Flaxseed oil

Source: https://webprod.hc-sc.gc.ca/nhpid-bdipsn/atReq?atid=flaxseed.lin.oil.huile2⟨=eng

Extracted: 2025-08-26T06:32:59.097797

FLAXSEED OIL Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 70 KB) 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 applicant's 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) Linum usitatissimum Flax Oil Flaxseed Oil Linseed Oil Linum usitatissimum 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 Form(s)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 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 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 1 Children 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. 2 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. 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 conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations . All products, except those encapsulated Refrigerate after opening (Nykter 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. References Cited Bove M. An Encyclopedia of Natural Healing for Children and Infants. 2nd edition. Toronto (ON): McGraw-Hill; 2001. Brayfield A, Cadart C, editors. Martindale: The Complete Drug Reference. London (GB): Pharmaceutical Press; 2024. [Accessed 2024 November 21]. Available from: https://www.medicinescomplete.com/#/browse/martindale CGC 2022: Canadian Grain Commission. Quality of western Canadian Flaxseed 2022. Winnipeg (MB): Canadian Grain Commission. [Accessed 2024 December 12]. Available from: https://publications.gc.ca/collections/collection_2023/ccg-cgc/A92-15-2022-eng.pdf CNF 2023: Canadian Nutrient File, Food and Nutrition, Health Canada. [Accessed 2024 October 1]. Available from: https://food-nutrition.canada.ca/cnf-fce EMA/CHMP 2006: European Medicines Agency: Pre-authorization Evaluation of Medicines for Human Use. Committee for Medicinal Products for Human Use. Reflection Paper: Formulations of choice for the paediatric population.[Accessed 2024 October 1]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-formulations-choice-paediatric-population_en.pdf Fischer VS, Honigmann G, Hora C, Schimke E, Beitz J, Hanefeld M, Leonhardt W, Haller H, Förster W, Schliack V. Results of linseed oil and olive therapy in hyperlipoproteinemia patients. Deutsche Zaitschrift für Verdauungs - und Stoffwechselkrankheiten 1984;44(5):245-251. Gardner Z, McGuffin M, editors. 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Eur. 2023: European Pharmacopoeia. 11th edition. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM); 2023. RSC 2024: Royal Society of Chemistry: The Merck Index Online [Accessed 2024 October 1]. Available from: https://merckindex.rsc.org/ Schwab US, Callaway JC, Erkkilä AT, Gynther J, Uusitupa MI, Järvinen T. Effects of hempseed and flaxseed oils on the profile of serum lipids, serum total and lipoprotein lipid concentrations and haemostatic factors. European Journal of Nutrition 2006;45(8):470-477. USDA 2024: United States Department of Agriculture, Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2024 October 1]. Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch USP-NF 2023: United States Pharmacopeia and the National Formulary. Rockville (MD): The United States Pharmacopeial Convention, Inc.; 2023. 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blood coagulation and fibrinolytic factors in moderately hyperlipidemic humans. Journal of Nutrition 2003;133(7):2210-2213. Freese R, Mutanen M. Alpha-linolenic acid and marine long-chain n-3 fatty acids differ only slightly in their effects on hemostatic factors in healthy subjects. American Journal of Clinical Nutrition 1997;66(3):591-598. Hallund J, Ravn-Haren G, Bugel S, Tholstrup T, Tetens I. A lignan complex isolated from flaxseed does not affect plasma lipid concentrations or antioxidant capacity in healthy postmenopausal women. The Journal of Nutrition 2006;136(1):112-116. Jenkins DJ, Kendall CW, Vuksan V, Augustin LS, Mehling C, Parker T, Vidgen E, Lee B, Faulkner D, Seyler H, Josse R, Leiter LA, Connelly PW, Fulgoni V 3rd. Effect