Althaeae radix
Marshmallow Root

2019
ALTHAEÆ RADIX
Marshmallow Root

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Plant illustrated on the cover: Althaea officinalis
FOREWORD

It is a great pleasure for me to introduce the online era of ESCOP Monographs. Interest in herbal medicinal products continues to stimulate research on herbal substances and the body of knowledge in this field is steadily growing. ESCOP takes account of this by preparing new monographs and - as the only organisation in the field at the moment - particularly through regular revision of our published monographs. In order to provide readers and authorities with balanced compilations of scientific data as rapidly as possible, ESCOP Monographs will be published online from now on. This contemporary way of publishing adds further momentum to ESCOP’s endeavours in the harmonization of European standards for herbal medicinal products.

The Board of ESCOP wishes to express its sincere gratitude to the members of the Scientific Committee, external experts and supervising editors, and to Peter Bradley, the final editor of every monograph published up to March 2011. All have voluntarily contributed their time and scientific expertise to ensure the high standard of the monographs.

Dr. Tankred Wegener
Chair of the Board of ESCOP

PREFACE

Over the 15 years since ESCOP published its first monographs, initially as loose-leaf documents then as two hardback books, ESCOP Monographs have achieved a reputation for well-researched, comprehensive yet concise summaries of available scientific data pertaining to the efficacy and safety of herbal medicinal products. The Second Edition, published in 2003 with a Supplement in 2009, covered a total of 107 herbal substances.

The monograph texts are prepared in the demanding format of the Summary of Product Characteristics (SPC), a standard document required in every application to market a medicinal product for human use within the European Union and ultimately providing information for prescribers and users of individual products.

As a change in style, literature references are now denoted by the name of the first author and year of publication instead of reference numbers; consequently, citations at the end of a monograph are now in alphabetical order. This is intended to give the reader a little more information and perspective when reading the text.

Detailed work in studying the pertinent scientific literature and compiling draft monographs relies to a large extent on the knowledge, skills and dedication of individual project leaders within ESCOP Scientific Committee, as well as invited experts. After discussion and provisional acceptance by the Committee, draft monographs are appraised by an eminent Board of Supervising Editors and all comments are taken into account before final editing and approval. In this way a wide degree of consensus is achieved, but it is a time-consuming process.

To accelerate the publication of new and revised monographs ESCOP has therefore decided to publish them as an online series only, commencing in 2011. We trust that rapid online access will prove helpful and convenient to all users of ESCOP Monographs.

As always, ESCOP is indebted to the many contributors involved in the preparation of monographs, as well as to those who provide administrative assistance and hospitality to keep the enterprise running smoothly; our grateful thanks to them all.
NOTES FOR THE READER

From 2011 new and revised ESCOP Monographs are published as an online series only. Earlier monographs are available in two books, ESCOP Monographs Second Edition (2003) and the Second Edition Supplement 2009, but are not available online for copyright reasons.

After purchase of a single monograph, the specific items to be downloaded are:

- Front cover
- Title page
- Verso
- Foreword and Preface
- Notes for the Reader
- Abbreviations
- The monograph text
- Back cover

Information on the member organizations and people involved in ESCOP’s activities can be found on the website (www.escop.com):

- Members of ESCOP
- Board of Supervising Editors
- ESCOP Scientific Committee
- Board of Directors of ESCOP
ABBREVIATIONS used in ESCOP monographs

