NATURAL HEALTH PRODUCT

SAGE – SALVIA OFFICINALIS – BUCCAL & TOPICAL

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

March 22, 2013

Proper name(s)

*Salvia officinalis* L. (Lamiaceae) (USDA 2001; McGuffin et al. 2000)

Common name(s)

- Sage (USDA 2001; McGuffin et al. 2000)
- Common sage (McGuffin et al. 2000)
- Dalmation sage (McGuffin et al. 2000)
- Garden sage (McGuffin et al. 2000)

Source material(s)

leaf (Blumenthal et al. 2000; BHP 1983; Cook 1869)

Route(s) of administration

- buccal (Barnes 2007; BHP 1983)
- topical (BHC 2006; Bone 2003)

Dosage form(s)
Those dosage forms suited to buccal administration which allow for direct contact between the affected tissue and the medicinal ingredient such as gargles, lozenges, rinses, and mouthwashes.

Those pharmaceutical dosage forms suited to topical administration.

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

(Traditionally) used in Herbal Medicine to provide relief for the inflammation of nose and throat mucosa (such as sore throat), gingivitis and aphthous ulcer/canker sore (BHC 2006; Mills and Bone 2005; Witchl 2004; Blumenthal et al. 2000; ESCOP 1996; BHP 1983; Culbreth 1927; Felter 1922).

Note
A claim for a traditional use must include the term “Herbal Medicine”.

Dose(s) Statement(s) to the effect of

Sub-population(s)

adults (≥ 19 years)

Quantity(ies)

Fluidextract:
3-12 g, per day (1:1 extract, 45% alcohol, 3-12 ml) (BHP 1983)

Infusion or powder:
1-12 g dried leaf, per day (Mills and Bone 2005; BHP 1983).

Directions for use

Buccal:
Gargle, mouthwash or rinse:
  ▶ Pour 100 ml boiling water over 3 g of dried leaf and infuse (BHC 2006); or
  ▶ For each 5 ml of fluidextract, dilute with 150 ml of water (Blumenthal et al. 2000).

Topical:
Fluidextract:
Apply the undiluted fluidextract to the affected area with a brush or swab (Blumenthal et al. 2000).

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

**Duration of use**

No statement required.

**Risk information**

Statement(s) to the effect of

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

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**

Must be chosen from the current NHPD *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 NHPD *Quality of Natural Health Products Guide*.
- The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

**References cited**


References reviewed


Brinker, F. Updates and Additions for Herb Contraindications and Drug Interactions, 3rd ed including extensive Appendices addressing common problematic conditions, medications and nutritional supplements, and influences on Phase I, II & III metabolism with new appendix on botanicals and complementary adjuncts with drugs. [Internet] Sandy (OR): Eclectic Medical Publications. [Updated July 13, 2010; Accessed 2012 April 18]. Available from: http://www.eclecticherb.com/emp/updatesHCDI.html


Appendix 1  Examples of dosage preparations and directions for use

Mills and Bone 2005

- 3 to 12g/day of dried leaf or by infusion
- 2 to 12 ml/day of a 1:1 liquid extract

Blumenthal et al. 2000

4-6 g per day of cut leaf for infusions, alcoholic extracts for gargles, rinses and other topical applications, and for internal use.

External:
Gargle or rinse: Use warm infusion: 2.5g cut leaf in 100 ml water; or use 5 ml of fluidextract diluted in 1 glass of water.
Paint: Apply the undiluted alcoholic fluidextract to the affected area with a brush or swab.

BHC 2006

Topical use in mouthwashes and gargles:
2.5g of dried leaf to 100 ml of water as an infusion.

Blumenthal et al. 1998

Gargles and rinses: 2.5g of herb in 100 ml of water as infusion or 5g of alcoholic extract in 1 glass water

External:
Undiluted alcohol extract

BHP 1983

(thrice daily):
Dried herb. Dose 1-4g or by infusion.
Liquid extract 1:1 in 45% alcohol. Dose 1-4 ml.