

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)
Althaea officinalis	MarshmallowWhite-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 (Giacoia 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

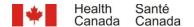
Subpopulation(s)		Dried root (g/day)		Dried root (g/single dose)
		Minimum	Maximum	Maximum
Children	3-5 years	$1.5g^1$	$3g^1$	1g
	6-11 years	1.5g ¹	4.5g ¹	1.5g
Adolescents	12-17 years	$1.5g^2$	15g ²	5g
Adults	18 years and older	$1.5g^2$	15g ²	5g

¹EMEA 2009

Note: Dried or powdered root should be prepared as a cold infusion (see direction for use).



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



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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