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Evaluation of Medicines for Human Use

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**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

DRAFT

**COMMUNITY HERBAL MONOGRAPH ON
MELILOTUS OFFICINALIS (L.) LAM., HERBA**

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	September 2007 October 2007
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REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Melilotus officinalis</i> (L.) LAM.; Meliloti herba; Melilot
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**COMMUNITY 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}

<u>Well-established use</u>	<u>Traditional use</u>
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended i) Herbal substance Whole or cut, dried aerial parts of <i>Melilotus officinalis</i> (L.) Lam. ii) Herbal preparations - comminuted herbal substance - powdered herbal substance - Dry extracts (3 - 5:1), water - Liquid extracts (1:1), ethanol 30 % V/V - Dry Extracts (5 - 7:1), ethanol 50 % V/V - Dry extracts (4 - 8:1), ethanol 25 % m/m - Dry extracts (4.2-7.5:1), methanol 50 % V/V - Dry extracts (4 - 8:1), ethanol 35 % V/V - Dry extracts (6 - 9:1), ethanol 90 % V/V - Dry extracts (7 - 9:1), methanol 30 V/V - Emplastrum Meliloti: prepared by extraction of 10 parts of pulverized drug, wetted with 2 parts of ethanol, with 90 parts of semi-solid base (Rapae oleum, Cera flava, Colophonium) Final DER 0.11:1

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

¹ The material complies with the Ph. Eur. monograph (ref. 04/2005:2120 corrected 5.3).

² The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u> <u>Oral use:</u> 1. Traditional herbal medicinal product to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances. <u>Topical use:</u> 2. Traditional herbal medicinal product to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances. 3. Traditional herbal medicinal product for symptomatic treatment of bruises and sprains. Topical use of Emplastrum Meliloti 4. Traditional herbal medicinal product used for symptomatic treatment of insect bites. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.
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4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u> Posology <i>Adults, elderly</i> Daily dosage The daily dose should not exceed 5 mg of coumarin in the final preparation. <u>Oral use</u> i) Single dose: 0.25 - 1 g herbal substance for infusion up to 3 times daily ii) powdered herbal substance: Single dose: 0.25 - 1.6 g daily dose: 0,75 g - 1.6 g Dry extracts (3 - 5:1), water: Single dose: 200 mg, twice daily. Liquid extracts (1:1), ethanol 30 % V/V: Single dose: 1.14 g, 3times daily. Dry extracts (5 - 7:1), ethanol 50 % V/V: Single dose: 160 mg extract, 3 times daily.
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	Dry extracts (4 - 8:1), ethanol 25 % m/m: Single dose: 100 mg extract, 3 times daily. Dry extracts (4.2 - 7.5:1), methanol 50 % V/V: Single dose: 200 mg extract, 3 times daily. Dry extracts (4 - 8:1), ethanol 35 % V/V: Single dose: 252 mg extract; once daily. Dry extracts (5 - 7:1), ethanol 50 % V/V: Single dose: 160 mg extract, 3 times daily. Dry extracts (4 - 8:1), ethanol 25 % m/m: Single dose: 100 mg extract, 3 times daily. Dry extracts (4.2 - 7.5:1), methanol 50 % V/V: Single dose: 200 mg extract, 3 times daily. Dry extracts (4 - 8:1), ethanol 35 % V/V: Single dose: 252 mg extract; once daily. Dry extracts (6 - 9:1), ethanol 90 % V/V: 24 mg extract, 2 - 3 times daily. Dry extracts (7 - 9:1), methanol 30 V/V: Single dose: 30 mg extract, 2 - 3 times daily. <u>Topical use</u> i) not applicable ii) comminuted herbal substance for decoctions: 2 - 4 g / 150 ml decoction (indications 2-4). Emplastrum Meliloti: for single use (indication 4) <i>Children, adolescents</i> There is no traditional indication for the use in children and adolescents. Duration of use Indications 1 - 3: If the symptoms persist for more than 2 weeks, a doctor or a qualified health care practitioner should be consulted. Indication 4: If the symptoms persist for more than 3 days, a doctor should be consulted. Method of administration - Oral use. - Topical use.
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4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u>
	Hypersensitivity to the active substance(s). Not to be used concomitantly with anticoagulant therapy. Patients with a history of liver disease.

4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u>
	If there is inflammation of the skin, thrombophlebitis, varicosis or subcutaneous induration, ulcers, sudden swelling of one or both legs, cardiac or renal insufficiency, a doctor should be consulted. If symptoms 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. For extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

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

<u>Well-established use</u>	<u>Traditional use</u>
	Interactions between anticoagulants and Melilotus-containing medicinal products have been reported.

4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u>
	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

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

4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u>
	Gastrointestinal complaints and 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

<u>Well-established use</u>	<u>Traditional use</u>
	Nausea, vomitus, headache and weakness have been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u>
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u>
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u>
	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

<u>Well-established use</u>	<u>Traditional use</u>
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

31 October 2007