



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

Date

October 30, 2018

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)	Preparation(s)
<i>Salvia officinalis</i>	<ul style="list-style-type: none"> ▶ Common sage ▶ Dalmatian sage ▶ Garden sage ▶ Sage 	<i>Salvia officinalis</i>	Leaf	Dried

References: Proper name: USDA 2018, McGuffin et al. 2000; Common names: USDA 2018, McGuffin et al. 2000; Source information: Blumenthal et al. 2000, BHP 1983, Cook 1869.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

- ▶ Source of/Provides antioxidants (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

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Antioxidant

Methods of preparation: Dry, Infusion

Not to exceed 12 grams of dried leaf, per day (BHC 2006; Mills et Bone 2005; Blumenthal et al. 2000; BHP 1983; Culbreth 1927).

Note: Dried leaves should be prepared as an infusion (see direction for use).

Method of preparation: Tincture

Not to exceed 2.25 grams of dried leaf, per day (EMEA 2009; Mills and Bone 2005; ESCOP 2003).

Method of preparation: Fluid extract

Not to exceed 6 grams of dried leaf, per day (EMEA 2009; BHC 2006; Mills and Bone 2005; ESCOP 2003; BHP 1983).

Other uses

Methods of preparation: Dry, Infusion

1-12 grams of dried leaf, per day (Mills and Bone 2005; Blumenthal et al. 2000; BHP 1983; Culbreth 1927).

Note: Dried leaves should be prepared as an infusion (see direction for use).

Method of preparation: Tincture

0.3-2.25 grams dry leaf, per day (EMEA 2009; Mills and Bone 2005; ESCOP 2003).

Method of preparation: Fluid extract

1-6 grams of dried leaf, per day (EMEA 2009; BHC 2006; Mills and Bone 2005; ESCOP 2003; BHP 1983).

Direction(s) for use

Night sweats

Take one hour before bedtime (EMEA 2009).

Dried leaf – All uses

Pour hot boiled water on dried herb and steep.

Dried leaf - Antihidrotic

Let infusion cool before drinking (BHC 2006; Mills and Bone 2005; BHP 1983; Culbreth 1927; Felter 1922).

Dried leaf - Diaphoretic

Drink infusion while still warm (PDR 2007; Culbreth 1927; Felter 1922; Cook 1869).



Duration(s) of use

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 4 weeks (Wichtl 2004; ESCOP 2003; McGuffin et al. 1997).

Risk information

Caution(s) and warning(s)

Carminative, Diaphoretic, Antihidrotic and Antigalactagogue:

Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.

Contraindication(s)

Do not use this product if you are pregnant, breastfeeding or have a seizure disorder such as epilepsy (BHC 2006; Mills and Bone 2005; McGuffin et al. 1997).

Known adverse reaction(s)

No statement required.

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

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 Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

- ▶ Sage contains thujone. For adults, the upper limit for total daily intake of thujone from health products is 6 mg. Product licence applications for oral products should include a copy of a certificate of analysis or any other equivalent document demonstrating that the thujone content of a daily dose of the product is acceptable. Because thujone content of the herbal materials can vary, the thujone content should be determined for each batch during production of the product.

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