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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Olea europaea* L., folium

Final

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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 August 2011
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<b>Keywords</b>	Herbal medicinal products; HMPC; Community herbal monographs; traditional <i>Olea europaea</i> L., folium; Oleae folium; olive leaf
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BG (bългарski): Маслина, лист  
CS (čeština): Olivovníkový list  
DA (dansk): Olivenblad  
DE (Deutsch): Ölbaumblätter  
EL (elliniká): Φύλλο Ελιάς  
EN (English): Olive leaf  
ES (español): Olivo, hoja de  
ET (eesti keel): Õlipuu leht  
FI (suomi): Oliivipuu, lehti (oliivinlehti)  
FR (français): Olivier (feuille d')  
HU (magyar): Olajfa levél  
IT (italiano): Olivo foglia

LT (lietuvių kalba):  
LV (latviešu valoda): Olīvu lapas  
MT (malti):  
NL (nederlands): Olijfblad  
PL (polski): Liść oliwki  
PT (português): Oliveira, folha  
RO (română): frunză de măslin  
SK (slovenčina): Olivový list  
SL (slovenščina): List divje oljke  
SV (svenska): Olivträd, blad  
IS (íslenska):  
NO (norsk): Olivenblad



# Community herbal monograph on *Olea europaea* 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
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended  <i>Olea europaea</i> L., folium (olive leaf)  i) Herbal substance  Fresh or dried leaves  ii) Herbal preparations  a) Comminuted herbal substance (dried leaves) b) Powdered herbal substance (dried leaves)

## 3. Pharmaceutical form

Well-established use	Traditional use
	Herbal substance and comminuted herbal substance as herbal tea for oral use.  Herbal preparations in solid dosage forms for oral 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
	Traditional herbal medicinal product used to promote the renal elimination of water, in mild

<sup>1</sup> The material complies with the Ph. Eur. monograph (ref.: 01/2009:1878).

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

Well-established use	Traditional use
	<p>cases of water retention after serious conditions have been excluded by a medical doctor.</p> <p>The product is a traditional herbal medicinal product for use in the specified indication 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><i>Adults and elderly</i></p> <p>Herbal tea:</p> <p>10 g of fresh leaves or up to 5 g of dried leaves in 150 ml of boiling water as a <i>decoction</i>, 2 times daily. Decoction time: allow to simmer to reach 100 ml of decoction.</p> <p>To be consumed hot, morning and evening.</p> <p>7–8 g of dried leaves in 150 ml of boiling water as a <i>herbal infusion</i>, 3-4 times daily. Infusion time: 30 minutes</p> <p>Herbal preparations:</p> <p>a) Single dose: 6–10 g (corresponding to 600 mg dry aqueous extract) up to 3 times daily.</p> <p>Daily dose: up to 30 g</p> <p>b) Single dose: 200-275 mg 3-5 times daily or 210–400 mg 3 times daily.</p> <p>Daily dose: 600–1375 mg.</p> <p>The use in children and adolescents under 18 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>The herbal substance is traditionally used over a period of 2-4 weeks.</p> <p>If the symptoms persist longer than one week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</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><b>Method of administration</b></p> <p>Oral use.</p>

#### **4.3. Contraindications**

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance(s) and to other plants of the Oleaceae family.</p> <p>Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease).</p>

#### **4.4. Special warnings and precautions for use**

Well-established use	Traditional use
	<p>If symptoms of organic heart disease or of hypertension occur, a medical doctor should be consulted.</p> <p>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.</p> <p>If symptoms worsen during the use of the medicinal product, a medical doctor or a qualified health care practitioner should be consulted.</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>No fertility data available</p> <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>

#### **4.7. Effects on ability to drive and use machines**

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

#### **4.8. Undesirable effects**

<b>Well-established use</b>	<b>Traditional use</b>
	Pollinosis in the form of rhinitis or bronchial asthma has 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**

<b>Well-established use</b>	<b>Traditional use</b>
	No case of overdose has been reported.

### **5. Pharmacological properties**

#### **5.1. Pharmacodynamic properties**

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

#### **5.2. Pharmacokinetic properties**

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

#### **5.3. Preclinical safety data**

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

22 November 2011