



## 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 ingredient

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

Proper name(s)	Common name(s)	Source ingredient		
		Source material(s)	Part(s)	Preparation(s)
<i>Althaea officinalis</i>	<ul style="list-style-type: none"> <li>▶ Marshmallow</li> <li>▶ White-mallow</li> </ul>	<i>Althaea officinalis</i>	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 (Giacioia 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 <sup>1</sup>	3g <sup>1</sup>	1g
	6-11 years	1.5g <sup>1</sup>	4.5g <sup>1</sup>	1.5g
Adolescents	12-17 years	1.5g <sup>2</sup>	15g <sup>2</sup>	5g
Adults	18 years and older	1.5g <sup>2</sup>	15g <sup>2</sup>	5g

<sup>1</sup>EMEA 2009

<sup>2</sup>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 milliliters of 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.

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