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)

- 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)

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 $\geq 2.4$ 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**


References reviewed


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).