



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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date: July 18, 2017

Proper name(s):

Althaea officinalis L. (Malvaceae) (USDA 2013; McGuffin et al. 2000)

Common name(s):

- ▶ Marshmallow (USDA 2013; McGuffin et al. 2000)
- ▶ White-mallow (USDA 2013; Wiersema and León 1999)

Source material(s):

Root (Blumenthal et al. 2000, 1998; BHP 1983; Grieve 1971)

Route(s) of administration:

Oral

Dosage form(s):

This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Dosage forms by age group:



- **Children 3-5 years:** The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giaccoia et al. 2008; EMEA/CHMP 2006).
- **Children 6-12 years, Adolescents 13-17 years, and Adults ≥ 18 years:** The acceptable dosage forms include, but are not limited to capsules, chewables (e.g., gummies, tablets), liquids, powders, strips or tablets.

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, peptic and duodenal ulceration, enteritis (Mills and Bone 2005; Wichtl 2004; Hoffman 2003; Blumenthal et al. 2000, 1998; Ellingwood 1998 (1919); BHC 1992; BHP 1983; Grieve 1971; Cook 1869).

Dose(s):

Subpopulation(s) and Quantity(ies)

RELIEF OF ORAL AND PHARYNGEAL MUCOSA IRRITATION & DRY COUGH

Cold infusion/Macerate or powder

Subpopulation		Dried root (g/day)	
		Minimum	Maximum
Children	3-6 y	1.5 ¹	3 ¹
	6-12 y	1.5 ¹	4.5 ¹
Adolescents and Adults	≥ 13 y	1.5 ²	15 ²

¹EMEA 2009

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

Tincture

Adults (≥ 18 years): 1-15 g dried root, per day (1:5, in 25% ethanol) (Blumenthal et al. 2000; BHC 1992)

Directions for use

All products



- ▶ Take in 3 divided doses, per day (EMEA 2009; BHC 2006; Blumenthal et al. 2000).
- ▶ Take a few hours before or after taking other medications or natural health products (Mills and Bone 2005; Blumenthal et al. 2000).

Cold infusion/Macerate

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

RELIEF OF GASTROINTESTINAL IRRITATION

Cold infusion/Macerate

Adults (≥ 18 years): 6-15 g dried root, per day (EMEA 2009; BHC 2006; Mills and Bone 2005; BHP 1983).

Directions for use

- ▶ Take in 3 divided doses, per day (EMEA 2009; BHC 2006; Blumenthal et al. 2000).
- ▶ Take a few hours before or after taking other medications or natural health products (Mills and Bone 2005; Blumenthal et al. 2000).
- ▶ Add powder/dried herb to 150 ml cold water and let steep for 30 minutes. Stir frequently. Strain and warm (if desired) before drinking (Blumenthal 2000; BHC 1996).

Duration of use:

No statement required.

Risk information:

Caution(s) and warning(s)

- ▶ If symptoms persist or worsen, consult a health care practitioner.
- ▶ If you are pregnant or breastfeeding, consult a health care practitioner prior to use.

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

Storage conditions:

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.

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.
- ▶ The medicinal ingredient may comply with the specifications outlined in the pharmacopoeial monographs listed in Table 1 below.

Table 1 Marshmallow monographs published in the British (BP) and European (Ph.Eur.) pharmacopoeias

Pharmacopoeia	Monograph
BP	Marshmallow Root
Ph.Eur.	

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.

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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.

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

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

USDA 2013: 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. Last updated: 23-Aug-1994; Accessed 2013 May 10]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl

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

References reviewed:

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

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