(s)

As specified below.

Quantity(ies)

Method 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 ^{1,2}		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



Uses or Purposes	Subpopulations ^{1,2}		Oil g/day		Oil ml/day	
			Min.	Max.	Min.	Max.
	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

¹Children and adolescent doses were calculated as a proportion of the adult dose (JC 2024). The use of Flaxseed oil in children and adolescents is supported by Bove 2001.

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

Method of preparation: Standardized fixed oil

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

- 35-65 % ALA (Ph. Eur. 2023; CGC 2022; HC 2008; Hoffmann 2003)
- 11-24 % LA (Ph. Eur. 2023; HC 2008; Hoffmann 2003)

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

- 11-35% oleic acid (Ph. Eur. 2023)
- XX% total omega-3 fatty acids
- XX% total omega-6 fatty acids

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)

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

All products, except those encapsulated

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

All products (information for industry; not for labelling)

To be packaged in airtight container, protected from light (Ph.Eur. 2023; USP-NF 2023).

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).



EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts	
Medicinal ingredient in each scoop	
<i>Linum usitatissimum</i> (Flaxseed oil – Seed)	XX g
Uses • Source of essential fatty acids for the maintenance of good health. • Source of omega-3 fatty acids for the maintenance of good health. • Source of alpha-linolenic acid for the maintenance of good health. • Source of omega-6 fatty acids for the maintenance of good health. • Source of linoleic acid for the maintenance of good health.	
Warnings	
If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites Contains aspartame	
Directions Adults 18 years and older: Take X scoop(s), X time(s) per day.	
Other information Refrigerate after opening ² .	
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.

²All products, except those encapsulated.

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