Health Canada Santé Canada

NATURAL HEALTH PRODUCT

BORAGE 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)
Borago officinalis	▸ Borage oil ▸ Borage seed oil ▸ Borago officinalis seed oil	*Borago officinalis*	Seed

References: Proper name: USDA 2018; Common names: Sweetman 2007, McGuffin et al. 2000; Source material: Sweetman 2007, Hoffmann 2003.

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; Hoffmann 2003).
- Source of omega-6 fatty acids for the maintenance of good health (Ziboh 2004; van Gool 2003; IOM 2002).
- Source of linoleic acid (LA) for the maintenance of good health (Ziboh 2004; van Gool 2003; IOM 2002).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Method of preparation: Non-standardized fixed oil

3.7-5.0 grams of borage oil, per day (Schirmer and Phinney 2007; Ziboh 2004; Hoffman 2003; Takwale et al. 2003; van Gool 2003; IOM 2002).

Method of preparation: Standardized fixed oil

3.7-5.0 grams of borage oil, per day (Schirmer and Phinney 2007; Ziboh 2004; Hoffman 2003; Takwale et al. 2003; van Gool 2003; IOM 2002) standardized to:

- 0.2-10% alpha-linolenic acid (ALA), and/or
- 18-27% gamma-linolenic/gamolenic acid (GLA), and/or
- 23-37 % 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

Hoffmann D. 2003. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press.

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

IOM 2003: Institute of Medicine. Committee on Food Chemicals Codex, Food and Nutrition Board, Institute of Medicine. 2003. Food Chemicals Codex, 5th edition. Washington (DC): National Academies Press.

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

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

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

Schirmer MA, Phinney SD. 2007. Gamma-linolenate reduces weight regain in formerly obese humans. The Journal of Nutrition 137(6):1430-1435.

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

Takwale A, Tan E, Agarwal S, Barclay G, Ahmed I, Hotchkiss K, Thompson JR, Chapman T, Berth-Jones J. 2003. Efficacy and tolerability of borage oil in adults and children with atopic eczema: randomised, double blind, placebo controlled, parallel group trial. British Medical Journal 327(7428):1385.

USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [online]. 2000. *Borago officinalis* 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

van Gool CJ, Thijs C, Henquet CJ, van Houwelingen AC, Dagnelie PC, Schrander J, Menheere PP, van den brandt PA. 2003. Gamma-linolenic acid supplementation for prophylaxis of atopic dermatitis--a randomized controlled trial in infants at high familial risk. American Journal of Clinical Nutrition 77(4):943-951.

Ziboh VA, Naguwa S, Vang K, Wineinger J, Morrissey BM, Watnik M, Gershwin ME. 2004. Suppression of leukotriene B4 generation by ex-vivo neutrophils isolated from asthma patients on dietary supplementation with gammalinolenic acid-containing borage oil: possible implication in asthma. Clinical and Developmental Immunology 11(1):13-21.

References reviewed

Brinker F. 2008. Online Updates and Additions to Herb Contraindications and Drug Interactions, 3rd edition. [online]. Sandy (OR): Eclectic Medical Publications. Available from: http://www.eclecticherb.com/emp/updatesHCDI.html [Accessed 30 May 2008].

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

Kernoff PBA, Willis AL, Stone KJ, Davies JA, McNicol GP. 1977. Antithrombotic potential of dihomo-gamma-linolenic acid in man. British Medical Journal 2(6100):1441-1444.

Laidlaw M, Holub BJ. 2003. Effects of supplementation with fish oil-derived n-3 fatty acids and gamma-linolenic acid on circulating plasma lipids and fatty acid profiles in women. American Journal of Clinical Nutrition 77(1):37-42.

Puri BK. 2007. The safety of evening primrose oil in epilepsy. Prostaglandins Leukotrienes and Essential Fatty Acids 77(2):101-103.

Stone KJ, Willis AL Hart M, Kirtland SJ, Kernoff PBA, McNicol GP. 1979. The metabolism of dihomo-γ-linolenic acid in man. Lipids 14(2):174-180.