28 January 2015
EMA/HMPC/680372/2013
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Eschscholzia californica* Cham., herba

Final

Discussion in Working Party on European Union monographs and list (MLWP)	November 2013 January 2014 March 2014 May 2014
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Eschscholzia californica* Cham., herba; Eschscholziae herba; California poppy

BG (bulgarski): Калифорнийски мак, стрък CS (čeština): nať sluncovky kalifornské DA (dansk): DE (Deutsch): Goldmohnkraut EL (elliniká): EN (English): California poppy ES (español): Amapola de California, partes aéreas de ET (eesti keel): läänemagunaürt FI (suomi): kaliforniantuliunikko, verso FR (français): HR (hrvatski): zelen kalifornijskog maka HU (magyar):	IT (italiano): LT (lietuvių kalba): Ešolcijų žolė LV (latviešu valoda): Ešolcijas laksts MT (Malti): NL (Nederlands): Slaapmutsje, kruid PL (polski): ziele eszolcji kalifornijskiej /ziele pozłotki kalifornijskiej PT (português): Papoila-da-Califórnia, partes aéreas RO (română): SK (slovenčina): Vňať slncovky SL (slovenščina): zel kalifornijskega zlatega maka SV (svenska): Sömntuta, ört *IS (íslenska)*: *NO (norsk):* Kaliforniavalmue

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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. *Eschscholzia californica* Cham., herba i) Herbal substance Not applicable ii) Herbal preparations Powdered herbal substance

3. Pharmaceutical form

Well-established use	Traditional use
	Powdered herbal substance in solid dosage forms for oral 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
	1) Traditional herbal medicinal product for relief of mild symptoms of mental stress. 2) Traditional herbal medicinal product to aid sleep. The product is a traditional herbal medicinal product for use in specified indications exclusively

[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 substances 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
	based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
Posology	**Posology** *Adults, Elderly* Indication 1) Powdered herbal substance: Single dose: 480-600 mg Daily dose: 960-1500 mg Indication 2) Powdered herbal substance: Single dose: 480-600 mg Daily dose: 960–1500 mg One single dose with dinner and another single dose 30-60 min before bedtime. 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** 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. **Method of administration** Oral 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.

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
	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 reported. 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 has been reported.

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

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation / last revision

28 January 2015