ALOE VERA

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. It is a referenced document to be used as a labelling standard.

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

Date: October 31, 2008

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) and Route(s) of administration:

Table 1  Source material(s) and route(s) of administration

<table>
<thead>
<tr>
<th>Source material(s)</th>
<th>Route(s) of administration</th>
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<tbody>
<tr>
<td>Leaf latex</td>
<td>Oral</td>
</tr>
<tr>
<td>Leaf gel</td>
<td>Topical</td>
</tr>
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</table>

1References: Barnes et al. 2007; Williamson 2003

Dosage form(s):
- Those pharmaceutical dosage forms suited to oral administration, including but not limited to chewables (eg. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons, are acceptable.
- This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.
Use(s) or Purpose(s): Statement(s) to the effect of:

Oral:

- (Traditionally used in Herbal Medicine as a) stimulant laxative (Williamson 2003; Bradley 1992; Felter and Lloyd 1983 [1898]; Grieve 1971 [1931]).
- (Used in Herbal Medicine for the) short-term relief of occasional constipation (EMEA 2006).
- (Used in Herbal Medicine to) promote(s) bowel movement (by direct action on the large intestine) (Sweetman 2007; EMEA 2006; WHO 1999).

Topical:

- (Traditionally used in Herbal Medicine to) help(s) relieve minor burns including sunburn (Barnes et al. 2007; Williamson 2003).
- (Traditionally used in Herbal Medicine to) assist(s) 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).

Note: Claims for traditional use must include the term “Herbal Medicine”.

Dose(s):

ORAL:

Subpopulation(s): Adults, and adolescents ≥ 12 years (EMEA 2006; Brinker 2001)

Quantity(ies):

- Preparations equivalent to 50-300 mg dried leaf latex, per day (Williamson 2003; Bradley 1992)
- Preparations equivalent to 10-30 mg hydroxyanthracene derivatives (calculated as barbaloin/aloin), per day (Barnes et al. 2007; EMEA 2006; Blumenthal et al. 1998)

Directions for use:

- Take two to three times per week. If results are not observed, the frequency of use may be increased up to once daily (EMEA 2006).
- Take a single dose at bedtime (Bradley 1992).
- Take a few hours before or after taking other medications or health products (McGuffin et al. 1997).
- Allow at least 6-12 hours for laxative effect to occur (EMEA 2006; Berardi et al. 2002).
- Optional (for products which provide a dosage range): The correct individual dose is the smallest one required to produce a
comfortable, soft-formed stool (EMEA 2006).

**TOPICAL:**

Subpopulation(s): Adults, adolescents, and children ≥ 2 years (McIntyre 2005; Bove 2001)

Quantity(ies): Preparations containing at least 10% leaf gel (WHO 1999)

**Directions for use:** Apply to affected area(s) as needed.

See Appendix 1 for examples of dosage preparations, frequencies of use and directions for use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

**Duration(s) of use:**

**ORAL:** Consult a health care practitioner for use beyond 7 days (EMEA 2006; Brinker 2001).

**TOPICAL:** No statement is required.

**Risk information:** Statement(s) to the effect of:

**Caution(s) and warning(s):**

**ORAL:**
- Consult a health care practitioner if symptoms persist or worsen.
- Consult a health care practitioner prior to use if you have faecal impaction or symptoms such as abdominal pain, nausea, vomiting or fever (EMEA 2006; Brinker 2001; McGuffin et al. 1997).
- Consult a health care practitioner prior to use if you have a kidney disorder, or are taking cardiac medications (e.g. cardiac glycosides or antiarrhythmic medications) (EMEA 2006; Brinker 2001; McGuffin et al. 1997).
- Consult a health care practitioner prior to use if you are taking thiazide diuretics, corticosteroids, licorice root, or other medications or health products that may aggravate electrolyte imbalance (EMEA 2006; Brinker 2001; McGuffin et al. 1997).
- Reduce dose or discontinue use if you experience abdominal pain, cramps, spasms and/or diarrhoea (EMEA 2006; Brinker 2001).

**TOPICAL:** Consult a health care practitioner if symptoms persist or worsen.
Contraindication(s):

**ORAL:**

- Do not use if you have abnormal constrictions of the gastrointestinal tract, potential or existing intestinal blockage, atonic bowel, appendicitis, inflammatory colon disease (e.g. Crohn's disease or ulcerative colitis), abdominal pain of unknown origin, undiagnosed rectal bleeding, severe dehydration with depleted water or electrolytes (Brinker 2008; EMEA 2006), hemorrhoids or diarrhoea (Brinker 2001; McGuffin et al. 1997).
- Do not use if you are pregnant or breastfeeding (Brinker 2001; McGuffin et al. 1997).

**Known adverse reaction(s):** Hypersensitivity, such as allergy, has been known to occur; in which case, discontinue use (Brinker 2008; EMEA 2006).

**Non-medicinal ingredients:** Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in the database.

**Specifications: **

- The finished product must comply with the minimum specifications outlined in the current NHPD *Compendium of Monographs*.
- The medicinal ingredient may comply with the specifications outlined in the pharmacopoeial monographs listed in Table 1 below.

### Table 1  Aloe vera monographs published in the British, European and U.S. pharmacopoeiae

<table>
<thead>
<tr>
<th>Pharmacopoeia</th>
<th>Monograph</th>
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<tbody>
<tr>
<td>British Pharmacopoeia (BP)</td>
<td>Barbados Aloes</td>
</tr>
<tr>
<td></td>
<td>Standardised Aloes Dry Extract</td>
</tr>
<tr>
<td>European Pharmacopoeia (Ph. Eur.)</td>
<td>Aloes, Barbados</td>
</tr>
<tr>
<td></td>
<td>Aloes Dry Extract, Standardised</td>
</tr>
<tr>
<td>U.S. Pharmacopoeia (USP)</td>
<td>Aloe</td>
</tr>
</tbody>
</table>

**References cited:**


References reviewed:


Livingstone.


Appendix 1: Examples of appropriate dosage preparations, frequencies of use and directions for use

**ORAL:**

Dried leaf latex:
- 100-300 mg, per day (Williamson 2003)
- 50-200 mg, per day (Bradley 1992)

Tincture: 50-200 mg dried equivalent, per day (1:40, 45% ethanol, 2-8 ml) (Bradley 1992)

Preparations providing the following quantities of hydroxyanthracene derivatives:
- 10-30 mg hydroxyanthracene derivatives (calculated as barbaloin/aloin), per day (Barnes et al. 2007; EMEA 2006)
- 20-30 mg hydroxyanthracene derivatives (calculated as anhydrous aloin), per day (Blumenthal et al. 1998)

**TOPICAL:**

Leaf gel: Preparations containing 10-70% leaf gel (WHO 1999)