



NATURAL HEALTH PRODUCT

MARSHMALLOW - *ALTHAEA OFFICINALIS* - ROOT

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient.

Notes

- ▶ Text in parentheses is additional optional information which can be included on the PLA and product label at the applicant's discretion.
- ▶ The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant.

Date

July 31, 2018

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)	
		Proper name(s)	Part(s)
<i>Althaea officinalis</i>	<ul style="list-style-type: none"> ▶ Marshmallow ▶ White-mallow 	<i>Althaea officinalis</i>	Root

References: Proper name: USDA 2018, McGuffin et al. 2000; Common names: USDA 2018, McGuffin et al. 2000, Wiersema and León 1999; Source material: Blumenthal et al. 2000, 1998, BHP 1983, Grieve 1971.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms by age group:

Children 3-5 years: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/liquid preparations (Giaccoia et al. 2008; EMEA/CHMP 2006).



Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older: The acceptable dosage forms for this age category and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

- ▶ (Traditionally) used in Herbal Medicine (as a demulcent) to relieve the irritation of the oral and pharyngeal mucosa and associated dry cough (Mills and Bone 2005; Wichtl 2004; Hoffman 2003; BHC 1992; BHP 1983; Grieve 1971).
- ▶ (Traditionally) used in Herbal Medicine (as a demulcent) to relieve mild inflammation of the gastro-intestinal mucosa (e.g. gastritis) (Mills and Bone 2005; Wichtl 2004; Hoffman 2003; Blumenthal et al. 2000, 1998; Ellingwood 1998; BHC 1992; BHP 1983; Grieve 1971; Cook 1869).

Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

Dose(s)

Subpopulation(s)

As specified below.

Quantity(ies)

Relief of the irritation of the oral and pharyngeal mucosa & dry cough

Methods of preparation: Cold infusion, Macerate or Powder

Subpopulation(s)		Dried root (g/day)	
		Minimum	Maximum
Children	3-5 years	1.5 ¹	3 ¹
	6-11 years	1.5 ¹	4.5 ¹
Adolescents	12-17 years	1.5 ²	15 ²
Adults	18 years and older	1.5 ²	15 ²

¹EMEA 2009

²EMEA 2009; Mills and Bone 2005; WHO 2002; ESCOP 1996; BHP 1983; Cook 1869

Not to exceed 5 grams per single dose



Methods of preparation: Tincture

Adults 18 years and older

1-15 grams dried root, per day; Not to exceed 5 grams per single dose (1:5, in 25% ethanol) (Blumenthal et al. 2000; BHC 1992)

Relief of mild inflammation of the gastro-intestinal mucosa

Methods of preparation: Cold infusion, Macerate

Adults 18 years and older

6-15 grams dried root, per day; Not to exceed 5 grams per single dose (EMEA 2009; BHC 2006; Mills and Bone 2005; BHP 1983).

Direction(s) for use

All Products

Take a few hours before or after taking other medications or natural health products (EMEA 2009; BHC 2006; Mills and Bone 2005; Blumenthal et al. 2000).

For Cold infusion/Macerate

Add powder/dried root to 150 milliliters of cold water and let steep for 30 minutes. Stir frequently. Strain and warm (if desired) before drinking (Blumenthal 2000; BHC 1996).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or breastfeeding.

Contraindication(s)

No statement required.



Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

Storage conditions

No statement required.

Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

References cited

BHC 1992: Bradley PR, editor. British Herbal Compendium Volume 1: A Handbook of Scientific Information on Widely Used Plant Drugs – Companion Volume 1 of the British Herbal Pharmacopoeia. Bournemouth (GB): British Herbal Medicine Association; 1992.

BHP 1983: British Herbal Medicine Association's Scientific Committee. British Herbal Pharmacopoeia. Bournemouth (GB): The British Herbal Medicine Association; 1983.

