28 March 2017
EMA/HMPC/44166/2016
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Melilotus officinalis* (L.) Lam., herba

Draft

Initial assessment	
Discussion in Working Party on European Union monographs and list (MLWP)	September 2007 October 2007
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Adoption by HMPC Monograph (EMA/HMPC/354177/2007) AR (EMA/HMPC/354183/2007) List of references (EMA/HMPC/476396/2007) Overview of comments received during public consultation (EMA/HMPC/220828/2008) HMPC Opinion (EMA/HMPC/305054/2008EN)	03 July 2008
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Initial assessment	
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; well-established medicinal use; traditional use; *Melilotus officinalis* (L.) Lam., herba; Meliloti herba; melilot

BG (bulgarski): Лечебна комунига, стрък CS (čeština): komonicová nať DA (dansk): Stenkløverurt DE (Deutsch): Steinkleekraut EL (elliniká): μελιλώτου πόα EN (English): melilot ES (español): meliloto, partes aéreas de ET (eesti keel): mesikaürt FI (suomi): rohtomesikkä FR (français): mélilot (parties aériennes de) HR (hrvatski): zelen kokotca HU (magyar): orvosi somkóró virágos hajtás IT (italiano): Meliloto parti aeree	LT (lietuvių kalba): Barkūnų žolė LV (latviešu valoda): Amoliņa laksti MT (Malti): trew NL (Nederlands): honingklaver PL (polski): Ziele nostrzyka PT (português): meliloto RO (română): iarbă de sulfină SK (slovenčina): vňať komonice SL (slovenščina): zel navadne medene detelje SV (svenska): sötväppling, ört *IS* (íslenska): *NO* (norsk): legesteinkløver

European Union herbal monograph on *Melilotus officinalis* (L.) Lam., herba

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 *Melilotus officinalis* (L.) Lam., herba (melilot) i) Herbal substance Not applicable ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Liquid extract, ratio of herbal substance to extraction solvent[3] 1:3, extraction solvents: ethanol 70% (V/V), rapeseed oil[4]

3. Pharmaceutical form

Well-established use	Traditional use
	a) Comminuted herbal substance as herbal tea, infusion, for oral use b) Herbal substance in solid dosage forms for oral use c) Herbal preparations in semi-solid dosage forms for cutaneous use The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

[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.: 2120).

[3] Ratio of herbal substance to extraction solvent is defined in general monograph *Herbal drug extracts* of European Pharmacopoeia 9.0 as *Drug solvent ratio* (DSR).

[4] Preparation method described in Farmakopea Polska IV, 1970, p. 198.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use Indication 2) Traditional herbal medicinal product used for the treatment of minor inflammations of the skin. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration[5]

Well-established use	Traditional use
	Posology Indication 1) *Adults and Elderly* a) Single dose: Herbal tea: 1.0–1.2 g of comminuted herbal substance in boiling water as an herbal infusion 2 times daily Daily dose: 2.0–2.4 g b) Single dose: Powdered herbal substance: 250 mg 3 times daily Daily dose: 750 mg Indication 2) c) Single dose: 3 g of liquid extract, as a cutaneous patch applied to the affected skin

[5] For guidance on herbal substance/herbal preparation administered as herbal tea or as infusion/decoction/macerate preparation, please refer to the HMPC 'Glossary on herbal teas' (EMA/HMPC/5829/2010 Rev.1).

Well-established use	Traditional use
	area. Daily dose: 3–6 g (up to two patches). 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** Indication 1) 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. Indication 2) If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Indication 1) Oral use Indication 2) Cutaneous 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. Indication 1) If the symptoms of thrombophlebitis or subcutaneous induration, sudden swelling of one or both legs, cardiac or renal insufficiency appear during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Well-established use	Traditional use
	Indication 2) If symptoms of skin inflammation worsen or signs of skin infections occur 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
	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
	Oral use Gastrointestinal complaints have been reported. The frequency is not known. *Cutaneous use* Allergic reactions have been reported. The frequency is not known. If other adverse reactions not mentioned above 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.

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

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable

7. Date of compilation / last revision

28 March 2017