



28 January 2015
EMA/HMPC/680597/2013
Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Agrimonia eupatoria* L., herba

Final

Discussion in Working Party on European Union monographs and list (MLWP)	November 2013 January 2014 March 2014
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Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; <i>Agrimonia eupatoria</i> L., herba; Agrimoniae herba; Agrimony
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BG (bulgarski): Камшик, стрък CS (čeština): řepíková nať DA (dansk): Agermåneurt DE (Deutsch): Odermennigkraut EL (elliniká): αγριμόνιο EN (English): Agrimony ES (español): Agrimonia, sumidad florida de ET (eesti keel): Maarjalepaürt FI (suomi): Maarianverijuuri FR (français): Aigremoine (sommité fleurie d') HU (magyar): Közönséges párlófű virágos hajtás HR (hrvatski): Turičina zelen IT (italiano): Agrimonia parti aeree	LT (lietuvių kalba): Dirvuolių žolė LV (latviešu valoda): Ancīša laksti MT (Malti): Agrimonju NL (Nederlands): Gewone agrimonie, kruid PL (polski): Ziele rzepiku PT (português): Agrimónia RO (română): Iarbă de turiță mare SK (slovenčina): Repíková vňať SL (slovenščina): Zel navadnega repika SV (svenska): Småborre IS (íslenska): NO (norsk): Åkermåne
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¹ No comments received during the period of public consultation. Therefore the final monograph is published together with the final assessment report and list of references, without an 'Overview of comments received during the public consultation'.



European Union monograph on *Agrimonia eupatoria* L., herba

1. Name of the medicinal product

To be specified for the individual finished product.

2. Qualitative and quantitative composition^{2, 3}

Well-established use	Traditional use
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Agrimonia eupatoria</i> L., herba, (Agrimony herb)</p> <p>i) Herbal substance</p> <p>Not applicable.</p> <p>ii) Herbal preparations</p> <p>a) Comminuted herbal substance</p> <p>b) Tincture (ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 45% (V/V)</p> <p>c) Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V)</p>

3. Pharmaceutical form

Well-established use	Traditional use
	<p>Comminuted herbal substance as herbal tea for oral use.</p> <p>Comminuted herbal substance for infusion preparation or decoction preparation for oromucosal use, cutaneous use or use as a bath additive.</p> <p>Herbal preparations in liquid dosage forms for oral use or oromucosal use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

² The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

³ The material complies with the Ph. Eur. Monograph (ref.: 01/2011:1587)

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	<p>Indication 1)</p> <p>Traditional herbal medicinal product for the symptomatic treatment of mild diarrhoea.</p> <p>Indication 2)</p> <p>Traditional herbal medicinal product for use as a gargle for the symptomatic relief of minor inflammations of the mouth and throat.</p> <p>Indication 3)</p> <p>Traditional herbal medicinal product for relief of minor skin inflammation and small, superficial wounds.</p> <p>The product is a traditional herbal medicinal product for use in the specified indications exclusively based upon long-standing use.</p>

4.2. Posology and method of administration⁴

Well-established use	Traditional use
	<p>Posology</p> <p><i>Adolescents, adults and elderly</i></p> <p>Indication 1)</p> <ul style="list-style-type: none">a) Herbal tea: 1.5–4 g of the comminuted herbal substance in 250 ml (or less) of boiling water as a herbal infusion, 2-3 times dailyb) Tincture: 1-4 ml, 3 times dailyc) Liquid extract: 1-3 ml, 3 times daily <p>Indication 2)</p> <ul style="list-style-type: none">a1) Comminuted herbal substance for infusion preparation: 1.5 g of the comminuted herbal substance in 150 ml of boiling water, 2–4 times daily as a gargle

⁴ 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
	<p>a2) Comminuted herbal substance for decoction preparation: 3–4.5 g of the comminuted herbal substance in 250 ml (or less) of water, 2–3 times daily as a gargle</p> <p>b) Tincture: 1-4 ml, 3 times daily as a gargle</p> <p>c) Liquid extract: 1-3 ml, 3 times daily as a gargle</p> <p>Indication 3)</p> <p>a1) Comminuted herbal substance for decoction preparation: 3-10 g of the comminuted herbal substance in 250 ml (or less) of water Apply as an impregnated dressing to the affected areas of the skin.</p> <p>a2) Comminuted herbal substance for decoction preparation: 3-10 g of the comminuted herbal substance in 250 ml (or less) of water, twice daily Use as a bath additive up to 30 minutes.</p> <p>The use in children under 12 years of age is not recommended (see section 4.4 Special warnings and precautions for use).</p> <p>Duration of use</p> <p>Indication 1)</p> <p>If the symptoms persist longer than 3 days during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indications 2) and 3)</p> <p>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 (see section 4.4 Special warnings and precautions for use).</p> <p>Method of administration</p> <p>Indication 1)</p> <p>Oral use.</p>

Well-established use	Traditional use
	<p>Indication 2)</p> <p>Oromucosal use.</p> <p>Indication 3)</p> <p>Cutaneous use.</p> <p>Use as a bath additive.</p>

4.3. Contraindications

Well-established use	Traditional use
	Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	<p>The use in children under 12 years of age has not been established due to lack of adequate data.</p> <p>For tinctures and 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.</p> <p>Indication 1)</p> <p>If recurrent diarrhoea or bloody stools occur, a doctor or a qualified health care practitioner should be consulted.</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>Indications 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>

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
	None known. If adverse reactions 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 data⁵

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. Tests on genotoxicity, carcinogenicity and reproductive toxicity have not been performed.

6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

7. Date of compilation/last revision

28 January 2015