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FINAL

COMMUNITY HERBAL MONOGRAPH ON *SALVIA OFFICINALIS* L., FOLIUM

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COMMUNITY HERBAL MONOGRAPH ON *SALVIA OFFICINALIS* L., FOLIUM

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION[1, 2]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Salvia officinalis* L., folium; Salviae officinalis folium (sage leaf) i) Herbal substance Not applicable ii) Herbal preparations Comminuted herbal substance Liquid extract (1:1), extraction solvent ethanol 70% V/V Dry extract (4-7:1), extraction solvent: water Liquid extract (1:3.5-5), extraction solvent: ethanol 31.5% V/V Liquid extract (1:4-5) extraction solvent: ethanol 50% V/V Liquid extract (1:7.2), extraction solvent: liquor wine : ethanol 96% V/V (38.25:61.75 m/m) Tincture (1:10), extraction solvent: ethanol 70% V/V

[1] The material complies with the Eur. Ph. monograph (ref.: 01/2008:1370).
[2] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Comminuted herbal substance (for preparation of an infusion) for oromucosal and cutaneous use. Herbal preparations in solid or liquid dosage forms for oral use. Liquid or semi-solid preparations for oromucosal use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	a) Traditional herbal medicinal product for symptomatic treatment of mild dyspeptic, complaints such as heartburn and bloating. b) Traditional herbal medicinal product for relief of excessive sweating. c) Traditional herbal medicinal product for the symptomatic treatment of inflammations in the mouth or the throat. d) Traditional herbal medicinal product for relief of minor skin inflammations. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults, elderly* Indication a) Comminuted herbal substance for tea preparation: 1-2 g herbal substance in boiling water three times daily . Dry extract: 320 mg divided in 3-4 doses. Liquid extract (1:7.2): 20 drops three times daily. Liquid extract (1:3.5-5): 10 drops three times daily in some liquid. Tincture: ethanol 70% V/V 2-3 ml three times daily. Indication b) Comminuted herbal substance for tea preparation: 2 g herbal substance in 160 ml boiling water. Liquid extract (1:3.5-5): 10-20 drops dissolved in liquid three times daily, for night sweat 1 hour directly before bedtime: 30 drops in liquid. Liquid extract (1:4-5): 50 drops (=2 ml) three times daily. Indication c) Comminuted herbal substance as an infusion: 2.5 g herbal substance in 100 ml boiling water. The infusion is used for gargle. Gel 20% liquid extract (1:1), 250 mg of gel up to 5 times daily on affected regions and massage gently. Liquid extract (1:3.5-5): 15 drops three times daily in warm water for gargle. Liquid extract (1:7.2): 3 spoons (15 ml) in a glass of water, rinse or gargle.

	Tincture: 1-2 spoons (5-10 ml) in a glass of water, rinse or gargle, undiluted tincture is applied locally on the affected regions. Indication d) Comminuted herbal substance as an infusion: 2.5 g herbal substance in 100 ml boiling water 2-4 times daily. The infusion is applied cutaneously. Indications a), b) and c) The intake of thujone should not exceed 5.0 mg/day. The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indications a) and b) Oral use. Sage preparations should not be taken for more than 2 weeks. Indication c) Oromucosal use. Sage preparations should not be taken for more than 1 week. Indication d) Cutaneous use. The average duration of use is 2 weeks. If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use. Oromucosal use. Cutaneous use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s).

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children and adolescents under 18 years of age is not recommended because data are not sufficient and medical advice should be sought. For extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported. The intake of Salviae folium preparations might influence the effect of medicinal products acting via GABA receptor (e.g. barbiturates, benzodiazepines), even if not seen clinically. Therefore the concomitant use with such medicinal products is not recommended.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	May impair ability to drive and use machines. Affected patients should not drive or operate machinery.

4.8. Undesirable effects

Well-established use	Traditional use
	None known. If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	Overdose has been reported with a sense of heat, tachycardia, vertigo and epileptic form convulsions (seizures) after intake corresponding to more than 15 g of sage leaves.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Thujone is reported to be neurotoxic and chemotypes with low content of thujone should be preferred. A daily intake of 5.0 mg/person is acceptable for a maximum duration of use of 2 weeks. Tests on reproductive toxicity genotoxicity and carcinogenicity have not been performed with preparations of Salviae officinalis folium covered by this monograph.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

12 November 2009