



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Herbal Medicinal Products (HMPC)

European Union list entry on *Achillea millefolium* L., herba Draft

Discussion in HMPC/MLWP	July 2019 September 2019 November 2019
Adopted by HMPC for release for consultation	20 November 2019
Start of public consultation	01 February 2020
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu .	30 April 2020

Keywords	Herbal medicinal products; HMPC; European Union list of herbal substance(s), preparation(s) and combinations thereof for use in traditional herbal medicinal products; traditional use; <i>Achillea millefolium</i> L.; Millefolii herba; yarrow
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Entry to list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products on *Achillea millefolium* L., herba

Scientific name of the plant	
<i>Achillea millefolium</i> L.	
Botanical family	
Asteraceae	
Herbal substance	
Millefolii herba	
Common name of herbal preparation in all EU official languages	
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 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): Ғaxixa tal-morliti NL (Nederlands): Duizendblad, kruid PL (polski): Ziele krwawnika PT (português): Milefólio RO (română): Iarbă de coada șoricelului SK (slovenčina): Vňať rebríčka SL (slovenščina): Zel navadnega rmana SV (svenska): Rölleka, ört IS (íslenska): NO (norsk): Ryllik
Herbal preparation(s)	
Comminuted herbal substance Dry extract (DER 6-9:1), extraction solvent water Dry extract (DER 5-10:1), extraction solvent water	
European Pharmacopoeia monograph reference	
Yarrow – Millefolii herba (07/2014:1382)	
Indication(s)	
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.	

<p>Indication 3)</p> <p>Traditional herbal medicinal product for the symptomatic treatment of minor spasm associated with menstrual periods.</p>
<p>Indication 4)</p> <p>Traditional herbal medicinal product for treatment of small superficial wounds.</p> <p>The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.</p>
<p>Type of tradition</p>
<p>European</p>
<p>Specified strength</p>
<p>Please see 'Specified posology'.</p>
<p>Specified posology</p>
<p><i>Adolescents, adults and elderly</i></p> <p>Single dose</p> <p>Indication 1) and 2)</p> <p>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.</p> <p>Daily dose: 6 to 16 g</p> <p>For the indication “loss of appetite”, the liquid preparations are to be taken 30 minutes before meals.</p> <p>Indication 2</p> <p>Dry extract (DER 6-9:1), extraction solvent water: 334 mg dry extract 3-4 times daily</p> <p>Daily dose: 1.002–1.336 g</p> <p>Indication 3)</p> <p>Herbal tea: 1–2 g comminuted herbal substance in 250 ml boiling water as a herbal infusion 2-3 times daily.</p> <p>Daily dose: 2–6 g</p> <p>Dry extract (DER 5-10:1), extraction solvent water: 250 mg dry extract 2-3 times daily.</p> <p>Daily dose: 0.5–0.75 g</p> <p>Indication 4)</p> <p>Comminuted herbal substance for infusion preparation for cutaneous use: from 3 to 4 g of the comminuted herbal substance in 250 mL of boiling water</p> <p>2–3 times daily.</p> <p>Daily dose: 6.0–12 g</p> <p>The use in children and adolescents under 12 years of age is not recommended (see section 'Special warnings and precautions for use').</p>

<p>Route of administration</p> <p>Indications 1), 2) and 3)</p> <p>Oral use</p> <p>Indication 4)</p> <p>Cutaneous use: to be applied on the affected area in a form of impregnated dressing.</p>
<p>Duration of use or any restrictions on the 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>Any other information necessary for the safe use</p> <p>Contraindications</p> <p>Hypersensitivity to the active substances and to other plants of the Asteraceae family.</p> <p>Special warnings and precautions for use</p> <p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>For Indications 1), 2) and 3)</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>For Indication 4),</p> <p>If signs of skin infection are observed, medical advice should be sought.</p> <p>Interactions with other medicinal products and other forms of interaction</p> <p>None reported</p> <p>Fertility, pregnancy and lactation</p> <p>Safety during pregnancy and lactation has not been established.</p> <p>In the absence of sufficient data, the use during pregnancy and lactation is not recommended.</p> <p>No fertility data available.</p> <p>Effects on ability to drive and use machines</p> <p>No studies on the effect on the ability to drive and use machines have been performed.</p> <p>Undesirable effects</p> <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>

Overdose

No case of overdose has been reported.

Pharmaceutical particulars

Not applicable

Pharmacological effects or efficacy plausible on the basis of long-standing use and experience

Not applicable

Date of compilation/Last revision

20 November 2019