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)**

- 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/flashes 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)**

**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; Felter 1922).

Diaphoretic

Infusion:
Pour hot boiled water on dried herb and steep. Drink infusion while still warm (PDR 2007; Culbreth 1927; Felter 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).

References cited


References reviewed


Brinker F. Final updates and additions for Herb Contraindications and Drug Interactions, 3rd edition, including extensive Appendices addressing common problematic conditions, medications and nutritional supplements, and influences on Phase I, II & III metabolism with new appendix on botanicals as complementary adjuncts with drugs. [Internet]. Sandy (OR): Eclectic Medical Publications. [Updated July 13, 2010; Accessed 2012 April 27]. Available from: http://www.eclecticherb.com/emp/updatesHCDI.html


Kennedy DO, Dodd FL, Robertson BC, Okello EJ, Reay JL, Scholey AB, Haskell CF. Monoterpenoid extract of sage (Salvia lavandulaefolia) with cholinesterase inhibiting properties


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 12 g/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:
3-6 g of dried leaf, usually as an infusion;
liquid extract 1:1 in 45% ethanol, 2-6 ml

**BHP 1983**
(thrice daily):
Dried herb. Dose 1-4 g by infusion.

**Culbreth 1927**
1-4 g per day as an infusion