EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2011
EMA/HMPC/430507/2009
Committee on Herbal Medicinal Products (HMPC)

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

Draft

Discussion in Working Party on Community monographs and Community list (MLWP)	November 2009 January 2010 March 2010 September 2010 January 2011
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	27 January 2011
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 Aug 2011
Rediscussion in Working Party on Community monographs and Community list (MLWP)	
Adoption by Committee on Herbal Medicinal Products (HMPC)	

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional *Olea europaea* L., folium; Oleae folium; olive leaf

BG (bălgarski): Маслина, лист	LT (lietuvių kalba):
CS (čeština): olivovníkový list	LV (latviešu valoda): Olīvu lapas
DA (dansk):	MT (malti):
DE (Deutsch): Ölbaumblätter	NL (nederlands):
EL (elliniká): Φύλλα Ελιάς	PL (polski): Liść oliwki
EN (English): Olive leaf	PT (português):
ES (espanol):	RO (română): frunză de măslin
ET (eesti keel): õlipuu leht	SK (slovenčina): Olivový list
FI (suomi):	SL (slovenščina):
FR (français): Olivier (feuille d')	SV (svenska): Olivträd, blad
HU (magyar): Olajfa levél	IS (íslenska):
IT (italiano):	NO (norsk): olivenblad

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7051
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Community 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 as amended *Olea europaea* L., folium (olive leaf) i) Herbal substance Fresh or dried leaves ii) Herbal preparations a) Comminuted 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 cases of water retention.

1 The material complies with the Ph. Eur. monograph (ref.: 01/2009:1878).
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
	The product is a traditional herbal medicinal product for use in specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology *Adults and elderly* a) Fresh or dried leaves Daily dose: up to 20 g of fresh leaves in 300 ml of water up to 10 g of dried leaves in 300 ml of water Single dose: 10 g of fresh leaves in 150 ml of water up to 5 g of dried leaves in 150 ml of water To be consumed hot, morning and evening (twice a day) b) Comminuted dried leaves Daily dose: up to 30 g of dried leaves per day Single dose: 6-10 g (corresponding to 600 mg dry aqueous extract) 3 times daily The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** The herbal substance is traditionally used over a period of 2-4 weeks. 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. **Method of administration** Oral use.

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance(s) and to other plants of the Oleaceae family. 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
	If symptoms of organic heart disease or of hypertension occur, a medical doctor should be consulted. The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. 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. 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
	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

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. 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

27 January 2011