Evening Primrose Oil

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EVENING PRIMROSE 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 - 50 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 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) Oenothera biennis Evening Primrose Oil Oenothera Biennis (Evening Primrose) Oil Primrose oil Oenothera biennis Seed References: Proper name: USDA 2018; Common names: Sweetman 2007, McGuffin et al. 2000; Source material: Sweetman 2007, WHO 2002. 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 any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document. Use(s) or Purpose(s) Source of essential fatty acids for the maintenance of good health (Sweetman 2007; IOM 2006). Source of omega-6 fatty acids for the maintenance of good health (EP 2008; IOM 2006; Mills and Bone 2005; WHO 2002). Source of linoleic acid for the maintenance of good health (EP 2008; IOM 2006; Mills and Bone 2005; WHO 2002). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Method of preparation: Non-standardized fixed oil 1.3-6 grams of evening primrose oil, per day (EP 2008; Sweetman 2007; IOM 2006; Mills and Bone 2005; WHO 2002; Keen et al. 1993). Method of preparation: Standardized fixed oil 1.3-6 grams of evening primrose oil, per day (EP 2008; Sweetman 2007; IOM 2006; Mills and Bone 2005; WHO 2002; Keen et al. 1993) standardized to: 7-14% gamma-linolenic/gamolenic acid (GLA), and/or 65-85% linoleic acid (LA). 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 No statement required. 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 EP 2008: European Pharmacopoeia, 6 th edition, Volume 2. Strasbourg (France): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM). IOM 2003: Institute of Medicine. Committee on Food Chemicals Codex, Food and Nutrition Board, Institute of Medicine. Food Chemicals Codex, 5 th edition. Washington (DC): National Academies Press. IOM 2006: Institute of Medicine. Otten JJ, Pitzi Hellwig J, Meyers LD, editors. 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Chasteberry tree? Seizures! Hospital Pharmacy 31:15531554. Vaddadi KS. 1981. The use of gamma-linolenic acid and linoleic acid to differentiate between temporal lobe epilepsy and schizophrenia. Prostaglandins and Medicine 6:375-379. Van Gool CJ, Zeegers MP, Thijs C. 2004. Oral essential fatty acid supplementation in atopic dermatitis - a meta-analysis of placebo-controlled trials. The British Journal of Dermatology 150:728-740. Veale D, Torley H, Richards IM, O'Dowd A, Fitzsimons C, Belch JJ, Sturrock RD. 1994. A double-blind placebo controlled trial of Efamol® Marine on skin and joint symptoms of psoriatic arthritis. British Journal of Rheumatology 33(10):8-954. Vericel E, Lagarde M, Mendy F, Courpron PH, Dechavanne M. 1986. Effects of gammalinolenic acid intake on platelet functions in elderly people. Thrombosis Research 42:499-509. Walker T, Singh PK, Wyatt KM, O'Brien PM. 1999. The effect of prostanoid precursors and inhibitors on platelet angiotensin II binding. 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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 No statement required.

DOSAGE FORM(S)

Acceptable dosage forms for any age category listed in this monograph for the specified route of administration are listed in the Compendium of Monographs Guidance Document.

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 No statement required.

STORAGE CONDITION(S)

No statement required.

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

Route of Administration Oral

Proper name(s)	Common name(s)	Source material(s)	
Proper name(s)	Part(s)		
Oenothera biennis	Evening Primrose OilOenothera Biennis (Ev	e Qiego Phienzolsie) n OiistPrimrose oil	Seed