Blumenthal M, Goldberg A, Brinckmann J, editors. Herbal Medicine: Expanded Commission E Monographs. Newton (MA): Integrative Medicine Communications; 2000.

Blumenthal M, Busse WR, Goldberg A, Gruenwald J, Hall T, Riggins CW, Rister RS. The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines. Austin (TX): American Botanical Council in Cooperation with Integrative Medicine Communications; 1998.

Cook WMH. The Physio-Medical Dispensatory: A Treatise on Therapeutics, Materia Medica, and Pharmacy, in Accordance with the Principles of Physiological Medication. [Internet] Cincinnati (OH): WH Cook; 1869. Reprint version by Medical Herbalism: Journal for the Clinical Practitioner [Accessed 2018 June 5]. Available from: <http://www.henriettesherbal.com/eclectic/cook/index.html>



Ellingwood F. *American Materia Medica, Therapeutics and Pharmacognosy*. Sandy (OR): Eclectic Medical Publications; 1998 [Reprint of 1919 original].

EMA 2009: EMA/HMPC/98717/2009 Community Herbal Monograph on *Althaea officinalis* L., Radix. London (GB): European Medicines Agency: Committee on Herbal Medicinal Products (HMPC); 14 May 2009. [Accessed 2018 June 5] Available from: <http://www.ema.europa.eu/>

EMA/CHMP 2006: European Medicines Agency: Pre-authorization Evaluation of Medicines for Human Use. Committee for Medicinal Products for Human Use. Reflection Paper: Formulations of choice for the paediatric population. [Accessed 2018 June 5]. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003782.pdf

ESCOP 1996: European Scientific Cooperative of Phytotherapy. *Monographs on the Medicinal Uses of Plant Drugs*. Exeter (GB): European Scientific Cooperative on Phytotherapy; 1996.

Giacoia GP, Taylor-Zapata P, Mattison D. Eunice Kennedy Shriver National Institute of Child Health and Human Development Pediatric Formulation Initiative: selected reports from working groups. *Clinical Therapeutics* 2008; 30(11):2097-2101.

Grieve M. *A Modern Herbal, Volume 2*. New York (NY): Dover Publications; 1971 [Reprint of 1931 Harcourt, Brace & Company publication].

Hoffmann D. *Medical Herbalism: The Science and Practice of Herbal Medicine*. Rochester (VT): Healing Arts Press; 2003.

McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. *Herbs of Commerce*. 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000.

Mills S, Bone K. *The Essential Guide to Herbal Safety*. St. Louis (MO): Elsevier Churchill Livingstone; 2005.

USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [Online Database]. National Germplasm Resources Laboratory, Beltsville (MD). [*Althaea officinalis* L.; Accessed 2018 June 5]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

WHO 2002: World Health Organization. *WHO Monographs on Selected Medicinal Plants, Volume 2*. Geneva (CH): World Health Organization; 2002.

Wichtl M, editor. *Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis*. 3rd edition. Stuttgart (DE): Medpharm Scientific Publishers; 2004.

Wiersema J, León B. *World Economic Plants: A Standard Reference*. Boca Raton (FL): CRC Press LLC; 1999.

References reviewed

Barnes J, Anderson LA, Phillipson JD. Herbal Medicines. 3rd edition. London (GB): Pharmaceutical Press; 2007.

Bartram T. Bartram's Encyclopedia of Herbal Medicine: The definitive guide to the herbal treatment of diseases. London (GB): Robinson Publishing Ltd; 1998.

Bradley PR, editor. British Herbal Compendium Volume 2: A Handbook of Scientific Information on Widely Used Plant Drugs—Companion to the British Herbal Pharmacopoeia. Bournemouth (GB): British Herbal Medicine Association; 2006.

