



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 June 2018
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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Oenothera biennis* L. or *Oenothera lamarckiana* L., oleum

Final

Discussion in Working Party on European Union monographs and European Union 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 MLWP	September 2011
Adoption by HMPC	22 November 2011
First systematic review	
Discussion in MLWP	September 2017 November 2017 January 2018 March 2018
Adoption by HMPC	05 June 2018

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Oenothera biennis</i> L. or <i>Oenothera lamarckiana</i> L., oleum; evening primrose oil.
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BG (bългарski): Пупалка, масло	LT (lietuvių kalba): Nakvišų aliejus
CS (čeština): pupalkový olej	LV (latviešu valoda): Divgadīgās naktssvecēs eļļa
DA (dansk): Kæmpenatlysolie	MT (malti): żejt tal-oenotheria
DE (Deutsch): Nachtkerzensamenöl	NL (nederlands): Teunisbloemolie
EL (elliniká): Οινοθήρας έλαιο	PL (polski): Olej wiesiolkowy
EN (English): evening primrose oil	PT (português): óleo de onagra
ES (español): onagra, aceite de	RO (română): ulei de luminița noapții
ET (eesti keel): kaheaastase kuningakepi õli	SK (slovenčina): pupalkový olej
FI (suomi): helokkiöljy	SL (slovenščina): olje dvoletnega svetlina
FR (français): onagre (huile d')	SV (svenska): nattljusolja
HR (hrvatski): noćurkovo ulje	IS (íslenska):
HU (magyar): ligetszépe-olaj	NO (norsk): nattlysolje
IT (italiano): Enotera (Rapunzia, Enagra, Bella di notte) olio	

European Union herbal monograph on *Oenothera biennis* L. or *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 16d(1) of Directive 2001/83/EC.</p> <p><i>Oenothera biennis</i> L. or <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>

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Traditional herbal medicinal product for the symptomatic relief of itching in acute and chronic dry skin conditions exclusively based upon long-standing use.</p>

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

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

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: 2-3 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.

Well-established use	Traditional use
	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
	<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.

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. 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

5 June 2018