

Aloe vera Leaf Gel - Oral

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ALOE VERA LEAF GEL - Oral 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 - 51 K) 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 the statements are synonymous. Either term or statement may be selected by the applicant on the label. Date March 28, 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) Preparation(s) Aloe vera Aloe Aloe vera Barbados aloe Curaçao aloe True aloe West Indian aloe Aloe vera Leaf gel Fresh References: Proper name: USDA 2023; Common names: USDA 2023; Gardner and McGuffin 2013; Source information: Tilgner 1999; WHO 1999. Route(s) 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 Compendial applications. Use(s) or Purpose(s) Source of antioxidants/Provides antioxidants (Sajjad 2014; Rajasekaran et al. 2005; Yagi et al. 2003; Yagi et al. 2002). Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (Sajjad 2014; Rajasekaran et al. 2005; Yagi et al. 2003; Yagi et al. 2002). Used in Herbal Medicine as a demulcent to help soothe irritation/inflammation of the gastrointestinal tract (Godfrey et al. 2010; Mills and Bone 2005; Tilgner 1999; Bartram 1998). Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Antioxidant Methods of preparation: Freeze-dried; Fresh; Juice; Juice powdered; Juice powdered, freeze-dried; Powdered; Extract liquid; Extract dry. Not to exceed 200 milliliters or 200 grams of fresh leaf gel, per day (Davis et al. 2006; Langmead et al. 2004). Demulcent Methods of preparation: Freeze-dried; Fresh; Juice; Juice powdered; Juice powdered, freeze-dried; Powdered. 7.5 - 200 milliliters or 7.5 - 200 grams fresh leaf gel, per day (Winston and Kuhn 2008; Davis et al. 2006; Langmead et al. 2004; Bartram 1998). Direction(s) for use Powder dosage forms Mix with liquid before use. Duration of use No statement required. Risk information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Brinker 2010; Mills and Bone 2005; Bartram 1998). Products providing 2.4 g or more fresh leaf gel, per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes (Huseini et al. 2012; Pizzorno and Murray 2006). Demulcent Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. 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 . 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. The amount of hydroxyanthracene derivatives (barbaloin/aloin) in the finished product of the Aloe vera leaf gel must be less than 10 ppm and the daily amount of aloin should not exceed 1 mg/day. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References cited Bartram T. Bartram's Encyclopedia of Herbal Medicine, 1st edition. London (GB): Robinson Publishing Ltd; 1998. Brinker F. Herb Contraindications and Drug Interactions, 4 th edition. Sandy (OR): Eclectic Medical Publications; 2010. Davis K, Philpott S, Kumar D, Mendall M. Randomised double-blind placebo-controlled trial of Aloe vera for irritable bowel syndrome. International Journal of Clinical Practice 2006; 60(9):1080-1086. Gardner Z, McGuffin M. editors. 2013. American Herbal Products Association's Botanical Safety Handbook, 2nd edition. Boca Raton (FL): CRC Press; 2013. Godfrey A, Saunders P, Barlow K, Gowan M. Principles and

