Sage - Salvia officinalis - Buccal

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SAGE - SALVIA OFFICINALIS - Buccal Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 131 KB) 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 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 on the label. Date March 28, 2025 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) Salvia officinalis Common sage Dalmatian sage Garden sage Sage Salvia officinalis Leaf Dry References: Proper name: USDA 2024; Gardner and McGuffin 2013; Common names: USDA 2024; Gardner and McGuffin 2013; Source information: Blumenthal et al. 2000; BHP 1983; Cook 1869. Route of Administration Buccal Dosage Form(s) Acceptable dosage forms when used according to the requirements indicated in this monograph: Gargle; Liquid; Loose; Mouthwash; Powder (Blumenthal 2000; ESCOP 1996; BHP 1983; Grieve 1971; Culbreth 1927; Felter 1922; Felter and Lloyd 1898). Use(s) or Purpose(s) (Traditionally) used in Herbal Medicine to help relieve minor mucous membrane inflammations of the mouth and throat (including aphthous ulcers/canker sores) (BHC 2006; Mills and Bone 2005; Wichtl 2004; Blumenthal et al. 2000; ESCOP 1996; BHP 1983; Culbreth 1927; Felter 1922). Notes For multi-ingredient products: To prevent the product from being represented as a “traditional medicine”, any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Sage is traditionally used in Herbal Medicine to help relieve minor mucous membrane inflammations of the mouth and throat). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required. Dose(s) Sub-population(s) Adults 18 years and older Quantity(ies) Note: On the PLA form, quantities can be expressed as percentage weight by weight (% w/w), percentage weight by volume (% w/v) or percentage volume by volume (% v/v), depending on the product formulation. On the product label, quantities can also be expressed in other equivalent concentration units (e.g., mg/mL). Loose/Powder dosage forms Methods of preparation: Dry, Powdered 100% dried leaf (Blumenthal 2000; ESCOP 1996) Note: Powdered and dried leaves must be prepared as an infusion by the consumer prior to use (see direction for use) and must provide an equivalent of 20 to 50 milligrams dried leaves per 1 milliliter of finished product. Gargle/Mouthwash dosage forms Methods of preparation: Non-Standardized Liquid Extracts (Decoction, Decoction concentrate, Infusion, Infusion concentrate, Liquid extract) 4 - 100% dried leaf extract preparation in the finished product (Blumenthal 2000; ESCOP 1995; Williamson 1988; Grieve 1931; Cook 1869). Notes: The extract ratio must be between 1:2 and 1:50. The formulation must be prepared in a way which is equivalent to a quantity of 20 to 50 milligrams crude dried leaves per 1 milliliter of finished product. For example, for an infusion prepared with a 1:20 w/w ratio, the concentration of infusion in the final formulation must be 40 to 100% (20 - 50 mg crude dried leaves * 20 w/v (dilution) = 400 - 1000 mg liquid extract in 1 mL finished product = 40 - 100% w/v extract preparation in the finished product). Solvents permitted for liquid extract preparations other than decoctions and infusions are vinegar and water only, in a 1:1 mixture. Method of preparation: Non-Standardized Ethanolic Liquid Extracts (Fluid extract, Tincture) 2 - 50% dried leaf extract preparation in the finished product (Mills and Bone 2005; Blumenthal 2000). Note: The extract ratio must be between 1:1 (fluid extract) and 1:10. The formulation must be prepared in a way which is equivalent to a quantity of 20 to 50 milligrams crude dried leaves per 1 milliliter of finished product. For example, for a tincture prepared with a 1:5 w/w ratio, the concentration of tincture in the finished product must be 2 to 5% (20 - 50 mg crude dried leaves * 5 w/w (dilution) = 100 - 250 mg liquid extract in 1 mL finished product = 10 - 25% w/v extract preparation in the finished product). Methods of preparation: Non-Standardized Dry Extracts (Extract dry) 0.5 - 2.5% dried leaf extract preparation in the finished product

(Mills and Bone 2005; Blumenthal 2000; ESCOP 1996). Notes: The extract ratio must be between 2:1 and 10:1. The formulation must be prepared in a way which is equivalent to a quantity of 20 to 50 milligrams crude dried leaves for 1 milliliter of finished product. For example, for a dry extract prepared with a 4:1 w/w ratio, the concentration of dry extract in the final formulation must be between 40 to 100% (20 - 50 mg crude dried leaves / 4 w/w (concentration) = 5 - 12.5 mg dry extract in 1 mL finished product = 0.5 - 1.25% w/w extract preparation in the finished product). The minimum quantity of 0.5% still applies for more concentrated extracts (e.g., a product containing 0.5% of a dry extract contains 5 mg dry extract in 1 g finished product; 5 mg of a 10:1 w/w dry extract is equivalent to 50 mg crude dried leaves). Solvents allowed for this method of preparation are water and/or ethanol, or a 1:1 mixture of vinegar and water. Liquid dosage form Method of preparation: Fluid extract 100% dried leaf extract preparation in the finished product (Blumenthal 2000). Note: The extract ratio must be 1:1 and the solvent must be ethanol or a mix of ethanol and water. Undiluted fluid extract preparations must be applied to the mouth with a brush or swab (see direction for use). Direction(s) for use Loose/Powder dosage forms Place [insert volume to be measured by consumer in order to obtain 2 to 5 grams dried leaves, e.g., ½ teaspoon] of product in ½ cup (125 mL) of boiling water, infuse for 10 minutes and strain. Let cool. Use 1 tablespoon (15 mL) as a mouthwash/gargle, 3 times a day (Keukenmeester et al. 2012; BHP 1983). Do not swallow (Berardi et al. 2002). Gargle/Mouthwash dosage forms Use 1 tablespoon (15 mL) as a mouthwash/gargle, 3 times a day (Keukenmeester et al. 2012; BHP 1983). Do not swallow (Berardi et al. 2002). Liquid dosage form Apply directly to affected area(s) with a brush or swab, 3 times per day (Blumenthal et al. 2000). Do not eat or drink for 30 to 60 minutes after applying. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) Stop use and ask a health care practitioner/health care provider/health care professional/ doctor/physician if symptoms worsen or last (for) more than 7 days. Contraindication(s) No statement required. 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations. 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. Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Barnes J, Anderson LA, Philipson JD. Herbal Medicines. 3 rd edition. London (GB): The Pharmaceutical Press; 2007. Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self- Care, 13th edition. Washington (DC): American Pharmaceutical Association; 2002. BHC 2006: Bradley PR, editor. British Herbal Compendium Volume 2: A Handbook of Scientific Information on Widely Used Plant Drugs - Companion to the British Herbal Pharmacopoeia. 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RISK INFORMATION

Caution(s) and warning(s) Stop use and ask a health care practitioner/health care provider/health care professional/ doctor/physician if symptoms worsen or last (for) more than 7 days. Contraindication(s) No statement required. 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 Must be established in accordance with the requirements described in the Natural Health Products Regulations.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations.

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. Example of Product Facts: Consult the Guidance Document,Labelling of Natural Health Productsfor more details.

REFERENCES

Route of Administration Buccal

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Salvia officinalis	Common sageDalmatian sageGarden sageSage	Salvia officinalis	Leaf	Dry