Health Canada Santé Canada

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 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 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	Dried

References: Proper name: USDA 2018, McGuffin et al. 2000; Common names: USDA 2018, McGuffin et al. 2000, Wiersema and León 1999; Source information: 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 for the age category listed in this monograph 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 (BHC 2006; Mills and Bone 2005; Wichtl 2004; Hoffman 2003; Blumenthal et al. 2000; 1998; BHP 1983; Grieve 1971).
- (Traditionally) used in Herbal Medicine (as a demulcent) to relieve mild inflammation of the gastro-intestinal mucosa (e.g. gastritis) (BHC 2006; Mills and Bone 2005; Wichtl 2004; Bone 2003; Hoffman 2003; Blumenthal et al. 2000; 1998; BHP 1983; Grieve 1971).

Note
Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Methods of preparation: Dry, Infusion, cold water

2-15 grams dried leaf, per day; Not to exceed 5 grams per single dose (Mills and Bone 2005)

Note: Dried leaves 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) (BHC 2006; Blumenthal et al. 2000)

Method of preparation: Powder

5 grams powdered dried leaf, per day (BHC 2006; Blumenthal et al. 2000, 1998; BHP 1983)

Direction(s) for use

All products

Take a few hours before or after taking other medications or natural health products (BHC 2006; Mills and Bone 2005; Blumenthal et al. 2000; BHP 1983).

Dried leaf

Add dried leaves 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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