



NATURAL HEALTH PRODUCT

SAGE - *SALVIA OFFICINALIS* - 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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date

March 25, 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)
- ▶ Dalmatian 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

oral

Dosage form(s)

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.

- ▶ 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

- ▶ Provides antioxidants for the maintenance of good health (BHC 2006; Lima et al. 2005).
- ▶ (Traditionally) used in Herbal Medicine as a carminative/ to help provide relief of upset stomach and flatulence (flatulent dyspepsia) (Godfrey et al. 2010; EMEA 2009; BHC 2006; Mills and Bone 2005; BHP 1983; Culbreth 1927; Felter 1922).
- ▶ Traditionally used in Herbal Medicine as a diaphoretic/ to increase perspiration/sweating (PDR 2007; Culbreth 1927; Felter 1922; Cook 1869).
- ▶ Traditionally used in Herbal Medicine to reduce hyperhidrosis/ excessive sweating or perspiration (antihidrotic) (EMEA 2009; BHC 2006; Mills and Bone 2005; BHP 1983; Culbreth 1927; Felter 1922).
- ▶ Used in Herbal Medicine to help reduce hot flushes/flushes and/or night sweats associated with menopause (Romm 2010; BHC 2006; Mills and Bone 2000).
- ▶ (Traditionally) used in Herbal Medicine to stop the production of breast milk (antigalactagogue) (Godfrey et al. 2010; Wichtl 2004; Yarnell et al. 2003; Felter and Lloyd 1983; Culbreth 1927; Cook 1869).

Note

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

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

Subpopulation(s)

adults (≥ 19 years)

Quantity(ies)

Antioxidant

Infusion:

up to 6 g dried leaf, per day (BHC 2006)

Carminative, Diaphoretic and Antihidrotic, and Antigalactagogue

Infusion:

1-12 g dried leaf, per day (Mills and Bone 2005; Blumenthal 2000; BHP 1983; Culbreth 1927)

All products

Fluidextract:

1-6 ml per day (1:1, 45% ethanol) (BHC 2006; BHP 1983)

Tincture:

0.3-1.5 g dried leaf, per day (1:4-10, 50-70% ethanol) (EMEA 2009; ESCOP 2003)

0.3-2.25 g dried leaf, per day (1:2-5, 31.5% ethanol) (EMEA 2009; Mills and Bone 2005)

Directions for use

Antihidrotic

Infusion:

Pour hot boiled water on dried herb and steep. Let infusion cool before drinking (BHC 2006; Mills and Bone 2005; BHP 1983; Culbreth 1927; Felten 1922).

Diaphoretic

Infusion:

Pour hot boiled water on dried herb and steep. Drink infusion while still warm (PDR 2007; Culbreth 1927; Felten 1922; Cook 1869).

Night sweats

Take one hour before bedtime (EMEA 2009).

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

Statement(s) to the effect of

Infusion:

For use beyond 4 weeks, consult a health care practitioner (Wichtl 2004; ESCOP 2003; McGuffin et al. 1997).

Other preparations:

For use beyond 2 weeks, consult a health care practitioner (EMEA 2009; Wichtl 2004; McGuffin et al. 1997).

Risk information

Statement(s) to the effect of

Caution(s) and warning(s)

Carminative, Diaphoretic, Antihidrotic and Antigalactagogue:
If symptoms persist or worsen, consult a health care practitioner.

Contraindication(s)

All products:

- ▶ If you are pregnant or breastfeeding, do not use this product (BHC 2006; Mills and Bone 2005; McGuffin et al. 1997).
- ▶ If you have a seizure disorder (e.g. epilepsy), do not use this product (BHC 2006; Mills and Bone 2005).

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 Statement(s) to the effect of

All products, except those encapsulated:
Store protected from light and moisture (Martindale 2010; Wichtl 2004)

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).

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Appendix 1 Examples of dosage preparations and directions for use

EMEA 2009

Tincture:

0.2-0.3 g dried leaf, three times per day (1:10, 70% ethanol, 2-3 ml)

0.4-0.5 g dried leaf, three times per day (1:4-5, 50% ethanol, 2 ml)

0.1-0.23 g dried leaf, three times per day (1:3.5-5, 31.5% ethanol, 0.4-0.8 ml)

0.24-0.34 g dried leaf, per day (1:3.5-5, 31.5% ethanol, 1.2 ml)

Mills and Bone 2005

Infusion: 3 to 12g/day of dried leaf

Tincture: 2 to 4.5 ml/day or a 1:2 liquid extract or equivalent in tablet or capsule form.

Blumenthal et al. 2000

Unless otherwise prescribed: 4-6 g per day of cut leaf for infusions.

Internal: Infusion: 1-3 g in 150 ml water, three times daily.

BHC 2006

Internal daily dose:

3-6g of dried leaf, usually as an infusion;

liquid extract 1:1 in 45% ethanol, 2-6 ml

BHP 1983

(thrice daily):

Dried herb. Dose 1-4g by infusion.

Culbreth 1927

1-4 g per day as an infusion