AA  arachidonic acid
ABTS  2,2'-azino-bis(3-ethylbenzthiazoline-6-sulphonic acid)
ACE  angiotensin converting enzyme
ADP  adenosine diphosphate
ALAT or ALT  alanine aminotransferase (= SGPT or GPT)
ALP  alkaline phosphatase
anti-IgE  anti-immunoglobulin E
ASA  acetylsalicylic acid
ASAT or AST  aspartate aminotransferase (= SGOT or GOT)
ATP  adenosine triphosphate
AUC  area under the concentration-time curve
BMI  body mass index
BPH  benign prostatic hyperplasia
b.w.  body weight
cAMP  cyclic adenosine monophosphate
CI  confidence interval
CCl4  carbon tetrachloride
Cmax  maximum concentration of a substance in serum
CNS  central nervous system
CoA  coenzyme A
COX  cyclooxygenase
CSF  colony stimulating factor
CVI  chronic venous insufficiency
CYP  cytochrome P450
d  day
der  drug-to-extract ratio
DHT  dihydrotestosterone
DMSO  dimethyl sulfoxide
DNA  deoxyribonucleic acid
DPPH  diphenylpicrylhydrazyl
DSM  Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association)
ECG  electrocardiogram
ED50  effective dose in 50% of cases
EDTA  ethylenediamine tetraacetate
EEG  electroencephalogram
EMA  European Medicines Agency
ENT  ear, nose and throat
ER  oestrogen receptor
ERE  oestrogen-responsive element
FSH  follicle-stimulating hormone
GABA  gamma-aminobutyric acid
Gal  galactose
GFR  glomerular filtration rate
GGTP  gamma-glutamyl transpeptidase
GOT  glutamate oxalacetate transaminase (= SGOT)
GPT  glutamate pyruvate transaminase (= SGPT)
GSH  glutathione (reduced)
GSSG  glutathione (oxidised)
HAMA  Hamilton Anxiety Scale
12-HETE  12-hydroxy-5,8,10,14-eicosatetraenoic acid
HDL  high density lipoprotein
HIV  human immunodeficiency virus
HMPC  Committee on Herbal Medicinal Products (of the EMA)
HPLC  high-performance liquid chromatography
5-HT  5-hydroxytryptamine (= serotonin)
IC50  concentration leading to 50% inhibition
ICD-10  International Statistical Classification of Diseases and Related Health Problems, Tenth Revision
ICH  The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSD  International Classification of Sleep Disorders
IFN  interferon
IL  interleukin
i.m.  intramuscular
iNOS  inducible nitric oxide synthase
Marshmallow Root

**DEFINITION**
Marshmallow root consists of the peeled or unpeeled, whole or cut, dried root of *Althaea officinalis* L. It has a swelling index of minimum 10, determined on the powdered herbal drug.

The material complies with the monograph of the European Pharmacopoeia [Marshmallow Root].

**CONSTITUENTS**
Characteristic constituents of the dried root are mucilage polysaccharides (from 5% up to 20% in late autumn and winter, in biennial roots), consisting of rhamnogalacturonans (≤30%), arabinans, glucans and arabinogalactans [Franz 1966; Karawya 1971; Tomoda 1977; Tomoda 1980; Capek 1983; Akhtardzhiev 1984; Rosik 1984; Capek 1984; Shimizu 1985; Capek 1987; Capek 1988; Evans 1996; Nosalova 2005; Blaschek 2014]. The mucilage can withstand temperatures of 40-60°C [Franz 1990].

Other constituents include flavone glycosides (ca. 0.2% as aglycones) [Gudej 1990; Shah 2011], mainly isoscutellarein 4'-methyl ether 8-glucoside-2''-sulphate, 4 sulfated hypolaetin-glucosides, phenolic acids, the coumarin scopoletin, fatty acids: linolenic acid (omega 3) and hexadecanoic acid [Gudej 1991; Ninov 1992; Valiei 2011; Sendker 2017], starch, pectin [Evans 1996; Blaschek 2014] and tannins [Bieloszabska 1966].

**CLINICAL PARTICULARS**

**Therapeutic indications**

a) Dry cough; irritation of the oral or pharyngeal mucosa [Braun 1987; Weiss 1991; Bradley 1992; Bone 1993; Barnes 2002; Sweetman 2002; Schulz 2004; Fasse 2005; Rouhi 2007; Wichtl 2009; Blaschek 2014].

b) For symptomatic relief of mild gastrointestinal discomfort and irritation of the gastric mucosa [Villar 1984; Schilcher 2003; Bäumler 2007; Blaschek 2014].

In these indications, efficacy is plausible on the basis of human experience and long-standing use.

**Dosage**

**a) Internal use for dry cough and irritation of the oral mucosa.**

**Adult single and daily dose:**

- 0.5-3 g herbal substance as an aqueous cold macerate* (several times daily up to an equivalent of 15 g of the drug).
- 10 ml of syrup (DER 1:20), repeated up to 6 times daily [Bradley 1992; Schilcher 2003; Schulz 2004; Wichtl 2009; Blaschek 2014].

**Daily dose for children, between 6 and 12 years of age, for dry cough:**

- 0.5-1.5 g as a macerate*, up to 3 times daily.
- 5-10 ml of syrup (DER 1:20), up to 4-6 times daily. [Weiss 1999; Schilcher 2003; Fasse 2005].

**Daily dose for children, between 3 and 6 years of age, for dry cough:**

- 0.5-1 g as a macerate*, up to 3 times daily.
- 2.5-5 ml of syrup (DER 1:20), up to 4-6 times daily. [Weiss 1999; Schilcher 2003; Fasse 2005].
b) **Internal use for gastrointestinal irritation.**

**Adult single and daily dose:**
- 3-5 g herbal substance, as an aqueous cold macerate*, up to 3 times daily
  [Bradley 1992; Schilcher 2003; Wichtl 2009].

