

NATURAL HEALTH PRODUCT

MARSHMALLOW – *ALTHAEA OFFICINALIS* – LEAF

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 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 on the label.

Date November 29, 2024

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

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

Proper name(s)	Common name(s)	Source information		
		Source material(s)	Part(s)	Preparation(s)
<i>Althaea officinalis</i>	<ul style="list-style-type: none"> • Marshmallow • White-mallow 	<i>Althaea officinalis</i>	Leaf	Dry

References: Proper name: USDA 2024; Gardner and McGuffin 2013; Common names: USDA 2024; Gardner and McGuffin 2013, Wiersema and León 1999; Source information: Blumenthal et al. 2000; BHP 1996, 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 for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.



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 (Bradley 2006; Mills and Bone 2005; Wichtl 2004; Hoffman 2003; Blumenthal et al. 2000; 1998; BHP 1996; Grieve 1971).
- (Traditionally) used in Herbal Medicine (as a demulcent) to relieve mild inflammation of the gastro-intestinal mucosa (e.g., gastritis) (Bradley 2006; Mills and Bone 2005; Wichtl 2004; Bone 2003; Hoffman 2003; Blumenthal et al. 2000; 1998; BHP 1996; Grieve 1971).

Notes

- The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g., Traditionally used in Herbal Medicine to relieve the irritation of the oral and pharyngeal mucosa and associated dry cough and mild inflammation of the gastro-intestinal mucosa).
- **For multi-ingredient products:**
 - To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Marshmallow is traditionally used in Herbal Medicine to relieve mild inflammation of the gastro-intestinal mucosa).
 - When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required.

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Methods of preparation: Dry, Powdered, Infusion, cold water

2 – 15 grams dried leaf, per day; Not to exceed 5 grams per single dose (EMA 2016; Bradley 2006; Mills and Bone 2005; Blumenthal et al. 2000; BHP 1996).

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



Method of preparation: Fluid extract

2 – 15 milliliters of dried leaf fluid extract, per day; Not to exceed 5 milliliters per single dose (1:1, in 25% ethanol) (EMA 2016; Bradley 2006; Blumenthal et al. 2000).

Direction(s) for use

All products

Take a few hours before or after taking other medications or health products (Bradley 2006; Mills and Bone 2005; Blumenthal et al. 2000; BHP 1996).

Dried/powdered leaf

Add dried/powdered leaf to 150 milliliters of cold water and let steep for 30 minutes. Stir frequently. Strain and warm (if desired) before drinking (Bradley 2006; Blumenthal 2000).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

- **Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.**
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician before 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

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

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.

EXAMPLE OF PRODUCT FACTS:

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts
Medicinal ingredient in each scoop <i>Althaea officinalis</i> (Marshmallow – leaf) XX g
Uses <ul style="list-style-type: none"> • Used in Herbal Medicine as a demulcent to relieve the irritation of the oral and pharyngeal mucosa and associated dry cough. • Traditionally used in Herbal Medicine to relieve mild inflammation of the gastro-intestinal mucosa.
Warnings
If applicable¹: Allergens: food allergens, gluten (gluten source), sulphites Contains aspartame
Ask a health care practitioner before use if you are pregnant or breastfeeding.
Ask a health care practitioner if symptoms persist or worsen.
Directions Adults 18 years and older: • Take X scoop(s), X time(s) per day • Take a few hours before or after taking other medications or health products • Add dried leaf to 150 milliliters of cold water and let steep for 30 minutes. Stir frequently. Strain and warm.
Other information (Add storage information).
Non-medicinal ingredients List all NMIs.
Questions? (Call) 1-XXX-XXX-XXXX

¹This section can be removed from the table if the product contains no allergen or aspartame.



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