EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Draft

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BG (bălgarski):	LT (lietuvių kalba):
CS (čeština):	LV (latviešu valoda):
DA (dansk):	MT (malti):
DE (Deutsch): Schafgarbenblüten	NL (nederlands):
EL (elliniká):	PL (polski):
EN (English): yarrow flower	PT (português):
ES (espanol):	RO (română):
ET (eesti keel):	SK (slovenčina):
FI (suomi):	SL (slovenščina):
FR (français): Achillée millefeuille (fleur d')	SV (svenska):
HU (magyar): Közönséges cickafark virág	*IS (íslenska)*:
IT (italiano):	*NO (norsk)*:

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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
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Achillea millefolium* L., flos[1], yarrow flower i) Herbal substance the dried inflorescence ii) Herbal preparations a) Comminuted herbal substance b) Liquid extract (DER 1:5.8); extraction solvent: liquor vine: ethanol 96 (v/v) 91:9 (m/m)

3. Pharmaceutical form

Well-established use	Traditional use
	Herbal substance and comminuted herbal substance as herbal tea for oral and cutaneous use. Liquid extract in liquid dosage form for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

1 The material complies with Ph. Helv.VII: Millefolii flos, (ref.: Ph.Helv.10-2006, 10.0/CH 184).
2 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1) Traditional herbal medicinal product used in temporary loss of appetite. Indication 2) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating and flatulence. Indication 3) Traditional herbal medicinal product for treatment of small superficial wounds. 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

Well-established use	Traditional use
	Posology *Adults* Oral and cutaneous use: 1.5 g herbal substance as infusion; 2 – 3 times daily. 2 g comminuted herbal substance in 250 ml water as infusion; once or twice daily. Oral use: Liquid extract: 10-20 drops; 2-3 times daily. 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) and 2) 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

Well-established use	Traditional use
	consulted. Indication 3) 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. **Method of administration** Indication 1) and 2) Oral use. Indication 3) Cutaneous use.

4.3. Contraindications

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

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	Indication 1), 2) and 3) The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication 3) If signs of skin infection are observed, medical advice should be sought. 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.

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

Well-established use	Traditional use
	None reported.

4.6. 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.

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
	Hypersensitivity reactions of the skin have been reported. The frequency is not known. If other adverse reactions not mentioned above 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. 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

15/09/2010