EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

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BG (bălgarski): Бял равнец, стрък	LT (lietuvių kalba):
CS (čeština): řebříčková nať	LV (latviešu valoda): Pelašķu laksti
DA (dansk): Røllike	MT (malti):
DE (Deutsch): Schafgarbenkraut	NL (nederlands): Duizendblad
EL (elliniká): πόα αχιλλείας	PL (polski): Ziele krwawnika
EN (English): Yarrow	PT (português): Milefólio
ES (espanol): Milenrama, sumidades floridas de	RO (română): iarbă de coada şoricelului
ET (eesti keel): raudrohuürt	SK (slovenčina): Rebríčková vňať
FI (suomi):	SL (slovenščina): zel navadnega rmana
FR (français): Achillée millefeuille (parties aériennes d')	SV (svenska): Rölleka
HU (magyar): Közönséges cickafark virágos hajtás	*IS (íslenska):*
IT (italiano): Achillea millefoglie parti aeree	*NO (norsk): Ryllik*

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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) i) Herbal substance Not applicable. ii) Herbal preparations a) Comminuted herbal substance b) Expressed juice from fresh herb (DER: 1:0.6-0.9) 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
	Comminuted herbal substance as herbal tea for oral use. Comminuted herbal substance for infusion preparation for cutaneous use. Herbal preparations in liquid dosage forms for oral use.

[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.: 07/2010:1382).

	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 for temporary loss of appetite. Indication 2) Traditional herbal medicinal product for the symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating, and flatulence. Indication 3) Traditional herbal medicinal product for the symptomatic treatment of minor spasm associated with menstrual periods. Indication 4) Traditional herbal medicinal product for the 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[3]

Well-established use	Traditional use
	Posology *Adolescents, adults and elderly* Single dose Indications 1) and 2) a) Herbal tea: 2-4 g of the comminuted herbal substance in 250 ml boiling water as a herbal infusion 3 or 4 times daily between meals. b) Expressed juice: 5-10 ml 2 or 3 times daily.

[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).

	c) Liquid extract: 2-4 ml 3 times daily. d) Tincture (ethanol 45% V/V): 2-4 ml 3 times daily. e) Tincture (ethanol 31.5% V/V): 4.3 ml (= 4.2 g) 4 times daily. For the indication "loss of appetite", the liquid preparations are to be taken 30 minutes before meals. Indication 3) Herbal tea: 1-2 g comminuted herbal substance in 250 ml boiling water as a herbal infusion 2-3 times daily. Indication 4) Comminuted herbal substance for infusion preparation for cutaneous use: 3.5 g of comminuted herbal substance in 250 ml water 2-3 times daily. The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indications 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 consulted. Indications 3) and 4) 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** Indications 1), 2) and 3) Oral use. Indication 4) Cutaneous use: to be applied on the affected area in a form of impregnated dressing.

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 under 12 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 4) 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. 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.

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

12 July 2011