EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 November 2015
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Committee on Herbal Medicinal Products (HMPC)

European Union herbal monograph on *Althaea officinalis* L., radix

Draft - revision

Discussion in Working Party on European Union monographs and European Union list (MLWP)	March 2008 May 2008 July 2008 January 2009
Adoption by Committee on Herbal Medicinal Products (HMPC) for release for consultation	17 July 2008
End of consultation	15 November 2008
Re-discussion in MLWP	January 2009 March 2009
Adoption by HMPC Monograph (EMEA/HMPC/98717/2008) AR (EMEA/HMPC/98718/2008) List of references (EMEA/HMPC/98716/2008) Overview of comments received during the public consultation (EMEA/HMPC/2920/2009) HMPC Opinion (EMEA/HMPC/109223/2009)	14 May 2009
First systematic review	
Discussion in MLWP	July 2015 September 2015
Adoption by HMPC	24 November 2015
Start of public consultation	11 December 2015
End of consultation (deadline for comments). Comments should be provided using this template to hmpc.secretariat@ema.europa.eu	15 March 2016

Keywords	Herbal medicinal products; HMPC; European Union herbal monographs; traditional use; *Althaea officinalis* L., radix; Althaeae radix; Marshmallow root

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BG (bulgarski): Лечебна ружа, корен CS (čeština): proskurníkový kořen DA (dansk): Altæarod DE (Deutsch): Eibischwurzel EL (elliniká): ριζα αλταιας- ριζα αλθαιας EN (English): Marshmallow root ES (español): Altea, raíz de ET (eesti keel): alteejuur FI (suomi): rohtosalkoruusu, juuri FR (français): Guimauve (racine de) HR (hrvatski): korijen običnog bijelog sljeza HU (magyar): orvosi ziliz gyökér IT (italiano): Altea radice	LT (lietuvių kalba): Svilarožių šaknys LV (latviešu valoda): Altejas saknes MT (Malti): Għerq tal-Ħobbejża Mediċinali NL (Nederlands): Echte Heemst PL (polski): Korzeń prawoślazu PT (português): Alteia, raiz RO (română): rădăcină de nalbă mare SK (slovenčina): Koreň ibiša SL (slovenščina): korenina navadnega sleza SV (svenska): Läkemalva, rot *IS (íslenska)*: *NO (norsk):* Altearot

European Union 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 (DER 1:19.5-23.5), extraction solvent water c) Macerate for preparation of syrup[3] d) Dry extract (DER 3-9:1), extraction solvent water e) Liquid extract (DER 1:1), extraction solvent ethanol 25% (V/V)

3. Pharmaceutical form

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral or oromucosal use. The pharmaceutical form should be described by

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

[2] The material complies with the Ph. Eur. monograph (ref.: 1126)

[3] Prepared in accordance with the pharmacopoeial monographs for Sirupus althaeae in Österreichisches Arzneibuch 1981, Československý lékopis1954, Farmakopea Polska 1970 and 2002 or with the monograph Eibischsirup in Deutscher Arzneimittel-Codex 1979

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

4. Clinical particulars

4.1. Therapeutic indications

Well-established use	Traditional use
	Indication 1 Traditional herbal medicinal product used as a demulcent preparation for the symptomatic treatment of oral or pharyngeal irritation and associated dry cough. Indication 2 Traditional herbal medicinal product used as a demulcent preparation 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[4]

Well-established use	Traditional use
	Posology **Oral use** **a) Comminuted herbal substance** Indication 1) *Adolescents, adults and elderly* Herbal tea: 0.5 - 3 g of the comminuted herbal substance in 150 ml of water as a macerate several times daily Maximum daily dose: 15 g *Children 6-12 years of age* Herbal tea: 0.5 – 1.5 g of the comminuted herbal substance in 150 ml of water as a macerate 3 times daily Daily dose: 1.5 – 4.5 g

[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
	Children 3-5 years of age Herbal tea: 0.5 – 1.0 g of the comminuted herbal substance in 150 ml of water as a macerate 3 times daily Daily dose: 1.5 – 3.0 g The use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). Indication 2) *Adolescents, adults and elderly* Herbal tea: 3 - 5 g of the comminuted herbal substance in 150 ml of water as a macerate 3 times daily Maximum daily dose: 15 g The use in children under 12 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **b) Liquid extract (DER 1:19.5-23.5)** Indication 1) *Adolescents, adults and elderly* Single dose: 4.6 g 3 – 6 times daily Daily dose: 13.8 – 27.6 g *Children 6-12 years of age* Single dose: 2.3 g 5 times daily Daily dose: 11.5 g *Children 3-5 years of age* Single dose: 1.9 g 4 times daily Daily dose: 7.6 g The use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **c) Macerate for preparation of syrup** Indication 1) *Adolescents, adults and elderly* Single dose: macerate amount corresponding to 0.21 to 0.87 g of the herbal substance (10 – 15 ml of syrup) 3 – 5 times daily

Well-established use	Traditional use
	Daily dose: macerate amount corresponding to 0.63 to 2.9 g of the herbal substance (30 – 50 ml of syrup) *Children 6-12 years of age* Single dose: macerate amount corresponding to 0.1 to 0.29 g of the herbal substance (5 ml of syrup) 3 - 5 times daily Daily dose: macerate amount corresponding to 0.32 to 1.45 g of the herbal substance (15 – 25 ml of syrup) *Children 3-5 years of age* Single dose: macerate amount corresponding to 0.1 to 0.29 g of the herbal substance (5 ml of syrup) up to 4 times daily Daily dose: macerate amount corresponding to 0.21 to 1.16 g of herbal substance (10 – 20 ml of syrup) The use in children under 3 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **e) Liquid extract (DER 1:1)** Indication 1) and 2) *Adults and elderly* Single dose: 2 – 5 ml 3 times daily Daily dose: 6 – 15 ml The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Oromucosal use** **d) Dry extract (DER 3-9:1)** Indication 1) *Adolescents, adults and elderly* Single dose: 160 mg several times daily Maximum daily dose: 1.6 g *Children 6-12 years of age* Single dose: 160 mg 3 times daily

Well-established use	Traditional use
	Daily dose: 480 mg The use in children under 6 years of age is not recommended (see section 4.4 'Special warnings and precautions for use'). **Duration of use** Indication 1) If the symptoms persist longer than 1 week during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. Indication 2) If the symptoms persist longer than 2 weeks during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. **Method of administration** ***Preparations a) b), c) and e)*** Oral use. ***Preparation d)*** Oromucosal use. The macerate should be used immediately after preparation.

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 1) 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. ***Preparations a), b) and c)*** The use in children under 3 years of age is not recommended because of concerns requiring

Well-established use	Traditional use
	medical advice. ***Preparation d)*** The use in children under 6 years of age is not recommended because of the pharmaceutical form (solid dosage form). ***Preparation e)*** The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. 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 2) ***Preparation a)*** The use in children under 12 years of age has not been established due to lack of adequate data. ***Preparation e)*** The use in children and adolescents under 18 years of age has not been established due to lack of adequate data. Indications 1) and 2) 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. If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. For 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.

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

6. Pharmaceutical particulars

Well-established use	**Traditional use**
	Not applicable.

7. Date of compilation/last revision

24 November 2015