Practices of Naturopathic Botanical Medicine: Volume 1: Botanical Medicine Monographs, 1st edition. Toronto (ON): CCNM Press Inc.; 2010. Huseini HF, Kianbakht S, Hajiaghvaei R, Dabaghian FH. Anti-hyperglycemic and anti-hypercholesterolemic effects of Aloe vera leaf gel in hyperlipidemic type 2 diabetic patients: a randomized double-blind placebo-controlled clinical trial. *Planta Medica* 2012;78(4):311-316. Langmead L, Feakins RM, Goldthorpe S, Holt H, Tsironi E, De Silva A, Jewell DP, Rampton D S. Randomized, double-blind, placebo-controlled trial of oral aloe vera gel for active ulcerative colitis. *Alimentary Pharmacology & Therapeutics* 2004;19:739-747. Mills S, Bone K. *The Essential Guide to Herbal Safety*. St. Louis (MO): Elsevier Churchill Livingstone; 2005. Pizzorno J E, Murray M T. *Text Book of Natural Medicine*, 3rd edition. St. Louis (MO): Elsevier Churchill Livingstone; 2006. Rajasekaran S, Sivagnanam K, Subramanian S. Antioxidant effect of Aloe vera gel extract in streptozotocin-induced diabetes in rats. *Pharmacology Reports* 2005;57:90-96. Sajjad A. Aloe vera: An Ancient Herb for Modern Dentistry - A Literature Review. *Journal of Dental Surgery*. 2014;Article ID 210463, 6 pages. [Accessed 2023 September 11]. Available from: <http://dx.doi.org/10.1155/2014/210463> Tilgner S. *Herbal Medicine From the Heart of the Earth*. Creswell (OR): Wise Acre Press; 1999. USDA 2023: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2023 September 11]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> WHO 1999: World Health Organization. *WHO Monographs on Selected Medicinal Plants, Volume 1*. Geneva (CH): World Health Organization; 1999. Williamson EM. *Potter's Herbal Cyclopaedia: The Authoritative Reference work on Plants with a Known Medical Use*. Saffron Walden (GB): The C.W. Daniel Company Limited; 2003. Winston D, Kuhn MA. *Herbal Therapy & Supplements - A Scientific and Traditional Approach*. Philadelphia (PA): Lippincott Williams & Wilkins; 2008. Yagi A, Kabash A, Mizuno K, Moustafa SM, Khalifa TI, Tsuji H. Radical scavenging glycoprotein inhibiting cyclooxygenase-2 and thromboxane A2 synthase from aloe vera gel. *Planta Medica* 2003;69(3):269-271. Yagi A, Kabash A, Okamura N, Haraguchi H, Moustafa S. M., Khalifa T.I. Antioxidant, free radical scavenging and anti-inflammatory effects of aloesin derivatives in Aloe vera. *Planta Medica* 2002;68(11):957-960. References reviewed Barnes J, Anderson LA, Philipson JD. 2007. *Herbal Medicines*, 3rd edition. London (GB): Pharmaceutical Press. Boudreau, MD, Beland FA. An evaluation of the biological and toxicological properties of Aloe Barbadensis (Miller), Aloe vera. *Journal of Environmental Science and Health, Part C: Environmental Carcinogenesis and Ecotoxicology Reviews* 2006;24(1):103-154. Choi S, Chung M-H. A review on the relationship between Aloe vera components and their biologic effects. *Seminars in Integrative Medicine* 2003;1:53-62. Eshun K, He Q. Aloe vera : A valuable ingredient for the food, pharmaceutical and cosmetic industries - A review. *Critical Reviews in Food Science and Nutrition* 2004;44:91-96. Loots du T, van der Westhuizen FH, Botes L. Aloe ferox leaf gel phytochemical content, antioxidant capacity, and possible health benefits. *Journal of Agricultural and Food Chemistry* 2007;55(17):6891-6896. Ni Y, Turner D, Yates KM, Tizard I. Isolation and characterisation of structural components of Aloe vera L. leaf pulp. *International Immunopharmacology* 2004;4:1745-1755. Reynolds T, Dweck A C. Aloe vera leaf gel: a review update. *Journal of Ethnopharmacology* 1999;68(1-3):3-37. Talmadge J, Chavez J, Jacobs L, Munger C, Chinnah T, Chow JT, Williamson D, Yates K. Fractionation of Aloe vera L. inner gel, purification and molecular profiling of activity. *International Immunopharmacology* 2004;4:1757-1773. Vinson JA, Al Kharat H, Andreoli L. Effect of Aloe vera preparations on the human bioavailability of vitamins C and E. *Phytomedicine* 2005;12(10):760-765. 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 the Natural Health Products Regulations.

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) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Brinker 2010; Mills and Bone 2005; Bartram 1998). Products providing 2.4 g or more fresh leaf gel, per day Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have diabetes (Huseini et al. 2012; Pizzorno and Murray 2006). Demulcent Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. 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.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations.

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. The amount of hydroxyanthracene derivatives (barbaloin/aloin) in the finished product of the Aloe vera leaf gel must be less than 10 ppm and the daily amount of aloin should not exceed 1 mg/day. EXAMPLE OF PRODUCT FACTS:

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Aloe vera	AloeAloe veraBarbados aloeCuraçao aloeTulsiAloe vera	Aloe veraWest Indian aloe	Leaf gel	Fresh