



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Oenothera biennis* L.; *Oenothera lamarckiana* L., oleum

Draft

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Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	31 March 2011
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>	15 August 2011
Rediscussion in Working Party on Community monographs and Community list (MLWP)	
Adoption by Committee on Herbal Medicinal Products (HMPC)	

<b>Keywords</b>	Herbal medicinal products; HMPC; Community herbal monographs; traditional use <i>Oenothera biennis</i> L.; <i>Oenothera lamarckiana</i> L., oleum; evening primrose oil
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BG (bългарски): Пупалка, масло CS (čeština): pupalkový olej DA (dansk): Kæmpenatlysolie DE (Deutsch): Nachtkerzensamenöl EL (elliniká): Οινοθήρας έλαιο EN (English): evening primrose oil ES (español): Onagra, aceite de ET (eesti keel): kaheaastase kuningakepi õli FI (suomi): FR (français): Onagre (huile d') HU (magyar): Ligetszépe-olaj IT (italiano): Enotera olio	LT (lietuvių kalba): LV (latviešu valoda): Divgadīgās naktsšveces eļļa MT (malti): Żejt tal-Oenotheria NL (nederlands): Teunisbloemolie PL (polski): Olej wiesiolkowy PT (português): Óleo de onagra RO (română): ulei de luminița nopții SK (slovenčina): Pupalkový olej SL (slovenščina): olje dvoletnega svetlina SV (svenska): Passionsblomma IS (íslenska): NO (norsk): Pasjonsblomst
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# Community herbal monograph on *Oenothera biennis* L.; *Oenothera lamarckiana* L., oleum

## 1. Name of the medicinal product

To be specified for the individual finished product.

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

Well-established use	Traditional use
	<p>With regard to the marketing authorisation application of Article 10(a) of Directive 2001/83/EC as amended</p> <p><i>Oenothera biennis</i> L.; <i>Oenothera lamarckiana</i> L., oleum (evening primrose oil)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>Fatty oil obtained from seeds of <i>Oenothera biennis</i> L. or <i>Oenothera lamarckiana</i> L. by extraction and/or expression.</p>

## 3. Pharmaceutical form

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

<sup>2</sup> The material complies with the Ph. Eur. monograph (ref.: 01/2010:2104).

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	Traditional herbal medicinal product for the symptomatic relief of itching in acute and chronic dry skin conditions.

### 4.2. Posology and method of administration

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><i>Adolescents, adults and elderly:</i></p> <p>Single dose: 2 g Daily dose: 4-6 g</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p><b>Duration of use</b></p> <p>If the symptoms persist longer than 8 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></p> <p>Oral use.</p>

### 4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

### 4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children under 12 years of age has not been established due to lack of adequate data.

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

<b>Well-established use</b>	<b>Traditional use</b>
	None reported.

#### ***4.6. Fertility, pregnancy and lactation***

<b>Well-established use</b>	<b>Traditional use</b>
	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***

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

#### ***4.8. Undesirable effects***

<b>Well-established use</b>	<b>Traditional use</b>
	<p>Gastrointestinal effects, indigestion, nausea, softening of stool, rise in temperature, hypersensitive reactions like exanthema and headache have been reported. The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

#### ***4.9. Overdose***

<b>Well-established use</b>	<b>Traditional use</b>
	The symptoms of overdosing are mild diarrhoea and abdominal pain. No special treatment is required.

## 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.  Adequate 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

31 March 2011