EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

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

Draft – Revision 1

| **Initial assessment** | |
|---|---|
| Discussion in Working Party on European Union monographs and European Union list (MLWP) | November 2009<br>May 2010<br>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 |
| Re-discussion in MLWP | March 2011<br>May 2011 |
| Adoption by HMPC<br>Monograph (EMEA/HMPC/290284/2009)<br>Assessment Report (EMEA/HMPC/290309/2009)<br>List of references (EMEA/HMPC/290282/2009)<br>Overview of comments received during the public consultation (EMEA/HMPC/238500/2011)<br>HMPC Opinion (EMEA/HMPC/544934/2011) | 12 July 2011 |
| **First systematic review** | |
| Discussion in HMPC/MLWP | July 2019<br>September 2019<br>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 |
| Re-discussion in HMPC/MLWP | |
| Adoption by HMPC | |


| Keywords | Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Achillea millefolium* L., herba; Millefolii herba; yarrow |
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| | |
|---|---|
| BG (bulgarski): Бял равнец, стрък<br>CS (čeština): Řebříčková nať<br>DA (dansk): Røllike<br>DE (deutsch): Schafgarbenkraut<br>EL (elliniká): Πόα αχιλλείας<br>EN (English): yarrow<br>ES (español): Milenrama, sumidades floridas de<br>ET (eesti keel): Raudrohuürt<br>FI (suomi): Siankärsämö<br>FR (français): Achillée millefeuille (parties aériennes d')<br>HR (hrvatski): Stolisnikova zelen<br>HU (magyar): Közönséges cickafark virágos hajtás | IT (italiano): Achillea millefoglie parti aeree<br>LT (lietuvių kalba): Kraujažolių žolė<br>LV (latviešu valoda): Pelašķu laksti<br>MT (Malti): Ħaxixa tal-morliti<br>NL (Nederlands): Duizendblad, kruid<br>PL (polski): Ziele krwawnika<br>PT (português): Milefólio<br>RO (română): Iarbă de coada şoricelului<br>SK (slovenčina): Vňať rebríčka<br>SL (slovenščina): Zel navadnega rmana<br>SV (svenska): Rölleka, ört<br>IS (íslenska):<br>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, 1]

| Well-established use | Traditional use |
|---|---|
| | With regard to the registration application of Article 16d(1) of Directive 2001/83/EC<br><br>*Achillea Millefolium* L., herba (yarrow)<br><br>i) Herbal substance<br><br>Not applicable<br><br>ii) Herbal preparations<br><br>a) Comminuted herbal substance<br><br>b) Expressed juice from fresh herb (DER: 1:0.65-0.93)<br><br>c) Liquid extract (DER 1:1), extraction solvent ethanol 25% V/V<br><br>d) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% V/V<br><br>e) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 31.5% V/V<br><br>f) Dry extract (DER 6-9:1), extraction solvent water<br><br>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.

[1] The material complies with the Ph. Eur. monograph (ref.: 1382).

| Well-established use | Traditional use |
|---|---|
| | oral use.<br><br>Herbal preparations in liquid or solid dosage forms for oral use.<br><br>Comminuted herbal substance for infusion preparation for cutaneous use.<br><br>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)<br><br>Traditional herbal medicinal product used for temporary loss of appetite.<br><br>Indication 2)<br><br>Traditional herbal medicinal product for the symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating, and flatulence.<br><br>Indication 3)<br><br>Traditional herbal medicinal product for the symptomatic treatment of minor spasm associated with menstrual periods.<br><br>Indication 4)<br><br>Traditional herbal medicinal product for the treatment of small superficial wounds.<br><br>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*[2]

| Well-established use | Traditional use |
|---|---|
| | **Posology**<br><br>*Adolescents, adults and elderly* |

[2] 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<br>Indications 1) and 2)<br>a) Herbal tea: 2-4 g of the comminuted herbal substance in 250 ml boiling water as herbal infusion 3 or 4 times daily between meals.<br>b) Expressed juice: 5-10 ml 2 or 3 times daily.<br>c) Liquid extract: 2-4 ml 3 times daily.<br>d) Tincture (ethanol 45% V/V): 2-4 ml 3 times daily.<br>e) Tincture (ethanol 31.5% V/V): 4.3 ml (= 4.2 g) 4 times daily.<br>For the indication “loss of appetite”, the liquid preparations are to be taken 30 minutes before meals.<br>Indication 2)<br>f) Dry extract (DER 6-9:1), extraction solvent water: 334 mg dry extract 3-4 times daily<br>Indication 3)<br>a) Herbal tea: 1-2 g of the comminuted herbal substance in 250 ml of boiling water as herbal infusion 2-3 times daily.<br>g) Dry extract (DER 5-10:1), extraction solvent water: 250 mg dry extract 2-3 times daily<br>Indication 4)<br>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.<br>The use in children under 12 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’).<br>**Duration of use**<br>Indications 1) and 2)<br>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)<br><br>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.<br><br>**Method of administration**<br><br>Indications 1), 2) and 3)<br><br>Oral use<br><br>Indication 4)<br><br>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.<br><br>Indications 1), 2) and 3)<br><br>If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.<br><br>Indication 4)<br><br>If signs of skin infection are observed, medical advice should be sought.<br><br>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.<br>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.<br>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[3]*

| 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.<br><br>The dry extract (DER 6-9:1; extraction solvent: water) did not reveal mutagenicity in the AMES-test.<br><br>Adequate tests on reproductive toxicity have not been performed.<br><br>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

20 November 2019