

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

Date August 28, 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)	Preparation(s)
<i>Aloe vera</i>	<ul style="list-style-type: none"> ▶ Aloe ▶ Aloe vera ▶ Barbados aloe ▶ Curaçao aloe ▶ True aloe ▶ West Indian aloe 	<i>Aloe vera</i>	Leaf gel	Fresh

References: Proper name: USDA 2018; Common names: USDA 2018, McGuffin et al. 2000; Source material: Tilgner 1999, WHO 1999.

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/Provides antioxidants (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: Fresh, Juice, Freeze-dried, Powdered, Juice 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: Fresh, Juice, Freeze-dried, Powdered, Juice 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

Freeze-dried, powdered and juice powdered preparations

Mix with liquid before use.



Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

All products

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to 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

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have diabetes (Huseini et al. 2012; Pizzorno and Murray 2006).

Demulcent

Consult 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

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.

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