

NATURAL HEALTH PRODUCT

EVENING PRIMROSE 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 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>Oenothera biennis</i>	<ul style="list-style-type: none"> ▶ Evening Primrose Oil ▶ Oenothera Biennis (Evening Primrose) Oil ▶ Primrose oil 	<i>Oenothera biennis</i>	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 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 (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 Product Ingredient 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, 6th 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, 5th edition. Washington (DC): National Academies Press.

IOM 2006: Institute of Medicine. Otten JJ, Pizzi Hellwig J, Meyers LD, editors. Dietary Reference Intakes: The Essential Guide to Nutrient Requirements. Washington (DC): National Academies Press.

Keen H, Payan J, Allawi J, Walker J, Jamal GA, Weir AI, Henderson LM, Bissessar EA, Watkins PJ, Sampson M, Gale EA, Scarpello J, Boddie HG, Hardy KJ, Thomas PK, Misra P, Halonen JP. 1993. Treatment of diabetic neuropathy with gamma-linolenic acid. The gammaLinolenic Acid Multicenter Trial Group. *Diabetes Care* 16(1):8-15.

McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. 2000. *Herbs of Commerce*, 2nd edition. Silver Spring (MD): American Herbal Products Association.

Mills S, Bone K. 2005. *The Essential Guide to Herbal Safety*. St. Louis (MO): Elsevier Churchill Livingstone.

O'Neil MJ, Smith A, Heckelman PE, Budavari S, editors. 2001. *Merck Index: An Encyclopedia of Chemicals, Drugs, & Biologicals*, 13th edition. Whitehouse Station (NJ): Merck & Co., Inc.

Sweetman SC, editor. 2007. *Martindale: The Complete Drug Reference*, 35th edition. London (UK): Pharmaceutical Press.

USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [online database]. *Oenothera biennis* L. Beltsville (MD): National Germplasm Resources Laboratory. [Accessed 2018 July 11]. Available from:
http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

WHO 2002: World Health Organization (WHO) Monographs on Selected Medicinal Plants, Volume 2. Geneva (CHE): World Health Organization.

References reviewed

Barnes J, Anderson LA, Philipson JD. 2007. Herbal Medicines, 3rd edition. London (UK): The Pharmaceutical Press.

Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. 2002. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 13th edition. Washington (DC): American Pharmaceutical Association.

BP 2008: British Pharmacopoeia, Volume 1. London (UK): British Pharmacopoeia Commission. The Stationary Office.

Brinker F. 2001. Herb Contraindication and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications.

Guivernau N, Meza N, Barja P, Roman O. 1994. Clinical and experimental study on the longterm effect of dietary gamma-linolenic acid on plasma lipids, platelet aggregation, thromboxane formation, and prostacyclin production. Prostaglandins, Leukotrienes, and Essential Fatty Acids 51(5):311-316.

Hoffmann D. 2003. Medical Herbalism. Rochester (VT): Healing Arts Press.

IOM 2002: Institute of Medicine. Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids. Washington (DC): National Academy Press.

Lovell CR, Burton JL, Horrobin DF. 1981. Treatment of atopic eczema with evening primrose oil [letter]. Lancet;1(8214):278.

Manku MS, Horrobin DF, Morse N, Kyte Vicki, Jenkins K. 1982. Reduced levels of prostaglandin precursors in the blood of atopic patients: defective delta-6-desaturase function as a biochemical basis for atopy. Prostaglandins Leukotrienes and Medicine 9:615-628.

Manku MS, Horrobin DF, Morse NL, Wright S, Burton JL. 1984. Essential fatty acids in the plasma phospholipids of patients with atopic eczema. The British Journal of Dermatology 110(6):8-643.

McFayden IJ, Forrest AP, Chetty U. 1992. Cyclical breast pain - some observations and the difficulties in treatment. The British Journal Clinical Practice 46(3):161-164.

McGregor L, Smith AD, Sidey M, Belin J, Zilkha KJ, McGregor JL. 1989. Effects of dietary linoleic acid and gamma linolenic acid on platelets of patients with multiple sclerosis. Acta Neurologica Scandinavica 80(1):23-27.