Brinker 2010: Brinker F. Final updates and additions for Herb Contraindications and Drug Interactions, 3rd edition, including extensive Appendices addressing common problematic conditions, medications and nutritional supplements, and influences on Phase I, II & III metabolism with new appendix on botanicals as complementary adjuncts with drugs. [Internet]. Sandy (OR): Eclectic Medical Publications. [Updated July 13, 2010; Accessed 2012 April 18]. Available from: <http://www.eclecticherb.com/emp/updatesHCIDI.html>

Brinker F. Herb Contraindications and Drug Interactions. 3rd edition. Sandy (OR): Eclectic Medical Publications; 2001.

Canada Vigilance Adverse Reaction Online Database. Ottawa (ON): Marketed Health Products Directorate, Health Canada; 2011. [Accessed 2012 April 19]. Available from: <http://webprod3.hc-sc.gc.ca/arquery-recherchei/index-eng.jsp>

Chandler F, editor. Herbs: Everyday Reference for Health Professionals. Ottawa (ON): Canadian Pharmacists Association and the Canadian Medical Association; 2000.

Faccolia S. Cornucopia II A source book of edible plants. Vista (CA): Kampong Publications; 1998.

Felter HW, Lloyd JU. King's American Dispensatory. Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original].

Felter HW, Lloyd JU. King's American Dispensatory. Volume 2, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original].

Felter HW. The Eclectic Materia Medica, Pharmacology and Therapeutics. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1922 original].

Hoffman D. Complete Illustrated Guide to The Holistic Herbal: A safe and practical guide to making and using herbal remedies. London (GB): Element, an imprint of Harper Collins Publishers; 2002.

Lust J. *The Herb Book: The Complete and Authoritative Guide to More than 500 Herbs*. New York (NY): Benedict Lust Publications; 2005.

McGuffin M, Hobbs C, Upton R, Goldberg A, editors. *American Herbal Products Association's Botanical Safety Handbook*. Boca Raton (FL): CRC Press; 1997.

Mills S, Bone K. *Principles and Practice of Phytotherapy, Modern Herbal Medicine*. Edinburgh: Churchill Livingstone; 2000.

Natural Health Products Compliance and Enforcement Policy. Ottawa (ON): Health Products and Food Branch. [Date Modified 2010-08-27; Accessed 2012 April 19]. Available from: http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/compli-conform/info-prod/prodnatur/complianconform-pol-eng.pdf

Natural Standard. *Mashmallow (Althaea officinalis L.)* Copyright 2012 [Internet]. [Accessed 2012 April 18]. Available from: <http://www.naturalstandard.com>.

Newall CA, Anderson LA, Phillipson JD. *Herbal Medicines: A guide for health-care professionals*. London (GB): The Pharmaceutical Press; 1996.

Remington JP, Woods HC, editors. *The Dispensatory of the United States of America* [Internet] 20th edition; 1918. Abridged; botanicals only. Scanned by Michael Moore, director, The Southwest School of Botanical Medicine, Bisbee (AZ). [Accessed 2012 April 19]. Available from: <http://www.swsbm.com/Dispensatory/USD-1918-complete.pdf>

Weiss RF, Fintelmann V. *Herbal Medicine*. 2nd edition, revised and expanded. New York (NY): Thieme; 2000.

WHO Food Additives Series: 63; FAO JECFA Monographs 8. *Safety evaluation of certain contaminants in food*. [Internet]. Geneva (CH): World Health Organization; 2011. [Accessed 2012 April 19]. Available from <http://www.inchem.org/documents/jecfa/jecmono/v63je01.pdf>

Williamson EM, Evans FJ, Wren RC. *Potter's New Cyclopaedia of Botanical Drugs and Preparations*. Saffron Walden (GB): C.W. Daniel Company Limited; 1998.

Williamson EM. *Potter's Herbal Cyclopaedia: The Authoritative Reference work on Plants with a Known Medical Use*. Saffron Walden (GB): The C.W. Daniel Company Limited; 2003.

Wren RC, Evans FJ. *Potter's New Encyclopedia of Botanical Drugs and Preparations*. Essex (GB); Potter's (Herbal Supplies) Limited; 1985 (Reprint of 1907).