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FINAL

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

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7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 75 23 70 51
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

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]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Melilotus officinalis* (L.) Lam., herba (melilot) i) Herbal substance Not applicable ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Dry extracts (3 - 5:1), water d) Liquid extracts (1:1), ethanol 30 % V/V e) Dry Extracts (5 - 7:1), ethanol 50 % V/V f) Dry extracts (4 - 8:1), ethanol 25 % m/m g) Dry extracts (4 - 8:1), methanol 50 % V/V h) Dry extracts (4 - 8:1), ethanol 35 % V/V i) Dry extracts (6 - 9:1), ethanol 90 % V/V j) Dry extracts (7 - 9:1), methanol 30 % V/V k) 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

[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

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Herbal preparations in liquid dosage forms for oral use or in semi-solid dosage forms for cutaneous use. Comminuted herbal substance as herbal tea for oral use or as decoction for cutaneous use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional use
	Oral use: 1. Traditional herbal medicinal product to relieve symptoms of discomfort and heaviness of legs related to minor venous circulatory disturbances. Cutaneous use: 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. Cutaneous 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.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults, elderly* Daily dosage The daily dose should not exceed 5 mg of coumarin in the final preparation. Oral use i) Not applicable ii) Herbal preparations a) Comminuted herbal substance for tea preparation Single dose: 0.25 - 1 g up to 3 times daily b) Powdered herbal substance: Single dose: 0.25 - 1.6 g daily dose: 0.75 g - 1.6 g c) Dry extracts (3 - 5:1), water: Single dose: 200 mg, twice daily. d) Liquid extracts (1:1), ethanol 30 % V/V: Single dose: 1.14 g, 3 times daily. e) Dry extracts (5 - 7:1), ethanol 50 % V/V: Single dose: 160 mg extract, 3 times daily. f) Dry extracts (4 - 8:1), ethanol 25 % m/m: Single dose: 100 mg extract, 3 times daily. g) Dry extracts (4 - 8:1), methanol 50 % V/V: Single dose: 200 mg extract, 3 times daily. h) Dry extracts (4 - 8:1), ethanol 35 % V/V: Single dose: 252 mg extract; once daily. i) Dry extracts (6 - 9:1), ethanol 90 % V/V: 24 mg extract, 2 - 3 times daily. j) Dry extracts (7 - 9:1), methanol 30 % V/V: Single dose: 30 mg extract, 2 - 3 times daily.

	Cutaneous use i) Not applicable ii) Herbal preparations a) Comminuted herbal substance for decoction: 2 - 4 g / 150 ml decoction (indications 2-4). k) Emplastrum Meliloti: for single use (indication 4) The use is not recommended in children and adolescents under 18 years of age (see section 4.4 'Special warnings and precautions for use'). **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. - Cutaneous use.

4.3. Contraindications

Well-established use	Traditional use
	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

Well-established use	Traditional use
	The use is not recommended in children and adolescents under 18 years of age as there are no data to support a traditional indication in this group. 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

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

4.6. 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
	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

Well-established use	Traditional use
	Nausea, vomitus, headache and weakness have 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 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. 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

3 July 2008