European Medicines Agency
Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT

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
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REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)	
ADOPTION BY HMPC	

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KEYWORDS	Herbal medicinal products; HMPC; Community herbal monographs; traditional use; *Althaea officinalis* 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]

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

3. PHARMACEUTICAL FORM

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

[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

Well-established use	Traditional use
	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.

4.2. Posology and method of administration

Well-established use	Traditional use
	Posology Indication a) *Adolescents and adults* A) single dose 0.5 – 3 g, 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 *Children between 6 and 12 years of age* A) single dose 0.5 – 1.5 g, 3 times daily B) single dose 2.5 ml, 5 times daily C) single dose 1 – 1.5 ml, 3 times daily *Children between 3 and 6 years of age* A) single dose 0.5 – 1 g, 3 times daily B) single dose 2.5 ml, 4 times daily C) single dose 0.5 – 1 ml, 3 times daily The use in children under 3 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’). Indication b) *Adolescents and adults* A) 3 – 5 g, 3 times daily The use in children under 12 years of age is not recommended (see section 4.4 ‘Special warnings and precautions for use’).

	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. **Duration of use** 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. **Method of administration** Oral and oromucosal use.

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
	Indication a) The use in children under 3 years of age is not recommended because medical advice should be sought. If symptoms worsen or if dyspnoea, fever or purulent sputum occurs during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted immediately. 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. Indication b) The use in children under 12 years of age is not recommended due to lack of adequate data for safety assessment.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	Absorption of concomitantly administered medicines may be delayed. For this reason the product should not be taken ½ to 1 hour before or after intake of other medicinal products.

4.6. 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.

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 reported. 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 data

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 reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	The macerate should be used immediately after preparation due to risk of microbiological contamination

7. DATE OF COMPILATION/LAST REVISION

3 July 2008