

NATURAL HEALTH PRODUCT

ALOE - *ALOE VERA*

Topical

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) 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

December 29, 2023

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)
<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

References: Proper name: USDA 2023; Common names: USDA 2023, McGuffin et al. 2000; Source information: Barnes et al. 2007, Williamson 2003.

Route of administration

Topical

Dosage form(s)

Acceptable dosage forms for topical 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)

- Used in Herbal Medicine to help relieve minor burns including sunburn (Barnes et al. 2007; Williamson 2003).
- Used in Herbal Medicine to assist healing of minor wounds such as cuts and burns, and minor skin irritations (Barnes et al. 2007; Boon and Smith 2004; Williamson 2003; WHO 1999; Fulton 1990).

Dose(s)

Subpopulation(s)

Children 2 to 11 years, adolescents 12 to 17 years and adults 18 years and older (McIntyre 2005; Bove 2001).

Quantity(ies)

Method of preparation: Fresh

10 - 100 % leaf gel (WHO 1999)

Direction(s) for use

Apply to affected area(s) as needed.

Duration(s) of use

No statement is required.

Risk information

Caution(s) and warning(s)

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)

Stop use if hypersensitivity/allergy occurs (Brinker 2018; EMEA 2006).

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 specifications outlined in the NHPID.

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts	
Medicinal ingredient (w/w)	
<i>Aloe vera</i> (Aloe) – Leaf gel	XX %
Uses	
<ul style="list-style-type: none"> • Used in Herbal Medicine to help relieve minor burns including sunburn • Used in Herbal Medicine to assist healing of minor wounds such as cuts and burns, and minor skin irritations 	
Warnings	
Ask a health care practitioner if symptoms persist or worsen.	
Stop use if hypersensitivity/allergy occurs.	
Directions	
Children 2 to 11 years, adolescents 12 to 17 years and adults 18 years and older: Apply to affected area(s) as needed.	
Other information	
(Add storage information)	

**Non-medicinal ingredients**

List all NMIs

Questions? Call 1-XXX-XXX-XXXX

References cited

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