EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

# European Union herbal monograph on *Olea europaea* L., folium

Final

| **Initial assessment** | |
|---|---|
| Discussion in Working Party on European Union monographs and list (MLWP) | November 2009<br>January 2010<br>March 2010<br>September 2010<br>January 2011 |
| Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation | 27 January 2011 |
| End of consultation (deadline for comments) | 15 August 2011 |
| Re-discussion in MLWP | September 2011 |
| Adoption by HMPC<br>Monograph (EMA/HMPC/430507/2009)<br>Assessment Report (EMA/HMPC/430506/2009)<br>List of references (EMA/HMPC/430505/2009)<br>Overview of comments (EMA/HMPC/736741/2011) | 22 November 2011 |
| **First systematic review** | |
| Discussion in Working Party on European Union monographs and list (MLWP) | May/June 2016<br>July 2016<br>September 2016<br>November 2016 |
| Adoption by HMPC | 31 January 2017 |


| Keywords | Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Olea europaea* L., folium; Oleae folium; olive leaf |
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| | |
|---|---|
| BG (bulgarski): Маслина, лист<br>CS (čeština): olivovníkový list<br>DA (dansk): Olivenblad<br>DE (Deutsch): Ölbaumblätter<br>EL (elliniká): φύλλο ελαίας<br>EN (English): olive leaf<br>ES (español): olivo, hoja de<br>ET (eesti keel): õlipuu leht<br>FI (suomi): oliivipuu, lehti<br>FR (français): olivier (feuille d')<br>HR (hrvatski): maslinov list<br>HU (magyar): olajfa levél<br>IT (italiano): Olivo foglia | LT (lietuvių kalba): Alyvmedžių lapai<br>LV (latviešu valoda): Olīvu lapas<br>MT (Malti): werqa taż-żebbuġa<br>NL (Nederlands): Olijfblad<br>PL (Poland): Liść oliwki<br>PT (português): oliveira, folha<br>RO (română): frunză de măslin<br>SK (slovenčina): list olivy<br>SL (slovenščina): list divje oljke<br>SV (svenska): olivträd, blad<br>*IS (íslenska)*:<br>*NO (norsk):* olivenblad |

# European Union herbal monograph on O*lea europaea* L., folium

## 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<br>*Olea europaea* L., folium (olive leaf)<br>i) Herbal substance<br>Fresh or dried leaves<br>ii) Herbal preparations<br>a) Comminuted dried leaves<br>b) Powdered dried leaves |

## 3. Pharmaceutical form

| Well-established use | Traditional use |
|---|---|
| | Herbal substance or comminuted herbal substance as herbal tea for oral use.<br>Powdered dried leaves in solid dosage forms for oral use.<br>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 cases of water retention after serious conditions have been excluded by a medical doctor.<br>The product is a traditional herbal medicinal |

1 The material complies with the Ph. Eur. monograph (ref.: 1878).
2 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 |
|---|---|
| | product for use in specified indication exclusively based upon long-standing use. |

## *4.2. Posology and method of administration*[3]

| Well-established use | Traditional use |
|---|---|
| | **Posology**<br>*Adults and elderly*<br>i) Herbal substance<br>Herbal tea: 10 g of fresh leaves or 5 g of dried leaves in 150 ml of water as a decoction 2 times daily (morning and evening)<br>Decoction time: allow to simmer to reach 100 ml of decoction.<br>i) Herbal substance and ii) herbal preparation<br>Dried leaves or a) comminuted dried leaves for infusion:<br>Single dose: 6–10 g up to 3 times daily.<br>Daily dose: 6–30 g<br>ii) Herbal preparation<br>b) Powdered dried leaves:<br>Single dose: 275 mg 3-5 times daily or<br>210–400 mg 3 times daily.<br>Daily dose: 630–1375 mg.<br>The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').<br>**Duration of use**<br>The herbal substance is traditionally used over a period of 2-4 weeks.<br>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.<br>**Method of administration**<br>Oral use |

[3] 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).

## 4.3. Contraindications

| Well-established use | Traditional use |
|---|---|
| | Hypersensitivity to the active substance.<br><br>Herbal substance and herbal preparation a)<br><br>Conditions where a reduced fluid intake is recommended (e.g. severe cardiac or renal disease). |

## 4.4. Special warnings and precautions for use

| Well-established use | Traditional use |
|---|---|
| | Patients with cardiac disease or renal impairment should seek medical advice before taking Olea medication.<br><br>The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.<br><br>If symptoms worsen during the use of the medicinal product, a medical doctor or a qualified health care practitioner should be consulted. |

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

## 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 |
|---|---|
| | None known.<br>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. |

### *5.2. Pharmacokinetic properties*

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

### *5.3. Preclinical safety data*

| Well-established use | Traditional use |
|---|---|
| | Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the safe use of the product.<br>Tests on reproductive toxicity, and carcinogenicity have not been performed.<br>Adequate data on genotoxicity have not been performed. |

## 6. Pharmaceutical particulars

| Well-established use | Traditional use |
|---|---|
| | Not applicable |

# 7. Date of compilation / last revision

31 January 2017