



London, 14 May 2009
Doc. Ref.: EMEA/HMPC/98717/2008

**COMMITTEE ON HERBAL MEDICINAL PRODUCTS
(HMPC)**

FINAL

COMMUNITY HERBAL MONOGRAPH ON *ALTHAEA OFFICINALIS* L., RADIX

DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	March 2008 May 2008 July 2008 January 2009
ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION	17 July 2008
END OF CONSULTATION (DEADLINE FOR COMMENTS)	15 November 2008
REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	January 2009 March 2009
ADOPTION BY HMPC	14 May 2009

KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; <i>Althaea officinalis</i> L.; Althaeae radix; marshmallow root
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COMMUNITY HERBAL MONOGRAPH ON *ALTHAEA OFFICINALIS* L., RADIX

1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION^{1,2}

<u>Well-established use</u>	<u>Traditional use</u>
	<p>With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended</p> <p><i>Althaea officinalis</i> L., radix (marshmallow root)</p> <p>i) Herbal substance Not applicable</p> <p>ii) Herbal preparations</p> <p>A) Comminuted herbal substance</p> <p>B) Liquid extract (1 : 19.5 – 23.5), extraction solvent water</p> <p>C) Syrup prepared from macerate, corresponding to 2 – 6.5 g of herbal substance/100 ml</p> <p>D) Dry extract (3 – 9 : 1), extraction solvent water</p>

3. PHARMACEUTICAL FORM

<u>Well-established use</u>	<u>Traditional use</u>
	<p>Comminuted herbal substance for macerate preparation or other mucilage containing herbal preparations in liquid or solid dosage forms for oral and oromucosal use.</p> <p>The pharmaceutical form should be described by the European Pharmacopoeia full standard term.</p>

¹ The material complies with the Eur. Ph. monograph (ref. 01/2008:1126 corrected 6.0)

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

<u>Well-established use</u>	<u>Traditional use</u> Traditional herbal medicinal product for use as a demulcent preparation a) for the symptomatic treatment of oral or pharyngeal irritation and associated dry cough b) for the symptomatic relief of mild gastrointestinal discomfort The product is a traditional herbal medicinal product for use in specified indications exclusively based upon long-standing use.
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4.2. Posology and method of administration

<u>Well-established use</u>	<u>Traditional use</u> Posology Indication a) <i>Adolescents and adults</i> A) single dose 0.5 – 3 g for macerate preparation, several times daily up to maximum daily dose of 15 g B) single dose 5 ml, 3-6 times daily C) single dose 2 – 10 ml, 3 times daily D) single dose corresponding to 0.5 – 3 g of herbal substance, several times daily up to a maximum daily dose of 15 g <i>Children between 6 and 12 years of age</i> A) single dose 0.5 – 1.5 g for macerate preparation, 3 times daily B) single dose 2.5 ml, 5 times daily C) single dose 1 – 1.5 ml, 4 times daily D) single dose corresponding to 0.5 – 1.5 g of herbal substance, 3 times daily <i>Children between 3 and 6 years of age</i> A) single dose 0.5 – 1 g for macerate preparation, 3 times daily B) single dose 2.5 ml, 4 times daily C) single dose 0.5 – 1 ml, 4 times daily D) single dose corresponding to 0.5 – 1 g of herbal substance, 3 times daily
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	<p>The use in children under 3 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’).</p> <p>Indication b)</p> <p><i>Adolescents and adults</i></p> <p>A) 3 – 5 g for macerate preparation, 3 times daily</p> <p>The use is not recommended in children under 12 years of age (see section 4.4 ‘Special warnings and precautions for use’).</p> <p>To make a macerate, pour 150 ml of water (maximum temperature of 40°C) over the comminuted herbal substance. Steep for 30 minutes stirring frequently. The macerate should be used immediately after preparation.</p> <p>Duration of use</p> <p>Indication a)</p> <p>If the symptoms persist for more than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Indication b)</p> <p>If the symptoms persist for more than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.</p> <p>Method of administration</p> <p>Oral and oromucosal use.</p>
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4.3. Contraindications

<u>Well-established use</u>	<u>Traditional use</u> Hypersensitivity to the active substance.
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4.4. Special warnings and precautions for use

<u>Well-established use</u>	<u>Traditional use</u> Indication a) The use in children under 3 years of age is not
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	<p>recommended because medical advice should be sought.</p> <p>If dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted immediately.</p> <p>For syrup the appropriate labelling for sucrose, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.</p> <p>Indication b)</p> <p>The use in children under 12 years of age is not recommended due to lack of adequate data.</p> <p>Absorption of concomitantly administered medicines may be delayed. As a precautionary measure, the product should not be taken ½ to 1 hour before or after intake of other medicinal products.</p>
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4.5. Interactions with other medicinal products and other forms of interaction

<u>Well-established use</u>	<u>Traditional use</u> None reported.
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4.6. Pregnancy and lactation

<u>Well-established use</u>	<u>Traditional use</u> Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.
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4.7. Effects on ability to drive and use machines

<u>Well-established use</u>	<u>Traditional use</u> No studies on the effect on the ability to drive and use machines have been performed.
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4.8. Undesirable effects

<u>Well-established use</u>	<u>Traditional use</u> None known. If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted.
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4.9. Overdose

<u>Well-established use</u>	<u>Traditional use</u> No case of overdose has been reported.
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5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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5.2. Pharmacokinetic properties

<u>Well-established use</u>	<u>Traditional use</u> Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
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5.3. Preclinical safety data

<u>Well-established use</u>	<u>Traditional use</u> 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 reproductive toxicity, genotoxicity and carcinogenicity have not been performed.
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6. PHARMACEUTICAL PARTICULARS

<u>Well-established use</u>	<u>Traditional use</u> The macerate should be used immediately after preparation due to risk of microbiological contamination.
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7. DATE OF COMPILATION/LAST REVISION

14 May 2009