

NATURAL HEALTH PRODUCT

ALOE VERA LEAF GEL - ORAL

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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date

January 20 , 2015

Proper name(s)

Aloe vera (L.) Burm. f. (Asphodelaceae/Aloaceae) (USDA 2002)

Common name(s)

- ▶ *Aloe vera* (McGuffin *et al.* 2000)
- ▶ Aloe (McGuffin *et al.* 2000)
- ▶ Barbados aloe (McGuffin *et al.* 2000)
- ▶ Curaçao aloe (McGuffin *et al.* 2000)

Source material(s)

Leaf gel (Tilgner 1999; WHO 1999)

Note

See Appendix 1 for definitions.

Route(s) of administration

Oral



Dosage form(s)

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- ▶ This monograph is not intended to include food-like dosage forms such as bars, chewing gums or beverages

Use(s) or Purpose(s) Statement(s) to the effect of

- ▶ Source of/provides antioxidants (Rajasekaran *et al.* 2005; Sajjad 2014; Yagi *et al.* 2002; Yagi *et al.* 2003).
- ▶ Used in herbal medicine as a demulcent to help soothe irritation/inflammation of the gastrointestinal tract (Mills and Bone 2005; Tilgner 1999; Godfrey *et al.* 2010; Bartram 1998).

Dose(s) Statement(s) to the effect of

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

Antioxidant

Preparations: fresh, juice, freeze-dried, powdered, juice powdered, extract liquid, extract dry
Preparations equivalent to a maximum of 200 ml or 200 g fresh gel, per day (Langmead *et al.* 2004; Davis *et al.* 2006).

Demulcent

Preparations: fresh, juice, freeze-dried, powdered, juice powdered
Preparation equivalent to 7.5-200 ml or 7.5-200 g fresh gel, per day (Bartram 1998; Kuhn and Winston 2008; Langmead *et al.* 2004; Davis *et al.* 2006).

Directions for use

For freeze-dried, powdered and juice powdered preparations

Preparations must be reconstituted in liquid before use.



Duration of use

No statement required.

Risk information Statement(s) to the effect of

Caution(s) and warning(s)

If you are pregnant or breastfeeding, consult a health care practitioner prior to use (Brinker 2001; Mills and Bone 2005; Bartram 1998).

Preparations equivalent to ≥ 2.4 g fresh gel/day

If you have diabetes, consult a health care practitioner prior to use (Huseini *et al.* 2012, 2007; Pizzorno and Murray 2006).

Demulcent

If symptoms persist or worsen, consult a health care practitioner.

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

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.
- ▶ 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.

References cited

Abo-Youssef A. M. H., Messiha B. A. S. Beneficial effects of *Aloe vera* in treatment of diabetes: Comparative in vivo and in vitro studies. Cairo University. Bulletin of Faculty of Pharmacy 2013 51:7-11.

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

Bartram T. Bartram's Encyclopedia of Herbal Medicine, 1st edition. London (GB): Robinson Publishing Ltd; 1998.

Bove M. An Encyclopedia of Natural Healing for Children and Infants. New Canaan (CT): Keats Publishing, Incorporated; 2001.

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

Chalaprawat M. The hypoglycemic effects of Aloe Vera in Thai diabetic patients. Journal of Clinical Epidemiology 1997;50(1):3S.

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):1080-6.

EFSA 2010: European Food Safety Authority. EFSA Journal 2010;8(10):1733.

Gardner Z, McGuffin M, editors. American Herbal Products Association's Botanical Safety Handbook, 2nd edition. Boca Raton (FL): Taylor and Francis Group; 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.

Hamman J H. Composition and applications of *Aloe vera* leaf gel. Molecules 2008;13(8):1599-616.

Huseini HF, Kianbakht S, Hajiaghaee 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):311-6.

Kim et al. 2014: Extraction of Antioxidants from Aloe vera Leaf Gel: a Response Surface Methodology Study. *Food Anal. Methods*.

Kirdpon S, Kirdpon W, Airarat W, Thepsuthammarat K, Nanakorn S. Changes in urinary compositions among children after consuming prepared oral doses of aloe (*Aloe vera* Linn). *Journal of the Medical Association of Thailand* 2006;89(8):1199-205.

Kirdpon S, Kirdpon W, Airarat W, Trevanicht A, Nanakorn S. Effect of aloe (*Aloe vera* Linn.) on healthy adult volunteers: changes in urinary composition. *Journal of the Medical Association of Thailand* 2006;89 Suppl 2:S9-14.

Winston D, Kuhn MA. *Herbal Therapy & Supplements – A Scientific and Traditional Approach*. Philadelphia (PA): Lippincott Williams & Wilkins; 2008.

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.

Tilgner S. *Herbal Medicine From the Heart of the Earth*. Creswell (OR): Wise Acre Press; 1999.

Sajjad A. Aloe vera: An Ancient Herb for Modern Dentistry—A Literature Review. *Journal of Dental Surgery*. 2014;Article ID 210463, 6 pages. [Accessed 19 June 2014]. Available from : <http://dx.doi.org/10.1155/2014/210463>

The International Aloe Science Council. IASC Aloe Vera FAQ; Version 1.0. 1996-2012. [Accessed 19 June 2014]. Available from: <http://www.iasc.org/faq.html>

Ulbricht C, Armstrong J, Basch E, Basch S, Bent S, Dacey C, Dalton S, Foppa I, Giese N, Hammerness P, Kirkwood C, Sollars D, Tanguay-Colucci S, Weissner W. An evidence-based systematic review of Aloe vera by the Natural Standard Research Collaboration. *Journal of Herbal Pharmacotherapy* 2007;7(3-4):279–323.



USDA 2002: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [Internet]. *Aloe vera* (L.) Burm. f. Beltsville (MD): National Germplasm Resources Laboratory. [Last updated 2002 December 10; Accessed 27 January 2014]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

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.

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):597-60.

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):269-71.

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 Barbadosis* (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):6891-6.

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 Kharrat H, Andreoli L. Effect of *Aloe vera* preparations on the human bioavailability of vitamins C and E. *Phytomedicine* 2005;12(10):760-5.



Appendix 1 Examples of Aloe preparations and definitions

Aloe vera leaf gel: Refer to the present monograph

Aloe vera gel is the mucilaginous gel obtained from the parenchyma tissue in the centre of the fresh leaves of *Aloe vera* (L.) Burm. f. by mechanical or chemical means. The gel is a viscous, colourless, transparent liquid (WHO 1999).

Aloe Vera leaf latex/Aloes: Refer to Aloe – Oral monograph

Aloe vera leaf latex known as Aloes is obtained by the evaporation of water from the bitter yellow juice obtained from the leaves of *Aloe vera* (L.) Burm. f. (Barnes 2007; WHO 1999). To obtain Aloes, leaves of Aloe are cut transversely near the base and arranged so that the juice runs out freely; collected over a period of about 6 hours the juice is then evaporated by heating to a solid residue (Barnes 2007).