



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

Community herbal monograph on *Achillea millefolium* L., flos

Final

Discussion in Working Party on Community monographs and Community list (MLWP)	March 2010 July 2010 September 2010
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	15 September 2010
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BG (bългарски): Бял равнец, цвят CS (čeština): řebříčkový květ DA (dansk): Røllikeblomst DE (Deutsch): Schafgarbenblüten EL (elliniká): άνθος αχιλλείας EN (English): Yarrow Flower ES (español): Milenrama, flor de ET (eesti keel): raudrohuõis FI (suomi): FR (français): Achillée millefeuille (fleur d') HU (magyar): Közönséges cickafark virág IT (italiano): Achillea millefoglie fiore	LT (lietuvių kalba): LV (latviešu valoda): Pelašku ziedi MT (malti): NL (nederlands): Duizendblad PL (polski): Kwiat krwawnika PT (português): Milefólio, flor RO (română): floare de coada șoricelului SK (slovenčina): Rebríčkový kvet SL (slovenščina): cvet navadnega rmana SV (svenska): Rölleka, blomma IS (islenska): NO (norsk): Ryllikblomst
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Community herbal monograph on *Achillea millefolium* L., flos

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>Achillea Millefolium</i> L., flos (yarrow flower)</p> <p>i) Herbal substance</p> <p>Dried inflorescence.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Liquid extract (DER 1:5.8), extraction solvent liquor vine : ethanol 96% V/V (91:9 m/m)</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Herbal substance and comminuted herbal substance as herbal tea for oral use.</p> <p>Herbal substance for infusion preparation for cutaneous use.</p> <p>Herbal preparation in liquid dosage forms 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
	Indication 1)

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 Ph. Helv.VII: Millefolii flos, (ref.: Ph.Helv.10-2006, 10.0/CH 184).

Well-established use	Traditional use
	<p>Traditional herbal medicinal product used for temporary loss of appetite.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for the symptomatic treatment of mild, spasmodic gastrointestinal complaints including bloating and flatulence.</p> <p>Indication 3)</p> <p>Traditional herbal medicinal product for the treatment of small superficial wounds.</p> <p>Indication 4)</p> <p>Traditional herbal medicinal product for the symptomatic treatment of minor spasm associated with menstrual periods.</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 administration

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, adults and elderly</i></p> <p>Indications 1) and 2)</p> <p>Herbal tea: 1.5-2 g of herbal substance or comminuted herbal substance in 250 ml boiling water as a herbal infusion 2 times daily.</p> <p>For the indication "loss of appetite", the herbal tea is to be taken 30 minutes before meals.</p> <p>Indication 2)</p> <p>Liquid extract: 10-20 drops 2-3 times daily.</p> <p>Indication 4)</p> <p>Herbal tea: 1-2 g of herbal substance or comminuted herbal substance in 250 ml boiling water as an herbal infusion 2-3 times daily.</p> <p>Indication 3)</p> <p>Herbal substance for infusion preparation for cutaneous use: 1.5 g of herbal substance in 250</p>

Well-established use	Traditional use
	<p>ml water 2–3 times daily.</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').</p> <p>Duration of use</p> <p>Indications 1) and 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>Indications 3) and 4)</p> <p>If the symptoms persist longer than 1 week 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>Indications 1), 2) and 4)</p> <p>Oral use.</p> <p>Indication 3)</p> <p>Cutaneous use: to be applied on the affected area in a form of an impregnated dressing.</p>

4.3. Contraindications

Well-established use	Traditional use
	<p>Hypersensitivity to the active substance and to other plants of the Asteraceae (Compositae) family.</p>

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>Indications 1-4)</p> <p>The use in children under 12 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 3)</p>

Well-established use	Traditional use
	<p>If signs of skin infection are observed, medical advice should be sought.</p> <p>For tinctures, 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.</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
	<p>Hypersensitivity reactions of the skin have been reported. The frequency is not known.</p> <p>If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.</p>

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. Adequate 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