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Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Commiphora molmol* Engler, gummi-resina

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	July 2010 September 2010
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End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a>	15 March 2011
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# Community herbal monograph on *Commiphora molmol* Engler, gummi-resina

## 1. Name of the medicinal product

To be specified for the individual finished product.

## 2. Qualitative and quantitative composition<sup>1, 2</sup>

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Commiphora molmol</i> Engler, gummi-resina (myrrh)</p> <p>i) Herbal substance Not applicable</p> <p>ii) Herbal preparations Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 90 % V/V)</p>

## 3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal preparation in liquid dosage forms for oromucosal or cutaneous 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>Indication 1)</p> <p>Traditional herbal medicinal product for treatment of minor ulcers and inflammation in the mouth</p>

1 The material complies with the Ph. Eur. monograph (ref.: 01/2008:1349 corrected 6.0).

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

	<p>(stomatitis and gingivitis).</p> <p><b>Indication 2)</b></p> <p>Traditional herbal medicinal product for treatment of minor wounds and small boils (furuncles).</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>
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#### 4.2. Posology and method of administration

<b>Well-established use</b>	<b>Traditional use</b>
	<p><b>Posology</b></p> <p><u>Oromucosal use</u></p> <p><b>Indication 1)</b></p> <p><i>Adolescents, adults and elderly</i></p> <p>i) 0.5-5 ml of tincture in 150 ml of water for rinsing or gargling 3 times daily.</p> <p>or</p> <p>ii) The undiluted tincture is applied to the affected areas with a cotton bud 2-3 times daily.</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><u>Cutaneous use</u></p> <p><b>Indication 2)</b></p> <p><i>Adolescents, adults and elderly</i></p> <p>The wound or furuncle is dabbed 2-3 times daily with undiluted (preferably) or diluted tincture in water.</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><b>Duration of use</b></p> <p>If the symptoms persist after 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Method of administration</b></p> <p>Oromucosal and cutaneous 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
	<p>Indications 1) and 2)</p> <p>The use in children under 12 years of age is not recommended due to lack of adequate data.</p> <p>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>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.</p> <p>Indication 2)</p> <p>If fever or signs of exacerbating skin infection are observed, a doctor or a qualified health care practitioner should be consulted.</p> <p>Small boils (furuncles) in the face should be treated by a medical doctor.</p> <p>Eye contact with myrrh tincture should be avoided.</p>

#### 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
	<p>Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p>

#### 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
	Allergic skin reactions have been reported. The frequency is not known.  The tincture contains alcohol, which may cause a transient pain and irritation on application to the mucosa or skin.  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 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.

	<p>Adequate tests on genotoxicity have not been performed.</p> <p>Tests on reproductive toxicity and carcinogenic potential have not been performed.</p>
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## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

## 7. Date of compilation/last revision

12 July 2011