

Marshmallow - *Althaea Officinalis* - Leaf

Source: [https://webprod.hc-sc.gc.ca/nhp/ids/bdipsn/atReq?atid=marshmallow.leaf.guimauve.feuille2\(=eng](https://webprod.hc-sc.gc.ca/nhp/ids/bdipsn/atReq?atid=marshmallow.leaf.guimauve.feuille2(=eng)

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MARSHMALLOW - ALTHAEA OFFICINALIS - LEAF 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 (PLA) 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) *Althaea officinalis* Marshmallow White-mallow *Althaea officinalis* 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 is 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.

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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 for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

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 CONDITION(S)

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.

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Althaea officinalis	MarshmallowWhite-mallow	Althaea officinalis	Leaf	Dry