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SCIENCE MEDICINES HEALTH

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Committee on Herbal Medicinal Products (HMPC)

## Community herbal monograph on *Agrimonia eupatoria* L., herba

Draft

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End of consultation (deadline for comments). Comments should be provided using this <a href="#">template</a> to <a href="mailto:hmpc.secretariat@ema.europa.eu">hmpc.secretariat@ema.europa.eu</a>	31 August 2014
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<b>Keywords</b>	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Agrimonia eupatoria</i> L., herba; Agrimony herb
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# Community herbal 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<sup>1, 2</sup>

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</p>

<sup>1</sup>The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance.

<sup>2</sup> The material complies with the Ph. Eur. Monograph (ref.: 01/2011:1587)

Well-established use	Traditional use
	the European Pharmacopoeia full standard term.

## 4. Clinical particulars

### 4.1. Therapeutic indications

Well-established use	Traditional use
	<p><b>Indication 1)</b></p> <p>Traditional herbal medicinal product for symptomatic treatment of mild diarrhoea.</p> <p><b>Indication 2)</b></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><b>Indication 3)</b></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 administration<sup>3</sup>

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

<sup>3</sup> 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 data-bbox="810 255 967 286"><b>Indication 2)</b></p> <p data-bbox="810 313 1407 452">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</p> <p data-bbox="810 479 1426 618">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 data-bbox="810 667 1369 698">b) Tincture: 1-4 ml, 3 times daily as a gargle</p> <p data-bbox="810 725 1347 788">c) Liquid extract: 1-3 ml, 3 times daily as a gargle</p> <p data-bbox="810 846 967 878"><b>Indication 3)</b></p> <p data-bbox="810 904 1426 1079">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 data-bbox="810 1106 1426 1281">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 data-bbox="810 1352 1404 1456">The use in children under 12 years of age is not recommended (see section 4.4 Special warnings and precautions for use).</p> <p data-bbox="810 1536 1015 1568"><b>Duration of use</b></p> <p data-bbox="810 1594 967 1626"><b>Indication 1)</b></p> <p data-bbox="810 1653 1401 1787">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 data-bbox="810 1814 1056 1845"><b>Indications 2) and 3)</b></p> <p data-bbox="810 1872 1433 2007">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</p>

Well-established use	Traditional use
	<p>for use).</p> <p><b>Method of administration</b></p> <p>Indication 1)</p> <p>Oral use.</p> <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</p>

Well-established use	Traditional use
	care practitioner should be consulted.

#### ***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

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<sup>4</sup>

Well-established use	Traditional use
	<p>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.</p> <p>Tests on genotoxicity, carcinogenicity and reproductive toxicity have not been performed.</p>

## 6. Pharmaceutical particulars

Well-established use	Traditional use
	Not applicable.

## 7. Date of compilation/last revision

6 May 2014