



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

12 July 2011  
EMA/HMPC/239271/2011  
Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Fraxinus excelsior* L. and *Fraxinus angustifolia* Vahl, folium

Draft

Discussion in Working Party on Community monographs and Community list (MLWP)	March 2011 May 2011
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	12 July 2011
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 November 2011
Redisussion in Working Party on Community monographs and Community list (MLWP)	
Adoption by Committee on Herbal Medicinal Products (HMPC)	

<b>Keywords</b>	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Fraxinus excelsior</i> L. and <i>Fraxinus angustifolia</i> Vahl, folium; ash leaf
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BG (bългарski): Ясен, лист CS (čeština): jasanový list DA (dansk): Askeblad DE (Deutsch): Eschenblätter EL (elliniká): EN (English): ash leaf ES (español): Fresno, hoja de ET (eesti keel): saareleht FI (suomi): FR (français): Frêne (feuille de) HU (magyar): Kőrisfa levél IT (italiano): Frassino foglia	LT (lietuvių kalba): LV (latviešu valoda): Oša lapas MT (malti): NL (nederlands): Es PL (polski): Liść jesionu PT (português): Freixo, folha RO (română): frunză de frasin SK (slovenčina): Jaseňový list SL (slovenščina): list velikega jesena SV (svenska): Askblad <i>IS (íslenska):</i> <i>NO (norsk):</i> Askeblad
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# Community herbal monograph on *Fraxinus excelsior L. and Fraxinus angustifolia Vahl, folium*

## Name of the medicinal product

To be specified for the individual finished product.

### 1. 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>Fraxinus excelsior L. and Fraxinus angustifolia Vahl, folium</i> (ash leaf)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>Comminuted herbal substance</p>

### 2. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance as herbal tea (decoction or infusion) for oral use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

### 3. Clinical particulars

#### 3.1. Therapeutic indications

Well-established use	Traditional use
	<p><b>Indication 1)</b></p> <p>Traditional herbal medicinal product used for relief of minor articular pain.</p>

<sup>1</sup> The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

<sup>2</sup> The material complies with the Ph. Eur. monograph (ref.: 01/2008:1600).

Well-established use	Traditional use
	<p data-bbox="810 255 970 286"><b>Indication 2)</b></p> <p data-bbox="810 311 1404 454">Traditional herbal medicinal product used to increase the amount of urine to achieve flushing of the urinary tract as an adjuvant in minor urinary complaints.</p> <p data-bbox="810 479 1423 584">The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>

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

Well-established use	Traditional use
	<p data-bbox="810 770 938 801"><b>Posology</b></p> <p data-bbox="810 826 1034 857"><i>Adults and elderly</i></p> <p data-bbox="810 882 1054 913">Average daily dose:</p> <p data-bbox="810 938 1423 1043">Herbal tea: 20 g of comminuted herbal substance in 1000 ml of water as a decoction, divided in 2-3 single doses.</p> <p data-bbox="810 1068 1417 1173">Herbal tea: 10-30 g of comminuted herbal substance in 1000 ml of boiling water as a herbal infusion, divided in 2-3 single doses.</p> <p data-bbox="810 1198 1426 1303">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 data-bbox="810 1328 1018 1359"><b>Duration of use</b></p> <p data-bbox="810 1384 970 1415"><b>Indication 1)</b></p> <p data-bbox="810 1440 1423 1583">If the symptoms persist longer than 4 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 1608 963 1639"><b>Indication 2)</b></p> <p data-bbox="810 1664 1423 1807">If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 1832 1145 1863"><b>Method of administration</b></p> <p data-bbox="810 1888 922 1919">Oral use.</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).

### 3.3. Contraindications

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

### 3.4. Special warnings and precautions for use

Well-established use	Traditional use
	<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 the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p><b>Indication 1)</b></p> <p>Articular pain accompanied by swelling of joints, redness or fever should be examined by a doctor.</p> <p><b>Indication 2)</b></p> <p>If minor urinary tract complaints worsen and symptoms such as fever, dysuria, spasm, or blood in the urine occur during the use of medicinal product, a doctor or a qualified health care professional should be consulted.</p> <p>To ensure an increase of the amount of urine, adequate fluid intake is required during treatment.</p>

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

Well-established use	Traditional use
	None reported.

### 3.6. 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.

Well-established use	Traditional use
	No fertility data available.

### 3.7. 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.

### 3.8. Undesirable effects

Well-established use	Traditional use
	None known.  If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.

### 3.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

## 4. Pharmacological properties

### 4.1. Pharmacodynamic properties

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

### 4.2. Pharmacokinetic properties

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

### 4.3. 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.

## 5. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

## 6. Date of compilation/last revision

12 July 2011