



1 July 2014  
EMA/HMPC/680372/2013  
Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Eschscholzia californica* Cham., herba

### Draft

Discussion in Working Party on Community monographs and Community list (MLWP)	November 2013 January 2014 March 2014 May 2014
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	1 July 2014
End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a>	31 October 2014
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<b>Keywords</b>	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Eschscholzia californica</i> , herba; California poppy
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BG (bългарски): Калифорнийски мак, стрък с цвят CS (čeština): nař sluncovky kalifornské s květem DA (dansk): Californisk guldvalmue DE (Deutsch): Goldmohnkraut mit Blüten EL (elliniká): Εσσολζίας της καλιφορνιακής άνθος EN (English): California poppy ES (español): Amapola de California, partes aéreas floridas ET (eesti keel): läänemagunaürt koos õitega FI (suomi): kaliforniantuliunikko, verso kukkineen FR (français): Eschscholtzia, parties aériennes fleuries d' HU (magyar): Kaliforniai kakukkmák virágos hajtás HR (hrvatska): nař sluncovky kalifornské s květem	IT (italiano): LT (lietuvių kalba): Ešolcijų žolė su žiedais LV (latviešu valoda): Ešolcijas laksti ar ziediem MT (malti): Ғaxixa u fjuri tal-Peprin ta' Kalifornja NL (nederlands): slaapmutsje PL (polski): Ziele pozłotki kalifornijskiej z kwiatem PT (português): Papoila-da-Califórnia RO (română): SK (slovenčina): Slncovková vňar s kvetom SL (slovenščina): zel in cvet kalifornijskega zlatega maka SV (svenska): Sömntuta, ovanjordiska delar i blom IS (íslenska): NO (norsk): Californiavalmue, urt med blomst
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# Community herbal monograph on *Eschscholzia californica* Cham., herba

## 1. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>1</sup>

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended.</p> <p><i>Eschscholzia californica</i> Cham., herba</p> <p>i) Herbal substance</p> <p>Not applicable</p> <p>ii) Herbal preparations</p> <p>Powdered herbal substance</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Powdered herbal substance in solid dosage forms for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<p>1) Traditional herbal medicinal product for relief of mild symptoms of mental stress.</p> <p>2) Traditional herbal medicinal product to aid sleep.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

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

## 4.2. Posology and method of administration

Well-established use	Traditional use
<p><b>Posology</b></p>	<p><b>Posology</b> <i>Adults, Elderly</i></p> <p><b>Indication 1)</b></p> <p>Powdered herbal substance: Single dose: 480-600 mg Daily dose: 960-1500 mg</p> <p><b>Indication 2)</b></p> <p>Powdered herbal substance: Single dose: 480 mg Daily dose: 960–1500 mg</p> <p>One single dose with dinner and another single dose 30-60 min before bedtime.</p> <p>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><b>Duration of use</b> 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.</p> <p><b>Method of administration</b> Oral use.</p>

## 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 12 years of age has not been established due to lack of adequate data.

Well-established use	Traditional use
	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

1 July 2014