EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 September 2020
EMA/HMPC/376416/2019
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Achillea millefolium* L., herba

Final – Revision 1

Initial assessment	
Discussion in Working Party on European Union monographs and European Union list (MLWP)	November 2009 May 2010 July 2010
Adopted by Committee on Herbal Medicinal Products (HMPC) for release for consultation	15 September 2010
End of consultation (deadline for comments)	15 February 2011
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Adoption by HMPC Monograph (EMEA/HMPC/290284/2009) Assessment Report (EMEA/HMPC/290309/2009) List of references (EMEA/HMPC/290282/2009) Overview of comments received during the public consultation (EMEA/HMPC/238500/2011) HMPC Opinion (EMEA/HMPC/544934/2011)	12 July 2011
Revision	
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BG (bulgarski): Бял равнец, стрък CS (čeština): Řebříčková nať DA (dansk): Røllike DE (deutsch): Schafgarbenkraut EL (elliniká): Πόα αχιλλείας EN (English): yarrow ES (español): Milenrama, sumidades floridas de ET (eesti keel): Raudrohuürt FI (suomi): siankärsämö, verso FR (français): Achillée millefeuille (parties aériennes d') HR (hrvatski): Stolisnikova zelen HU (magyar): Közönséges cickafark virágos hajtás	IT (italiano): Achillea millefoglie parti aeree LT (lietuvių kalba): Kraujažolių žolė LV (latviešu valoda): Pelašķu laksti MT (Malti): Ħaxixa tal-morliti NL (Nederlands): Duizendblad PL (polski): Ziele krwawnika PT (português): Milefólio RO (română): Iarbă de coada şoricelului SK (slovenčina): Vňať rebríčka SL (slovenščina): Zel navadnega rmana SV (svenska): Rölleka, ört IS (íslenska): NO (norsk): Ryllik

European Union 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 *Achillea Millefolium* L., herba (yarrow) i) Herbal substance Not applicable ii) Herbal preparations a) Comminuted herbal substance b) Expressed juice from fresh herb (DER: 1:0.65-0.93) 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 f) Dry extract (DER 6-9:1), extraction solvent water g) Dry extract (DER 5-10:1), extraction solvent water

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for

[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.: 1382).

Well-established use	Traditional use
	oral use. Herbal preparations in liquid or solid dosage forms for oral use. Comminuted herbal substance for infusion preparation for cutaneous 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 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*

[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 Indications 1) and 2) a) Herbal tea: 1.5-4 g of the comminuted herbal substance in 150-250 ml boiling water as herbal infusion 3 or 4 times daily between meals. b) Expressed juice: 5-10 ml 2 or 3 times daily. 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 2) f) Dry extract (DER 6-9:1), extraction solvent water: 334 mg dry extract 3-4 times daily Indication 3) a) Herbal tea: 1-2 g of the comminuted herbal substance in 250 ml of boiling water as herbal infusion 2-3 times daily g) Dry extract (DER 5-10:1), extraction solvent water: 250 mg dry extract 2-3 times daily Indication 4) a) Comminuted herbal substance for infusion preparation for cutaneous use: 3-4 g of the comminuted herbal substance in 250 ml of boiling 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.

Well-established use	Traditional use
	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 substances 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. Indications 1), 2) and 3) 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. 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
	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.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC, unless necessary for the safe use of the product. The dry extract (DER 6-9:1; extraction solvent: water) did not reveal mutagenicity in the AMES-test. Adequate tests on reproductive toxicity have not been performed. Tests on carcinogenicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
Not applicable	Not applicable

7. Date of compilation/last revision

23 September 2020