

Borage Oil

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Borage Oil (PDF Version - 60 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) *Borago officinalis* Borage oil Borage seed oil *Borago officinalis* Seed References: Proper name: USDA 2024; Common names: Brayfield and Cadart 2024; Gardner and McGuffin 2013; Source information: Brayfield and Cadart 2024; 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compndial applications. Use(s) or Purpose(s) Source of essential fatty acids for the maintenance of good health (Brayfield and Cadart 2024; 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). Note: The above uses can be combined on the product label (e.g., Source of essential fatty acids, including linoleic acid, for the maintenance of good health). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Method of preparation: Non-standardized fixed oil 3.7 - 5 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 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). Note: The following potency information is considered as additional information and can be included on the label: 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 (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. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited 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> Gardner Z, McGuffin M, editors. American Herbal Products Association's Botanical Safety Handbook. 2nd edition. Boca Ration (FL): Taylor and Francis Group; 2013. Hoffmann D. Medical Herbalism: The Science and Practice of Herbal Medicine. Rochester (VT): Healing Arts Press; 2003. IOM 2002: Institute of Medicine. 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; 2002. 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; 2003. IOM 2006: Institute of Medicine. Otten JJ, Pitzzi Hellwig J, Meyers LD, editors. Institute of Medicine Dietary Reference Intakes: The Essential Guide to Nutrient Requirements. Washington (DC): National Academies Press; 2006. Ph. 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 May 23]. Available from: <https://merckindex.rsc.org/> Schirmer MA, Phinney SD. Gamma-linolenate reduces weight regain in formerly obese humans. *The Journal of Nutrition* 2007;137(6):1430-1435. Takwale A, Tan E, Agarwal S, Barclay G, Ahmed I, Hotchkiss K, Thompson JR, Chapman T, Berth-Jones J. Efficacy and tolerability of borage oil in adults and children with atopic eczema: randomised, double blind, placebo controlled, parallel group trial. *British Medical Journal* 2003;327(7428):1385. 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 May 23]. 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. van Gool CJ, Thijs C, Henquet CJ, van Houwelingen AC, Dagnelie PC, Schrandt J, Menheere PP, van den brandt PA. Gamma-linolenic acid supplementation for prophylaxis of atopic dermatitis--a randomized controlled trial in infants at high familial risk. *American Journal of Clinical Nutrition* 2003;77(4):943-951. Ziboh VA, Naguwa S, Vang K, Wineinger J, Morrissey BM, Watnik M, Gershwin ME. 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* 2004;11(1):13-21. References Reviewed Brinker F. *Herb Contraindications and Drug Interactions*, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010. Kernoff PBA, Willis AL, Stone KJ, Davies JA, McNicol GP. Antithrombotic potential of dihomo-gamma-linolenic acid in man. *British Medical Journal* 1977;2(6100):1441-1444. Laidlaw M, Holub BJ. 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* 2003;77(1):37-42. Puri BK. The safety of evening primrose oil in epilepsy. *Prostaglandins Leukotrienes and Essential Fatty Acids* 2007;77(2):101-103. Stone KJ, Willis AL Hart M, Kirtland SJ, Kernoff PBA, McNicol GP. The metabolism of dihomo- γ -linolenic acid in man. *Lipids* 1979;14(2):174-180. 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.

DOSAGE FORM(S)

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.

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 theNatural Health Products Regulations. 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.

| Proper name(s) | Common name(s) | Source information | |
|--------------------|---------------------------|--------------------|------|
| Source material(s) | Part(s) | | |
| Borago officinalis | Borage oilBorage seed oil | Borago officinalis | Seed |