* To make a macerate pour 150 ml of water (max. temp. 40°C) over one dose of comminuted marshmallow root. Steep for 30 min., stirring frequently. The filtered macerate should be used immediately after preparation.

**Method of administration**
For oral administration.

**Duration of administration**
If symptoms persist or worsen, medical advice should be sought.

**Contraindications**
None known.

**Special warnings and special precautions for use**
For dry cough: the use in children under 3 years of age is not recommended [Fasse 2005].

**Interaction with other medicinal products and other forms of interaction**
The absorption of other drugs taken simultaneously may be retarded [Barnes 2002; Blaschek 2014]. As a precaution, marshmallow root should be taken ½ to 1 hour before or 2 hours after intake of other medicinal products.

**Pregnancy and lactation**
No data available. In accordance with general medical practice, the product should not be used during pregnancy and lactation, without medical advice.

**Effects on ability to drive and use machines**
None known.

**Undesirable effects**
None reported.

**Overdose**
No case of overdose reported.

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**PHARMACOLOGICAL PROPERTIES**

**Pharmacodynamic properties**
The mucilage from marshmallow root covers the mucosa, especially of the mouth and pharynx, and the gastric mucosa, protecting them from local irritation [Meyer 1956; Müller-Limmroth 1980; Braun 1987; Franz 1989; Weiss 1999; Schulz 2004; Wichtl 2009; Shah 2011; Blaschek 2014].

**In vitro experiments**

**Antimicrobial activity**
A dry methanol extract (15 g extracted, filtered and evaporated) demonstrated significant antibacterial activity against periodontal pathogenic bacteria resident in the oral cavity (*Porphyromonas gingivalis*, *Prevotella* spp., *Actinomyces* spp.). The MIC for 9/12 strains was ≤3125 mg/L [Iauk 2003].

Antimicrobial activity against *Pseudomonas aeruginosa*, *Proteus vulgaris* and *Staphylococcus aureus* has been documented for chloroform and methanol extracts of marshmallow root [Recio 1989].

Good antimicrobial activity was reported for hexane extracts containing mainly fatty acids and hexadecanoic acid methyl ester. The strongest antibacterial effects, by zone of inhibition (mm), were demonstrated for *Bacillus subtilis* (18.9 mm), *Staphylococcus aureus* (16.8 mm), *S. epidermidis* (17.3 mm) and *Escherichia coli* (16.0 mm). Antifungal effects were observed against *Candida albicans* (14.7 mm) and *Saccharomyces cerevisiae* (14.7 mm) [Valiet 2011].

**Protection of mucilage**
Mucociliary transport in isolated, ciliated epithelium of the frog oesophagus was inhibited up to 17% by 200 µl of a cold, 30-minute macerate of marshmallow root (6.4 g/140 ml) [Müller-Limmroth 1980].

In a study of the bioadhesive effects of purified polysaccharides (>95%) on isolated porcine buccal membranes, polysaccharides from marshmallow root showed dose dependent moderate adhesion to epithelial tissue [Schmidigall 2000].

A dried cold aqueous extract (100 g powdered root yielding 9.9 g (w/w) dry extract), at 10 µg/ml, stimulated cell viability (marginally) and proliferation (significantly, p<0.01) of human epithelial cells. Isolated polysaccharides, at 10 µg/ml, significantly (p<0.01) increased cell viability but not proliferation. Primary dermal human fibroblasts were not stimulated by the extract or the polysaccharides. Fluorescence-labelled-polysaccharides were detected inside epithelial cells with detectable changes in cell physiology. The fibroblasts did not demonstrate any internalisation, but were found to be covered with a bioadhesive layer of polysaccharides [Deters 2010].

A 50% methanolic extract, depleted of high molecular weight material by alcohol precipitation, yielded 8.1% plant material (relative to the dried drug) in a raw extract. This low molecular weight raw extract contained, among others, flavonoid glycosides, four hypolaetin glycosides and coumarins. The raw extract inhibited human hyaluronidase-1 activity (expressed on *E. coli*) and hyaluronidase mRNA expression in keratinocytes (representing skin and mucosal epithelial cells) at 125 and 250 µg/ml [Sendker 2017].

