

# Marshmallow - *Althaea officinalis* - Root

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Marshmallow - ALTHAEA OFFICINALIS - Root Help on accessing alternative formats, such as Portable Document Format ( PDF ), Microsoft Word and PowerPoint ( PPT ) files, can be obtained in the alternate format help section. (PDF Version - 36 K) 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 ingredient(s) Table 1. Proper name(s), Common name(s), Source ingredient(s) Proper name(s) Common name(s) Source ingredient(s) Source material(s) Part(s) Preparation(s) *Althaea officinalis* Marshmallow White-mallow *Althaea officinalis* Root Dried References: Proper name: USDA 2018, McGuffin et al. 2000; Common names: USDA 2018, McGuffin et al. 2000, Wiersema and León 1999; Source ingredient: 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: Dry, Powdered, Infusion, cold water Table 2. Dose information for marshmallow root presented as dose per day and per single dose Subpopulation(s) Dried root(g/day) Dried root (g/single dose) Minimum Maximum Maximum Children 3-5 years 1.5g 1 3g 1 1g 6-11 years 1.5g 1 4.5g 1 1.5g Adolescents 12-17 years 1.5g 2 15g 2 5g Adults 18 years and above 1.5g 2 15g 2 5g 1 EMEA 2009 2 EMEA 2009; Mills and Bone 2005; WHO 2002; ESCOP 1996; BHP 1983; Cook 1869 Note: Dried or powdered root should be prepared as a cold infusion (see direction for use). Method 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: Dry, Powdered, Infusion, cold water 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). Note: Dried or powdered root should be prepared as a cold infusion (see direction for use). 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). Dried root Add dried root to 150 ml cold water and let steep for 30 minutes. Stir frequently. Strain and warm (if desired) before drinking (Blumenthal 2000; BHC 1996). Powdered root Add powdered 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 â€” 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. 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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/complian-conform-pol-eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/compli-conform/info-prod/prodnatur/complian-conform-pol-eng.pdf) Natural Standard. Marshmallow ( *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. Second 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). Report a problem on this page Date modified: 2019-03-01

## **DOSAGE FORM(S)**

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.

## **STORAGE CONDITION(S)**

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**

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 (Giacchia 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.

Proper name(s)	Common name(s)	Source ingredient(s)		
Source material(s)	Part(s)	Preparation(s)		
Althaea officinalis	MarshmallowWhite-mallow	Althaea officinalis	Root	Dried

Subpopulation(s)	Dried root(g/day)	Dried root (g/single dose)		
Minimum	Maximum	Maximum		
Children				
3-5 years	1.5g1	3g1	1g	
6-11 years	1.5g1	4.5g1	1.5g	
Adolescents				
12-17 years	1.5g2	15g2	5g	
Adults	18 years and above	1.5g2	15g2	5g
Adults	18 years and above	1.5g2	15g2	5g