- McGuffin M, Hobbs C, Upton R, Goldberg A, editors. 1997. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press.
- Mills S, Bone K. 2000. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone.
- Morse NL, Clough PM. 2006. A meta-analysis of randomized, placebo-controlled clinical trials of efamol evening primrose oil in atopic eczema. Where do we go from here in light of more recent discoveries? *Current Pharmaceutical Biotechnology* 7(6):24-503.
- Morse PF, Horrobin DF, Manku MS, Stewart JC, Allen R, Littlewood S, Wright S, Burton J, Gould DJ, Holt PJ, Jansen CT, Mattila L, Meigel W, Dettke TH, Wexler D, Guenther L, Bordoni A, Patrizi A. 1989. Meta-analysis of placebo-controlled studies of the efficacy of epogam in the treatment of atopic eczema. Relationship between plasma essential fatty acid changes and clinical response. *The British Journal of Dermatology* 121(1):75-90.
- Ockerman P, Bachrack I, Glans S, Rassner S. 1986. Evening primrose oil as a treatment of premenstrual syndrome. *Recent Advances in Clinical Nutrition* 2:405-404.
- Oliwiecki S, Armstrong J, Burton J, Bradfield J. 1993. The effect of essential fatty acids on epidermal atrophy due to topical steroids. *Clinical and Experimental Dermatology* 18(4):8-326.
- Oliwiecki S, Burton J. Evening primrose oil and marine oil in the treatment of psoriasis. 1994. *Clinical and Experimental Dermatology* 19(2):9-127.
- Pashby NL, Mansel RE, Hughes LE, Hanslip J, Preece PE. 1981. A clinical trial of evening primrose oil in mastalgia. *The British Journal of Surgery* 68:801.
- Puolakka J, Mäkäräinen L, Viinikka L, Ylikorkala O. 1985. Biochemical and clinical effects of treating the premenstrual syndrome with prostaglandin synthesis precursors. *The Journal of Reproductive Medicine* 30:149-153.
- Puri BK. The safety of evening primrose oil in epilepsy. 2007. *Prostaglandins, Leukotrienes and Essential Fatty Acids* 77:101-103.
- Schäfer L, Kragballe K. 1991. Supplementation with evening primrose oil in atopic dermatitis: effect on fatty acids in neutrophils and epidermis. *Lipids* 26(7):60-557.
- Schalin-Karrila M, Mattila L, Jansen CT, Uotila P. 1987. Evening primrose oil in the treatment of atopic eczema: effect on clinical status, plasma phospholipid fatty acids and circulating blood prostaglandins. *The British Journal of Dermatology* 117(1):11-19.

- Sharpe GR, Farr PM. 1990. Evening primrose oil and eczema. *Lancet* 335:667-668.
- Shuster J. 1996. Black cohosh root? Chasteberry tree? Seizures! *Hospital Pharmacy* 31:1553-1554.
- 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 gamma-linolenic 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. *Journal of Obstetrics and Gynaecology* 19(1):56-58.
- Wetzig N. 1994. Mastalgia: a 3 year Australian study. *The Australian and New Zealand Journal of Surgery* 64(5):31-329.
- Whitaker D, Cilliers J, de Beer C. 1996. Evening primrose (Epogam®) in the treatment of chronic hand dermatitis: disappointing therapeutic results. *Dermatology* 193(2):20-115.
- Wiersema J, León B. 1999. *World Economic Plants: A Standard Reference*. Boca Raton (FL): CRC Press LLC.
- Williamson EM, Evans FJ, Wren RC. 1988. *Potter's New Cyclopaedia of Botanical Drugs and Preparations*. Saffron Walden (UK): C.W. Daniel Company Limited.
- Wright S, Burton JL. 1982. Oral evening primrose seed oil improves atopic eczema. *Lancet* 2(8308):1120-1122.
- Yoon S, Lee J & Lee S. 2002. The therapeutic effect of evening primrose oil in atopic dermatitis patients with dry scaly skin lesions is associated with the normalization of serum gamma-interferon levels. *Skin Pharmacology and Applied Skin Physiology* 15:20-25.
- Yoshimoto-Furuie K, Yoshimoto K, Tanaka T, Saima S, Kikuchi Y, Shay J, Horrobin DF, Echizen H. 1999. Effects of oral supplementation with evening primrose oil for six weeks on

plasma essential fatty acid and uremic skin symptoms in hemodialysis patients. Nephron 91:9151.