The bioadhesive properties of 2 mucopolysaccharide-containing aqueous marshmallow root extracts, added to 2 commercial cough syrups (syrup 1: 2.5 g extract (DER: 7-9:1) in 100 ml syrup; syrup 2: 35.6 g extract (DER: 1:19.5-23.5) in 100 g syrup), were investigated in isolated porcine buccal mucosa (attached to glass plates) kept humid by artificial saliva, which was also used as a control solution. The positive adherence of these 2 syrups (coloured with eosin) to porcine mucosa was demonstrated by measuring a reduction in flow-velocity (6% flow for syrup 1; 25% flow for syrup 2) compared to the control solution which did not demonstrate any adhesive properties (100% flow). A subsequent experiment, using the same 2 marshmallow extract-containing syrups and an identical mucosal test system, measured inhibition of caffeine transport through the mucosa (a protective property). Both syrups inhibited caffeine transport: syrup 1 by 30% and syrup 2 by 10%; compared to 100% transport of caffeine alone. A control marshmallow extract (DER: 7-9:1) showed only slight inhibition, indicating that the galenic composition of the syrup supports the inhibitory activity of the marshmallow polysaccharides [Appel 2018].

**Immunological activity and effects on melanocytes and keratinocytes**

An acidic polysaccharide isolated from marshmallow root, *althaea-mucilage O*, exhibited weak anti-complement activity (alternative route) in normal human serum at concentrations of 100-1000 µg/ml [Yamada 1985].
A filtered extract (dissolved in 45% 1,3-butylene glycol) was found to inhibit intracellular calcium mobilization in normal human melanocytes (involved in pigmentation) and to strongly inhibit endothelin-1 induced proliferation of melanocytes. The extract also reduced the secretion of endothelin-1 in normal human keratinocytes. The authors suggest that because of these effects, the extract may be a useful ingredient in a whitening agent [Kobayashi 2002].

 Pronounced antioxidant activity (tests: ABTS+ radical cation scavenging assay; hypochlorous acid scavenging assay; trolox as positive control) of ethanol/water extracts (50:50 and 70:30 V/V) of marshmallow root (100 mg/ml) was found to correlate well with the phenolic and flavonoid content of the extracts [Benbassat 2013].

In vivo experiments
Mucilaginous herbs like marshmallow root may inhibit coughing by forming a protective coating on the mucosal lining of the respiratory tract, shielding it from irritants.

Anti-tussive effects
Extracts from marshmallow root and isolated mucilage polysaccharides were administered orally to cats at doses of 50 or 100 mg/kg b.w. in order to investigate their anti-tussive effects in comparison with controls. Both the extract and isolated polysaccharides, as well as syrupus Althaeae (1000 mg/kg), significantly diminished the intensity and amount of coughing induced by mechanical irritation [Nosalova 1992a, 1992b, 1993].

Cats (with experimentally induced cough reflex, induced by mechanical stimulation of the airway mucosa) were treated orally with either a syrup (1 g/kg b.w.), or an aqueous extract (1 g/kg), or root mucilage [prepared as a crude mixture of polysaccharides obtained by precipitation of the aqueous extract with ethanol and subsequent dialysis of the precipitate; 100 mg/kg], or with isolated rhamnogalacturonan (50 mg/kg). These were compared to commonly used cough suppressants, both a narcotic (codeine at 10 mg/kg) and a non-narcotic drug (dropropizine at 100 mg/kg). The marshmallow-derived polysaccharides exhibited impressive anti-tussive activity after 30 min., 1, 2 and up to 5 hours, for various cough-related parameters. Rhamnogalacturonan was 2.5 times more active than the other marshmallow preparations [Nosalova 2005].

Anti-tussive activity of the marshmallow polysaccharide, rhamnogalacturonan, was shown to be dose dependent (25 mg/kg and 50 mg/kg b.w.), when given orally to unsensitized guinea pigs, with experimental citric acid aerosol-induced airways inflammation. The highest oral rhamnogalacturonan dose with strong cough reflex suppressant activity was comparable to the effect of codeine at 10 mg/kg b.w. This dose suppressed the cough reflex significantly (p<0.01) up to 5 hours after application [Sutovska 2011].

Anti-inflammatory effects
An ointment containing an aqueous marshmallow root extract (20%), applied topically to the external ear of rabbits, reduced irritation induced by ultraviolet irradiation or tetrahydrofurfuryl alcohol; the anti-inflammatory effect was less than that of an ointment containing dexamethasone (0.05%). An ointment containing alcohol; the anti-inflammatory effect was less than that of phenylbutazone, but gastric erosions were only seen after phenylbutazone [Villar 1984]. Hypolaein 8-glucoside also showed gastric anti-ulcer activity in rats [Alcaraz 1988] and was more potent than troxerutin in inhibiting histamine-induced capillary permeability in rats [Villar 1987].

