EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2010
EMA/HMPC/290284/2009
Committee on Herbal Medicinal Products (HMPC)

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

Draft

Discussion in Working Party on Community monographs and Community list (MLWP)	November 2010 May 2010 July 2010
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	15 September 2010
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 February 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; *Achillea millefolii* L., herba; Millefolii herba; yarrow herb

BG (bălgarski):	LT (lietuvių kalba):
CS (čeština):	LV (latviešu valoda):
DA (dansk):	MT (malti):
DE (Deutsch): Schafgarbenkraut	NL (nederlands):
EL (elliniká):	PL (polski):
EN (English): yarrow herb	PT (português):
ES (espanol):	RO (română):
ET (eesti keel):	SK (slovenčina):
FI (suomi):	SL (slovenščina):
FR (français): Achillée millefeuille (sommité fleurie d')	SV (svenska):
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Community herbal monograph on Achillea millefolium L., 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 *Achillea Millefolium* L. herba, yarrow herb i) Herbal substance Not applicable ii) Herbal preparations a) Comminuted herbal substance b) Expressed juice (DER 1:0.6-0.9) from fresh herb[3] c) Liquid extract (DER 1:1), extraction solvent: ethanol 25% (V/V) d) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 45% (V/V) e) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent: ethanol 31.5% (V/V)

3. Pharmaceutical form

Well-established use	**Traditional use**
	Communited herbal substance as herbal tea for oral use or cutaneous use. Other herbal preparations in liquid dosage forms

1 The material complies with the Ph. Eur. Monograph 6th ed.- Yarrow. (ref.: 01/2008:1382 corrected 6.0;3243).
2 The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.
3 The fresh material complies with the Ph. Eur. Monograph (ref.: 01/2008:1382 corrected 6.0;3243) when dried.

Well-established use	**Traditional use**
	for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

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 symptomatic treatment of minor spasms associated with menstrual periods. Indication 4) 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* i) Herbal substance Not applicable. ii) Herbal preparations Indication 1) and 2)

Well-established use	Traditional use
	a) 2-4 g comminuted herbal substance as infusion three or four times daily between meals b) Expressed juice: 5 -10 ml twice or three times daily c) Liquid extract: 2-4 ml three times daily d) Tincture (1:5, ethanol 45%): 2-4 ml three times daily e) Tincture (1:5, ethanol 31.5%): 4.3 ml (= 4.2 g) four times daily Indication 3) 1-2 g comminuted herbal substance per cup, as infusion 2-3 times daily Cutaneous use Indication 4) 3.5 g of comminuted herbal substance as infusion applied as cold compresses 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 more than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication 3) and 4) If the symptoms persist more 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), 2) and 3) Oral use. Indication 4) 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
	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. 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. Indication 4) If signs of skin infection are observed, medical advice should be sought.

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

Well-established use	Traditional use
	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 September 2010