



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 the statements are synonymous. Either term or statement may be selected by the applicant.

Date

May 21, 2013

Proper name(s)

Althaea officinalis L. (Malvaceae) (USDA 2013; McGuffin et al. 2000)

Common name(s)

- ▶ Marshmallow (USDA 2013; McGuffin et al. 2000)
- ▶ White-mallow (USDA 2013; Wiersema and León 1999)

Source material(s)

Leaf (Blumenthal et al. 2000, 1998; BHP 1983; Grieve 1971)

Route(s) of administration

Oral

Dosage form(s)

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- ▶ This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Use(s) or Purpose(s)

Statement(s) to the effect of

- ▶ (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, peptic and duodenal ulceration, enteritis (BHC 2006; Mills and Bone 2005; Wichtl 2004; Bone 2003; Hoffman 2003; Blumenthal et al. 2000; 1998; BHP 1983; Grieve 1971).

Dose(s)

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

Cold infusion/Macerate

2-15 g dried leaf, per day (Mills and Bone 2005)

Fluidextract

2-15 ml, per day (1:1, in 25% ethanol) (BHC 2006; Blumenthal et al. 2000)

Powder

5 g cut or ground leaf, per day (Blumenthal et al. 2000, 1998; BHC 2006; BHP 1983)

Directions for use

All products

- ▶ Take in 3 divided doses, per day (BHC 2006; Blumenthal et al. 2000; BHP 1983).
- ▶ Take a few hours before or after taking other medications or natural health products (Mills and Bone 2005; Blumenthal et al. 2000).

Cold infusion/macerate

Add powder/dried herb to 150 ml cold water and let steep for 30 minutes. Stir frequently. Strain and warm (if desired) before drinking (Blumenthal 2000; BHC 1996).

Duration of use

No statement required.

Risk information Statement(s) to the effect of

Caution(s) and warning(s)

- ▶ If symptoms persist or worsen, consult a health care practitioner.
- ▶ If you are pregnant or breastfeeding, consult a health care practitioner prior to use.

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

Storage conditions

No statement required.

Non-medicinal ingredients

Must be chosen from the current NHPD *Natural Health Products Ingredients Database* (NHPID) and must meet the limitations outlined in the database.

Specifications

- ▶ The finished product specifications must be established in accordance with the requirements described in the NHPD *Quality of Natural Health Products Guide*.
- ▶ The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID). In addition, the medicinal ingredient may comply with the specifications outlined in the pharmacopoeial monographs listed in Table 1 below.

Table 1 Marshmallow monographs published in the British (BP) and European (Ph.Eur.) pharmacopoeias

Pharmacopoeia	Monograph
BP	Marshmallow Leaf
Ph.Eur.	

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