Hypoglycaemic activity
Mucilage polysaccharides isolated from marshmallow root and administered intraperitoneally to mice at doses of 10, 30 and 100 mg/kg reduced plasma glucose levels respectively to 74%, 81% and 65% of the control level after 7 hours, demonstrating significant hypoglycaemic activity [Tomoda 1987].

Phagocytic activity, immunemodulatory effect
Isolated mucilage polysaccharides from marshmallow root, administered intraperitoneally to mice at 10 mg/kg, produced a 2.2-fold increase in phagocytic activity of macrophages in the carbon-clearance test [Wagner 1985; Hänsel 2014].

Clinical studies
In a randomized, double-blind, placebo-controlled clinical study 63 adults suffering from dry cough, associated with angiotensin-converting enzyme inhibitors, were assessed using a cough score of 0 to 4 (0 = no cough, 1 = tickling in throat, 2 = mild cough; 3 = moderate tolerable cough; 4 = severe persistent cough). The patients were randomized to receive 20 drops 3 times per day of either a marshmallow root preparation (not further defined) or a placebo for 4 weeks. After 4 weeks the severity of cough in the marshmallow group was significantly (p<0.05) reduced. Eight patients in the marshmallow group showed almost complete abolition of cough, as opposed to 1 patient in the placebo group. Three patients were excluded from the study because of noncompliance with the test drug [Rouhi 2007].

In a postmarketing surveillance study, 313 children in 3 groups (0-3 y, n=100; 3-6y, n=115; 6-12 y, n=98) were treated 4-6 times daily with 2.5, 5 and 10 ml (according to their age group) of marshmallow root syrup (Phytohustil®; DER: 1:20). Duration of treatment was three days for ¾ of the patients and was continued longer for the remaining ¼ (2.2% were treated for < 3 days). Three children were excluded from efficacy evaluation due to disallowed concomitant medication. The following cough symptoms were evaluated: cough intensity, cough frequency and extent of coughing periods per day. Coughing intensity and frequency as well as cough-dependent symptoms were strongly reduced after three days. Two adverse events occurred in the 0-3 age group which were not attributed to the drug. Tolerability of marshmallow root was reported as very good [Fasse 2005].

Pharmacokinetic properties
No data available.

Preclinical safety data
No data available.

Clinical safety data
A total of 373 adults and children with cough were treated with various doses of marshmallow root in 2 clinical studies. In thirty patients treated with 3 x 40 mg/d marshmallow root for 4 weeks, adverse events were not reported [Rouhi 2007]. In the study with 313 children that received a marshmallow root
containing syrup (Phytostabil\textregistered; DER 1:20), for 3 days or more, one adverse event (development of obstructive bronchitis) and one serious adverse event (development of bronchopneumonia resulting in hospitalisation) occurred in the 0-3 years age group, but these were not attributed directly to the drug. The tolerability of marshmallow root was reported as very good [Fasse 2005].

REFERENCES


Marshmallow Root - Althaea radix. European Pharmacopoeia, Council of Europe.


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The second edition of ESCOP Monographs, published as a hardback book in 2003 with a Supplement in 2009, has been widely acclaimed for its authoritative information on the therapeutic uses of herbal medicines. Monographs covering a total of 107 herbal substances include extensive summaries of pharmacological, clinical and toxicological data, and copious references to scientific literature form an important part of each text.

Although publication in the form of books was convenient in the past, ESCOP recognizes that online publication now offers a number of advantages, not least in facilitating rapid publication of individual monographs as soon as all stages of preparation have been completed. Commencing from 2011, therefore, new and revised monographs will be published online only.

The European legislative framework for herbal medicines has advanced considerably over the past decade. Directive 2004/24/EC introduced a simplified registration procedure for traditional herbal medicinal products in EU member states and imposed a 2011 deadline for the registration of certain products on the market. The Committee on Herbal Medicinal Products (HMPC), established in 2004 as part of the European Medicines Agency, has made substantial progress in the preparation of Community Herbal Monographs and associated documentation to provide a more harmonized approach to the scientific assessment of herbal medicinal products throughout the European Community.

Whether the evaluation of a herbal medicine is based on evidence of clinical efficacy (well-established use) or on experience and historical use of that product (traditional use) those involved at all levels of the regulatory process need access to detailed, reliable and structured summaries of the available efficacy and safety data. ESCOP monographs meet that requirement and offer an invaluable source of scientific information on herbal medicines to regulators, manufacturers, academics, researchers, health professionals and numerous others.