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*Evaluation of Medicines for Human Use*

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**FINAL**

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

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| **DISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)** | March 2008<br>May 2008<br>July 2008<br>January 2009 |
| **ADOPTION BY HMPC FOR RELEASE FOR CONSULTATION** | 17 July 2008 |
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| **REDISCUSSION IN WORKING PARTY ON COMMUNITY MONOGRAPHS AND COMMUNITY LIST (MLWP)** | January 2009<br>March 2009 |
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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<br><br>*Althaea officinalis* L., radix (marshmallow root)<br><br>i) Herbal substance<br>Not applicable<br><br>ii) Herbal preparations<br>A) Comminuted herbal substance<br>B) Liquid extract (1 : 19.5 – 23.5), extraction solvent water<br>C) Syrup prepared from macerate, corresponding to 2 – 6.5 g of herbal substance/100 ml<br>D) Dry extract (3 – 9 : 1), extraction solvent water |

## 3. PHARMACEUTICAL FORM

| Well-established use | Traditional use |
|---|---|
| | Comminuted herbal substance for macerate preparation or other mucilage containing herbal preparations in liquid or solid dosage forms for oral and oromucosal use.<br><br>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<br>a) for the symptomatic treatment of oral or pharyngeal irritation and associated dry cough<br>b) for the symptomatic relief of mild gastrointestinal discomfort<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

| Well-established use | Traditional use |
|---|---|
| | **Posology**<br><br>Indication a)<br><br>*Adolescents and adults*<br><br>A) single dose 0.5 – 3 g for macerate preparation, several times daily up to maximum daily dose of 15 g<br>B) single dose 5 ml, 3-6 times daily<br>C) single dose 2 – 10 ml, 3 times daily<br>D) single dose corresponding to 0.5 – 3 g of herbal substance, several times daily up to a maximum daily dose of 15 g<br><br>*Children between 6 and 12 years of age*<br><br>A) single dose 0.5 – 1.5 g for macerate preparation, 3 times daily<br>B) single dose 2.5 ml, 5 times daily<br>C) single dose 1 – 1.5 ml, 4 times daily<br>D) single dose corresponding to 0.5 – 1.5 g of herbal substance, 3 times daily<br><br>*Children between 3 and 6 years of age*<br><br>A) single dose 0.5 – 1 g for macerate preparation, 3 times daily<br>B) single dose 2.5 ml, 4 times daily<br>C) single dose 0.5 – 1 ml, 4 times daily<br>D) single dose corresponding to 0.5 – 1 g of herbal substance, 3 times daily |

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| | The use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use').<br><br>Indication b)<br><br>*Adolescents and adults*<br><br>A) 3 – 5 g for macerate preparation, 3 times daily<br><br>The use is not recommended in children under 12 years of age (see section 4.4 'Special warnings and precautions for use').<br><br>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.<br><br>**Duration of use**<br><br>Indication a)<br><br>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.<br><br>Indication b)<br><br>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.<br><br>**Method of administration**<br><br>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)<br><br>The use in children under 3 years of age is not |

| | |
|---|---|
| | recommended because medical advice should be sought.<br><br>If dyspnoea, fever or purulent sputum occurs, a doctor or a qualified health care practitioner should be consulted immediately.<br><br>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.<br><br>Indication b)<br><br>The use in children under 12 years of age is not recommended due to lack of adequate data.<br><br>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. |

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

| Well-established use | Traditional use |
|---|---|
| | None reported. |

**4.6. Pregnancy and lactation**

| Well-established use | Traditional use |
|---|---|
| | Safety during pregnancy and lactation has not been established.<br>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 known.<br><br>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.<br><br>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

14 May 2009