



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 March 2012
EMA/HMPC/239271/2011
Committee on Herbal Medicinal Products (HMPC)

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

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	March 2011 May 2011
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Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Fraxinus excelsior</i> L. or <i>Fraxinus angustifolia</i> Vahl, folium; Fraxini folium; ash leaf
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BG (bългарски): Ясен, лист CS (čeština): jasanový list DA (dansk): Askeblad DE (Deutsch): Eschenblätter EL (elliniká): Φύλλο Μελίας (Μελέγου ή Φράξου) EN (English): ash leaf ES (español): Fresno, hoja de ET (eesti keel): saareleht FI (suomi): saarni, lehti 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. or *Fraxinus angustifolia* Vahl, 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
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Fraxinus excelsior</i> L. or <i>Fraxinus angustifolia</i> Vahl or hybrids of these 2 species or of a mixture, folium (ash leaf)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>Comminuted herbal substance</p>

3. Pharmaceutical form

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

4. Clinical particulars

4.1 Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product used for relief of minor articular pain.</p> <p>Indication 2)</p>

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

² The material complies with the Ph. Eur. monograph (ref.: 07/2012:1600).

Well-established use	Traditional use
	<p>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>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 administration³

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adults and elderly</i></p> <p>Average daily dose:</p> <p>Herbal tea: 20 g of the comminuted herbal substance in 1000 ml of water as a decoction, divided in 2-3 single doses.</p> <p>Herbal tea: 10-30 g of the comminuted herbal substance in 1000 ml of boiling water as a herbal infusion, divided in 2-3 single doses.</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>Duration of use</p> <p>Indication 1)</p> <p>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>Indication 2)</p> <p>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>Method of administration</p> <p>Oral use.</p>

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
	<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>

4.4 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>Indication 1)</p> <p>Articular pain accompanied by swelling of joints, redness or fever should be examined by a doctor.</p> <p>Indication 2)</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>

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.

Well-established use	Traditional use
	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. 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. 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 March 2012