



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 December 2011
EMA/HMPC/277792/2009
Committee on Herbal Medicinal Products (HMPC)

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

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	March 2011
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	31 March 2011
End of consultation (deadline for comments)	15 August 2011
Rediscussion in Working Party on Community monographs and Community list (MLWP)	September 2011
Adoption by Committee on Herbal Medicinal Products (HMPC)	16 December 2011

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use <i>Oenothera biennis</i> L.; <i>Oenothera lamarckiana</i> L., oleum; evening primrose oil
-----------------	---

BG (bългарski): 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): Helokkiöljy FR (français): Onagre (huile d') HU (magyar): Ligetszépe-olaj IT (italiano): Enotera olio	LT (lietuvių kalba): LV (latviešu valoda): Divgadīgās naktssveces eļļa MT (malti): Żejt tal-Oenotheria NL (nederlands): Teunisbloemolie PL (polski): Olej wiesiolkowy PT (português): Óleo de onagra RO (română): ulei de luminița noptii SK (slovenčina): Pupalkový olej SL (slovenščina): Olje dvoletnega svetlina SV (svenska): Nattljusolja IS (íslenska): NO (norsk): Nattlysolje
--	---



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^{1,2}

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16 d(1) 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>

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.: 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>Posology</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>Duration of use</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>Method of administration</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

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.

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
	<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

Well-established use	Traditional use
	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

16 December 2011