2 February 2016
EMA/HMPC/277152/2015
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Salvia officinalis* L., folium

Draft - Revision

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	July 2008 September 2008 November 2008 January 2009
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	14 January 2009
End of consultation (deadline for comments)	15 May 2009
Rediscussion in MLWP	July 2009 September 2009 November 2009
Adoption by HMPC Monograph (EMEA/HMPC/251323/2006) AR (EMEA/HMPC/251324/2006) List of references (EMEA/HMPC/476255/2007) Overview of comments received during the public consultation (EMEA/HMPC/454136/2008) HMPC Opinion (EMEA/HMPC/584717/2008)	12 November 2009
First systematic review	
Discussion in MLWP	May 2015 July 2015 September 2015 November 2015
Adoption by HMPC	2 February 2016
Start of public consultation	15 February 2016
End of consultation (deadline for comments).Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 May 2016
Rediscussion in MLWP	
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Salvia officinalis* L.; Salviae officinalis folium; sage leaf

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BG (bulgarski): Градински чай, лист CS (čeština): list šalvěje lékařské DA (dansk): Salvieblad DE (Deutsch): Salbeiblätter EL (elliniká): Φασκομήλου ελελιφάσκου φύλλο EN (English): Sage leaf ES (español): Salvia, hoja de ET (eesti keel): aedsalveileht FI (suomi): salvia, lehti FR (français): Sauge officinale (feuille de) HR (hrvatski): kaduljin list HU (magyar): Orvosi zsálya levél IT (italiano): Salvia officinale foglia	LT (lietuvių kalba): Vaistinių šalavijų lapai LV (latviešu valoda): Ārstniecības salvijas lapas MT (Malti): Werqa tal-Salvja NL (Nederlands): Echte Salie PL (polski): Liść szałwii PT (português): Salva, folha RO (română): frunză de salvie SK (slovenčina): List šalvie lekárskej SL (slovenščina): list žajblja SV (svenska): Salvia, blad *IS (íslenska)*: *NO (norsk*): Salvieblad

European Union 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; *Salvia officinalis* folium (sage leaf) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance. b) Liquid extract (DER 1:1), ethanol 70% V/V c) Dry extract (DER 4-7:1), extraction solvent: water d) Liquid extract (DER 1:3.5-5), extraction solvent: ethanol 31.5% V/V e) Liquid extract (DER 1:4-5) extraction solvent: ethanol 50% V/V f) Liquid extract (DER 1:4-6), extraction solvent: liquor wine : ethanol 96% V/V (DER 38.25 : 61.75 m/m) g) Tincture (1:10) extraction solvent: ethanol 70% V/V h) Dry extract from fresh leaves (1:17-18), extraction solvent: ethanol 68 % V/V

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use.

[1] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

[2] Detailed specifications for the herbal substance shall be given by references to bibliographic sources in absence of a monograph in the European Pharmacopoeia, a national pharmacopoeia or national codex currently used officially in a Member State.

Well-established use	Traditional use
	Comminuted herbal substance for infusion for oromucosal and cutaneous use. Herbal preparations in solid or liquid dosage forms for oral use. Herbal preparations in liquid or semi-solid dosage forms for cutaneous use or 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
	Indication 1) Traditional herbal medicinal product for relief of mild dyspeptic complaints such as heartburn and bloating. Indication 2) Traditional herbal medicinal product for relief of excessive sweating. Indication 3) Traditional herbal medicinal product for relief of inflammations in the mouth or the throat. Indication 4) Traditional herbal medicinal product for relief of minor skin inflammations.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology *Adults and elderly* Indication 1) a) Single dose: Herbal tea: 1-2 g of the comminuted herbal substance in 150 ml boiling water as a herbal infusion three times daily. Daily dose: 3-6 g c) Single dose: 80-107 mg Daily dose: 320 mg

[3] For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1)

Well-established use	Traditional use
	d) Single dose: 0.5 ml in water Daily dose: 1.5 ml f) Single dose: 0.43 ml in warm water. Daily dose: 1.29 ml g) Single dose: 2-3 ml Daily dose: 6-9 ml Indication 2) a) Daily dose: Herbal tea: 2 g of comminuted herbal substance in 150 ml boiling water as a herbal infusion. d) Single dose: 0.5-1 ml in liquid Daily dose: 1.5-3 ml For nightsweat, 1.5 ml in liquid 1 hour directly before bedtime. e) Single dose: 2 ml in liquid Daily dose: 6 ml h) Single dose: 51 mg for oral use once daily Indication 3) a) Single dose: 2.5 g 2.5 g of the comminuted herbal substance in 100 ml boiling water. The infusion is used warm for gargle several times daily. b) Single dose: 250 mg 250 mg of gel for oromucosal use. Apply on affected regions and massage gently. Daily dose: up to 1250 mg c) Single dose: 0.75 ml 0.75 ml three times daily in 150 ml warm water for gargle. Daily dose: 2.25 ml f) Average daily dose: 0.65 ml in 150 ml water for rinse or gargle several times daily. g) Average daily dose: 5-10 ml 10 ml in a glass of water for rinse or gargle several times daily. Undiluted tincture is applied locally on the affected regions once daily. Indication 4) a) Average daily dose: 2.5 g Herbal tea: Comminuted herbal substance in boiling water as a herbal infusion for cutaneous use: 2.5 g in 100 ml water, divided in 2-4 single doses. The use in children and adolescents under 18 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’).

Well-established use	Traditional use
	Duration of use Indications 1) and 2) Not to be used for more than 2 weeks. Indication 3) Not to be used for more than 1 week. Indication 4) 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** Indication 1) and 2) - oral use Indication 3) - oromucosal use Indication 4) - 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 has not been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For tinctures and 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.

4.6. Fertility, 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. No fertility data available.

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

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
	No case of overdose from sage leaves has been reported. Intake of sage oil corresponding to more than 15 g of sage leaf is reported to cause sensation of heat, tachycardia, vertigo and epileptic form or convulsions (seizures).

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. Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	The amount of thujone has to be specified in the given product. The daily exposure has to be below 6.0 mg. For more details see the “Public statement on the use of herbal medicinal products containing thujone)” (EMA/HMPC/732886/2010).

7. Date of compilation / last revision

2 February 2016