of wheat bran on serum lipids: influence of particle size and wheat protein. Journal of the American College of Nutrition 1999;18(2):159-165. Jenkins DJA, Wolever TMS, Leeds AR, Gassull MA, Haisman P, Dilawari J, Goff DV, Metz GL, Alberti KG. Dietary fibres, fibre analogues, and glucose tolerance: importance of viscosity. British Medical Journal 1978;1(6124):1392-1398. Lemay A, Dodin S, Kadri N, Jacques H, Forest J-C. Flaxseed dietary supplement versus hormone replacement therapy in hypercholesterolemic menopausal women. The American Colege of Obstetricians and Gynecologists 2002;100(3):495-504. Li D, Sinclair A, Wilson A, Nakkote S, Kelly F, Abedin L, Mann N, Turner A. Effect of dietary alpha-linolenic acid on thrombotic risk factors in vegetarian men. American Journal of Clinical Nutrition 1999;69(5):872-882. Mills E, Duguoa J, Perri D, Koren G. Herbal Medicines in Pregnancy and Lactation. An Evidence-Based Approach. New York (NY): Taylor and Francis; 2006. Mills S, Bone K. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone; 2005. Pagana CD, Pagana TJ. Mosby's Manual of Diagnostic and Laboratory Tests. 2nd edition. St. Louis (MO): Mosby, Inc.; 2002. Pan A, Sun J, Chen Y, Ye X, Li H, Yu Z, Wang Y, Gu W, Zhang X, Chen X, Demark-Wahnefried W, Liu Y, Lin X. Effects of a flaxseed-derived lignan supplement in Type 2 diabetic patients: a randomized, double-blind, cross-over trial. PLoS ONE 2007;11:1-7. Sanders TA, Lewis F, Slaughter S, Griffin BA, Griffin M, Davies I, Millward DJ, Cooper JA, Miller GJ. Effect of varying the ratio of n-6 to n-3 fatty acids by increasing the dietary intake of alpha-linolenic acid, eicosapentaenoic and docosahexaenoic acid or both on fibrinogen and clotting factors VII and XII in persons aged 45-70 y: the OPTILIP Study. American Journal of Clinical Nutrition 2006;84(3):513-522. Simmer K, Schulzke SM, Patole S. Long-chain polyunsaturated fatty acid supplementation in preterm infants. Cochrane Database Syst Rev. 2008 Jan 23;(1):CD000375. Update of: Cochrane Database Syst Rev. 2004;(1):CD000375. Zhang W, Wang X, Liu Y, Tian H, Flickinger B, Empie MW, Sun SZ. Dietary flaxseed lignan extract lowers plasma cholesterol and glucose concentrations in hypercholestrolaemic subjects. British Journal of Nutrition 2008;99(6):1301-1309. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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 theNatural Health Products Regulations. All products, except those encapsulated Refrigerate after opening (Nykter 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).

DOSAGE FORM(S)

Acceptable Dosage Form(s)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 web-based Product Licence Application form for Compendial applications.

USE(S) OR PURPOSE(S)

Uses or PurposesSubpopulations1,2Oil g/dayOil ml/dayMin.Max.Min.Max. Source of essential fatty acids, omega-3 fatty acids, and/or ALAChildren2-4 years0.045.330.175.675-9 years0.0680.258.5010-11 years0.12160.517Adolescents12-14 years0.12160.51715-17 years0.2332134Adults18 years and older0.2332134Source of omega-6 fatty acids and/or LAChildren2-4 years1.285.331.335.675-9 years1.93828.5010-11 years3.8516417Adolescents12-14 years3.851641715-17 years7.7032834Adults18 years and older7.7032834

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 conditions Must be established in accordance with the requirements described in theNatural Health Products Regulations. All products, except those encapsulated Refrigerate after opening (Nykter 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).

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations. All products, except those encapsulated Refrigerate after opening (Nykter 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:

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source information	
Source material(s)	Part(s)		
Linum usitatissimum	Flax OilFlaxseed OilLinseed Oil	Linum usitatissimum	Seed

Uses or Purposes	Subpopulations1,2	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		
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	