EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

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
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BG (bălgarski): Брястолистно орехче, стрък CS (čeština): nať tužebníku jilmového DA (dansk): Almindelig mjødurt DE (Deutsch): Mädesüßkraut EL (elliniká): EN (English): meadowsweet ES (espanol): Ulmaria, partes aéreas de ET (eesti keel): angervaksaürt FI (suomi): FR (français): Reine des prés (parties aériennes de) HU (magyar): Réti legyezőfű virágos hajtás IT (italiano): Olmaria parti aeree	LT (lietuvių kalba): LV (latviešu valoda): Parastās vīgriezes laksti MT (malti): Filipendula NL (nederlands): Moerasspirea PL (polski): Ziele wiązówki PT (português): Rainha-dos-prados, parte aérea RO (română): iarbă de creţuşcă SK (slovenčina): Túžobníková vňať SL (slovenščina): zel brestovolistnega oslada SV (svenska): Älgört *IS (íslenska)*: *NO (norsk)*: Mjødurt

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

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 *Filipendula ulmaria* (L.) Maxim., herba (meadowsweet) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Powdered herbal substance c) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V)

3. Pharmaceutical form

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

[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.: 01/2008:1868 corrected 6.0).

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product for the supportive treatment of common cold. Indication 2) Traditional herbal medicinal product for the relief of minor articular pain. The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.

4.2. Posology and method of administration[3]

Well-established use	Traditional use
	Posology Indication 1) *Adults, Elderly* a) Comminuted herbal substance as herbal tea: single dose: 1.5-6 g, as an infusion daily dose: 2-18 g b) Powdered herbal substance: single dose: 250-500 mg daily dose: 250-1500 mg The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Indication 2) *Adults, Elderly* a) Comminuted herbal substance as herbal tea: single dose: 1.5-6 g, as an infusion daily dose: 2-18 g b) Powdered herbal substance: single dose: 250-500 mg daily dose: 250-1500 mg c) Tincture (1:5):

[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).

Well-established use	Traditional use
	single dose: 2-4 ml daily dose: 6-12 ml 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** Indication 1) The therapy should start at first signs of common cold. 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. Indication 2) Not to be used for more than 4 weeks. If the symptoms persist 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 salicylates. Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. Concomitant use with salicylates and other NSAIDs is not recommended without medical advice. Indication 1) 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

Well-established use	Traditional use
	or a qualified health care practitioner should be consulted. Indication 2) The product is not intended to be used in case of acute arthritis as this condition requires medical advice. For extracts containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

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. 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

12 July 2011