



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 July 2011
EMA/HMPC/434894/2010
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Filipendula ulmaria* (L.) Maxim., flos

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	July 2010 November 2010
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	25 November 2010
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 April 2011
Rediscussion in Working Party on Community monographs and Community list (MLWP)	May 2011
Adoption by Committee on Herbal Medicinal Products (HMPC)	12 July 2011

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Filipendula ulmaria</i> (L.) Maxim. (= <i>Spiraea ulmaria</i> (L.)), flos; Filipendulae ulmariae flos; meadowsweet flower
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BG (bългарски): Блатен тъжник, цвят CS (čeština): tužebníkový květ DA (dansk): Almindelig mjørdurtblomst DE (Deutsch): Mädesüßblüten EL (elliniká): EN (English): meadowsweet flower ES (español): Ulmaria, flor de ET (eesti keel): angervaksaõis FI (suomi): FR (français): Reine des prés (fleur de) HU (magyar): Réti legyezőfű virág IT (italiano): Olmaria fiore	LT (lietuvių kalba): LV (latviešu valoda): Parastās vīgriezēs ziedi MT (malti): NL (nederlands): Moerasspirea PL (polski): Kwiat wiązówki PT (português): Rainha-dos-prados, sumidade florida RO (română): floare de crețușcă SK (slovenčina): Túžobníkový kvet SL (slovenščina): list brestovolistnega oslada SV (svenska): Älgört, blomma IS (íslenska): NO (norsk): Mjørdurtblomst
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Community herbal monograph on *Filipendula ulmaria* (L.) Maxim., flos

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition¹

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>Filipendula ulmaria</i> (L.) Maxim., flos (meadowsweet flower)</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 for the supportive treatment of common cold.</p>

¹ 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 data-bbox="810 255 970 286">Indication 2)</p> <p data-bbox="810 311 1414 378">Traditional herbal medicinal product for the relief of minor articular pain.</p> <p data-bbox="810 405 1422 510">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 administration²

Well-established use	Traditional use
	<p data-bbox="810 696 938 728">Posology</p> <p data-bbox="810 752 1054 784">Indication 1) and 2)</p> <p data-bbox="810 808 991 840"><i>Adults, Elderly</i></p> <p data-bbox="810 864 1417 969">Comminuted herbal substance as herbal tea: daily dose: 2.5-6 g, as an infusion, divided in 1-3 single doses</p> <p data-bbox="810 994 1425 1099">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 1124 1018 1155">Duration of use</p> <p data-bbox="810 1180 970 1211">Indication 1)</p> <p data-bbox="810 1236 1417 1303">The therapy should start at first signs of common cold.</p> <p data-bbox="810 1328 1425 1478">If the symptoms persist longer than 7 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 1503 970 1534">Indication 2)</p> <p data-bbox="810 1559 1283 1590">Not to be used for more than 4 weeks.</p> <p data-bbox="810 1615 1401 1720">If the symptoms persist during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p data-bbox="810 1744 1145 1776">Method of administration</p> <p data-bbox="810 1800 922 1832">Oral use.</p>

² 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 salicylates. Hypersensitivity to the active substance.

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>Concomitant use with salicylates and other NSAIDs is not recommended without medical advice.</p> <p>Indication 1)</p> <p>If fever exceeds 39°C, persists or is associated with severe headache, or if symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication 2)</p> <p>The product is not intended to be used in case of acute arthritis as this condition requires medical advice.</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>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> <p>No fertility data available.</p>

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

12 July 2011