Health Canada Santé Canada

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 January 26, 2024

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 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

Freeze-dried; juice powdered; juice powdered, freeze-dried and powdered preparations

Mix with liquid before use.

Duration(s) 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.

Product Facts
Medicinal ingredient per teaspoon *Aloe vera* (Aloe) – leaf gel XX g or mL
Uses • Source of antioxidants/Provides antioxidants • 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 • Used in Herbal Medicine as a demulcent to help soothe irritation/inflammation of the gastrointestinal tract
Warnings
If applicable: **Allergens: food allergen, gluten (gluten source), sulphites** **Contains aspartame**
Ask a health care practitioner before use if • you are pregnant or breastfeeding. *Products providing 2.4 g or more fresh leaf gel, per day* • you have diabetes.
Demulcent **Ask a health care practitioner if** symptoms persist or worsen.
Directions Adults 18 years and older: • Take X teaspoon(s), X times a day. *Freeze-dried; juice powdered; juice powdered, freeze-dried and powdered preparations* • Mix with liquid before use.
Other information (Add storage information)
Non-medicinal ingredients List all NMIs
Questions? Call 1-XXX-XXX-XXXX

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