



25 November 2010
EMA/HMPC/434881/2010
Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Filipendula ulmaria* (L.) Maxim. (= *Spiraea ulmaria* (L.)), herba

Draft

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)	
Adoption by Committee on Herbal Medicinal Products (HMPC)	

Keywords	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Filipendula ulmaria</i> (L.) Maxim. (= <i>Spiraea ulmaria</i> (L.)), herba; <i>Filipendulae ulmariae</i> herba; meadowsweet
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BG (bălgarski): CS (čeština): nař tužebníku jilmového DA (dansk): DE (Deutsch): EL (elliniká): EN (English): meadowsweet ES (español): ET (eesti keel): FI (suomi): FR (français): HU (magyar): IT (italiano):	LT (lietuvių kalba): LV (latviešu valoda): MT (malti): NL (nederlands): Moerasspirea PL (polski): PT (português): RO (română): SK (slovenčina): SL (slovenščina): SV (svenska): <i>IS (islenska):</i> <i>NO (norsk):</i>
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Community herbal monograph on *Filipendula ulmaria* (L.) Maxim. (= *Spiraea ulmaria* (L.)), herba

Name of the medicinal product

To be specified for the individual finished product.

1. 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>Filipendula ulmaria</i> (L.) Maxim. (= <i>Spiraea ulmaria</i> (L.)), herba (meadowsweet)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance b) Powdered herbal substance</p>

2. Pharmaceutical form

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

¹ The material complies with the Ph. Eur. monograph (ref.: 01/2008:1868 corrected 6.0).

² The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

3. Clinical particulars

3.1. Therapeutic indications

Well-established use	Traditional use
	<p data-bbox="810 405 967 432">Indication 1)</p> <p data-bbox="810 461 1342 524">Traditional herbal medicinal product for the supportive treatment of common cold.</p> <p data-bbox="810 553 967 580">Indication 2)</p> <p data-bbox="810 609 1414 672">Traditional herbal medicinal product for the relief of minor articular pain.</p> <p data-bbox="810 701 1422 806">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

Well-established use	Traditional use
	<p data-bbox="810 994 935 1021">Posology</p> <p data-bbox="810 1050 991 1077"><i>Adults, Elderly</i></p> <p data-bbox="810 1106 1394 1211">a) Comminuted herbal substance as herbal tea: single dose: 1.5-6 g, as an infusion daily dose: 2-18 g</p> <p data-bbox="810 1272 1190 1377">b) Powdered herbal substance: single dose: 250-500 mg daily dose: 250-1500 mg</p> <p data-bbox="810 1406 1426 1512">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 1541 1018 1568">Duration of use</p> <p data-bbox="810 1597 967 1624">Indication 1)</p> <p data-bbox="810 1653 1417 1715">The therapy should start at first signs of common cold.</p> <p data-bbox="810 1744 1426 1879">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 1908 967 1935">Indication 2)</p> <p data-bbox="810 1964 1283 1991">Not to be used for more than 4 weeks.</p>

Well-established use	Traditional use
	<p>If the symptoms persist 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>

3.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to salicylates.</p> <p>Hypersensitivity to the active substance.</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>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>

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

Well-established use	Traditional use
	None reported.

3.6. 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.

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
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Well-established use	Traditional use
	<p>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.</p> <p>Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.</p>

5. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

6. Date of compilation/last revision

25 November 2010