EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 September 2016
EMA/HMPC/277152/2015
Committee on Herbal Medicinal Products (HMPC)

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

Final

Initial assessment	
Discussion in Working Party on European Union monographs and 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
Re-discussion in MLWP	July 2009 September 2009 November 2009
Adoption by HMPC Monograph (EMA/HMPC/331653/2008) AR (EMA/HMPC/330383/2008) List of references (EMA/HMPC/331645/2008) Overview of comments received during the public consultation (EMA/HMPC/443915/2009) HMPC Opinion (EMEA /HMPC/583001/2009)	12 November 2009
First systematic review	
Discussion in MLWP	March 2015 May 2015 July 2015 September 2015 November 2015
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Salvia officinalis* L. folium; Salviae officinalis folium; sage leaf

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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 *Salvia officinalis* L., folium, (sage leaf) i) Herbal substance Not applicable ii) Herbal preparations a) Comminuted herbal substance b) Liquid extract (DER 1:1), extraction solvent 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 (38.25:61.75 m/m) g) Tincture (ratio of herbal substance to extraction solvent 1:10) extraction solvent ethanol 70% V/V

3. Pharmaceutical form

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

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

Well-established use	Traditional use
	preparation for oromucosal or cutaneous use. Herbal preparations in liquid or solid 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. 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[3]

Well-established use	Traditional use
	Posology *Adults and elderly* Indication 1) **a) Comminuted herbal substance** Herbal tea: 1-2 g of the comminuted herbal substance in 150 ml boiling water as herbal

[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
	infusion 3 times daily. **c) Dry extract (DER 4-7:1)** 320 mg daily divided in 3-4 doses **d) Liquid extract (DER 1:3.5-5)** 0.5 ml in water 3 times daily. **f) Liquid extract (DER 1:4-6)** 0.43 ml 3 times daily **g) Tincture** 2-3 ml 3 times daily Indication 2) **a) Comminuted herbal substance** Herbal tea: 2 g of comminuted herbal substance in 150 ml boiling water as herbal infusion. **c) Dry extract (DER 4-7:1)** 80-160 mg 3 times daily **d) Liquid extract (DER 1:3.5-5)** 0.5-1 ml in some liquid 3 times daily. For night sweat: 1.5 ml in some liquid 1 hour directly before bedtime. **e) Liquid extract (DER 1:4.5)** 2 ml 3 times daily Indication 3) **a) Comminuted herbal substance**: 2.5 g comminuted herbal substance in 100 ml boiling water as an infusion. The infusion is used warm for gargle 3 times daily. **b) Liquid extract (DER 1:1)** 250 mg gel containing 20% liquid extract for oromucosal use. Apply on affected regions and massage gently up to 5 times daily. **d) Liquid extract (DER 1:3.5-5)** 0.5 ml in 150 ml warm water for gargle 3 times daily.

Well-established use	Traditional use
	f) Liquid extract (DER 1:4-6) 0.65 ml in 150 ml water for rinse or gargle 3 times daily. **g) Tincture** 5-10 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) Comminuted herbal substance** 2.5 g of the comminuted herbal substance in 100 ml water as herbal infusion to be applied on the affected area of the skin 2-4 times daily. 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 1) If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication 2) Long-term use is possible (see section 4.4 'Special warnings and precautions for use'). If the symptoms do not improve within 6 weeks of use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication 3) If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication 4) If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Well-established use	Traditional use
	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

Well-established use	Traditional use
	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 epileptiform 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.

5.2. Pharmacokinetic properties

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

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the safe use of the product. Thujone is reported to be neurotoxic, hence chemotypes with low content of thujone should be preferred. Adequate tests on genotoxicity and carcinogenicity have not been performed. Tests on reproductive toxicity 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

20 September 2016