



14 May 2013  
EMA/HMPC/196745/2012  
Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Melissa officinalis* L., folium

Final

<b>Initial assessment</b>	
Discussion in Working Party on Community monographs and Community list (MLWP)	March 2007 May 2007
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	8 May 2007
End of consultation (deadline for comments)	15 August 2007
Rediscussion in MLWP	October 2007
Adoption by Committee on Herbal Medicinal Products (HMPC) Monograph (EMA/HMPC/5341/2007) AR (EMA/HMPC/5342/2007) List of references (EMA/HMPC/207739/2007) Overview of comments received during the public consultation (EMA/HMPC/499295/2007) HMPC Opinion (EMA/HMPC/453710/2007)	31 October 2007
<b>First systematic review</b>	
Discussion in MLWP	May 2012 January 2013 March 2013
Adoption by HMPC for release for consultation	N/A
End of consultation (deadline for comments)	N/A
Rediscussion in MLWP	N/A
Adoption by HMPC	14 May 2013

A search for the versions adopted in September 2007 can be made via the EMA document search function, using the documents' reference number, at:  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/document\\_library/landing/document\\_library\\_search.jsp&mid=](http://www.ema.europa.eu/ema/index.jsp?curl=pages/document_library/landing/document_library_search.jsp&mid=)



<b>Keywords</b>	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Melissa officinalis</i> L., folium; Melissae folium; Melissa leaf
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<p>BG (bългарski): Маточина, лист</p> <p>CS (čeština): meduňková nať</p> <p>DA (dansk): Citronmelisseblad</p> <p>DE (Deutsch): Melissenblätter</p> <p>EL (elliniká): φύλλο μελίσσης</p> <p>EN (English): Melissa leaf</p> <p>ES (español): Melisa, hoja de</p> <p>ET (eesti keel): melissileht</p> <p>FI (suomi): sitruunamelissa, lehti</p> <p>FR (français): Mélisse (feuille de)</p> <p>HU (magyar): Citromfűlevél</p> <p>IT (italiano): Melissa foglia</p>	<p>LT (lietuvių kalba): Melisų lapai</p> <p>LV (latviešu valoda): Melisas lapas</p> <p>MT (malti): Werqa tal-Buriĥa / Melissa</p> <p>NL (nederlands): Citroenmelisse</p> <p>PL (polski): Liść melisy</p> <p>PT (português): Melissa, folha</p> <p>RO (română): frunză de roiniță</p> <p>SK (slovenčina): Medovkový list</p> <p>SL (slovenščina): list navadne melise</p> <p>SV (svenska): Citronmeliss, blad</p> <p><i>IS (islenska):</i></p> <p><i>NO (norsk):</i> Sitronmelisseblad</p>
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# Community herbal monograph on *Melissa officinalis* L., folium

## 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>Melissa officinalis</i> L., folium (Melissa leaf)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Powdered herbal substance</p> <p>c) Liquid extract (DER 1: 1), extraction solvent ethanol 45-53% V/V</p> <p>d) Tincture (ratio of herbal substance to extraction solvent 1: 5), extraction solvent ethanol 45-53% V/V</p> <p>e) Dried water or ethanol (45-53% V/V) extracts corresponding to the tea, liquid extract and tincture above.</p>

## 3. Pharmaceutical form

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

<sup>1</sup> The material complies with the Ph. Eur. monograph (ref. 01/2011:1447).

<sup>2</sup> 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

Well-established use	Traditional use
	<p><b>Indication 1)</b></p> <p>Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep.</p> <p><b>Indication 2)</b></p> <p>Traditional herbal medicinal product for symptomatic treatment of mild gastrointestinal complaints including bloating and flatulence.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

### 4.2. Posology and method of administration<sup>3</sup>

Well-established use	Traditional use
	<p><b>Posology</b></p> <p><b>Indications 1) and 2)</b></p> <p><i>Adolescents over 12 years of age, adults and elderly</i></p> <p>Single dose</p> <p>a) Herbal tea: 1.5-4.5 g of the comminuted herbal substance in 150 ml of boiling water as a herbal infusion, 1-3 times daily.</p> <p>b) Powdered herbal substance: 0.19-0.55 g, 2-3 times daily.</p> <p>c) Liquid extract: 2-4 ml, 1-3 times daily.</p> <p>d) Tincture: 2-6 ml, 1-3 times daily.</p> <p>e) Dried water or ethanol (45-53% V/V) extracts in doses corresponding to the posologies for tea, liquid extract and tincture above.</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 longer than 2 weeks</p>

<sup>3</sup> 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
	<p>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>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
	<p>Indication 1) and 2)</p> <p>The use in children under 12 years of age has not been established 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>For tinctures and liquid 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.</p>

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

Well-established use	Traditional use
	No data available.

### 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
	May impair ability to drive and use machines. Affected patients should not drive or operate machinery.

#### 4.8. Undesirable effects

Well-established use	Traditional use
	None known. If adverse reactions 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. Data from <i>in vitro</i> and animal studies indicate that the water extract of <i>Melissa officinalis</i> L., folium may inhibit the activity of thyroid stimulating hormone (TSH). The clinical relevance of these

Well-established use	Traditional use
	<p>findings is not known.</p> <p>Adequate tests on genotoxicity have not been performed.</p> <p>Tests on reproductive toxicity and carcinogenicity have not been performed.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

## 7. Date of compilation/last revision

14 May 2013