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

**Date:** July 18, 2017

**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):**

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

**Route(s) of administration:**

Oral

**Dosage form(s):**

This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

Dosage forms by age group:
- **Children 3-5 years**: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giacolia et al. 2008; EMEA/CHMP 2006).
- **Children 6-12 years, Adolescents 13-17 years, and Adults ≥ 18 years**: The acceptable dosage forms include, but are not limited to capsules, chewables (e.g., gummies, tablets), liquids, powders, strips or tablets.

**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; Wichl 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, peptic and duodenal ulceration, enteritis (Mills and Bone 2005; Wichl 2004; Hoffman 2003; Blumenthal et al. 2000, 1998; Ellingwood 1998 (1919); BHC 1992; BHP 1983; Grieve 1971; Cook 1869).

**Dose(s):**

**Subpopulation(s) and Quantity(ies)**

**RELIEF OF ORAL AND PHARYNGEAL MUCOSA IRRITATION & DRY COUGH**

*Cold infusion/Macerate or powder*

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Dried root (g/day)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children 3-6 y</td>
<td>1.5¹</td>
<td>1.5¹</td>
<td>3¹</td>
</tr>
<tr>
<td>6-12 y</td>
<td>1.5¹</td>
<td>1.5¹</td>
<td>4.5¹</td>
</tr>
<tr>
<td>Adolescents and Adults ≥ 13 y</td>
<td>1.5²</td>
<td>1.5²</td>
<td>15²</td>
</tr>
</tbody>
</table>

¹EMEA 2009
²EMEA 2009; Mills and Bone 2005; WHO 2002; ESCOP 1996; BHP 1983; Cook 1869

**Tincture**

Adults (≥ 18 years): 1-15 g dried root, per day (1:5, in 25% ethanol) (Blumenthal et al. 2000; BHC 1992)

**Directions for use**

*All products*
Take in 3 divided doses, per day (EMEA 2009; BHC 2006; Blumenthal et al. 2000).
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).

RELIEF OF GASTROINTESTINAL IRRITATION

_Cold infusion/Macerate_

Adults (≥ 18 years): 6-15 g dried root, per day (EMEA 2009; BHC 2006; Mills and Bone 2005; BHP 1983).

**Directions for use**

- Take in 3 divided doses, per day (EMEA 2009; BHC 2006; Blumenthal et al. 2000).
- Take a few hours before or after taking other medications or natural health products (Mills and Bone 2005; Blumenthal et al. 2000).
- 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:**

**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 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 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.
- 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

<table>
<thead>
<tr>
<th>Pharmacopoeia</th>
<th>Monograph</th>
</tr>
</thead>
<tbody>
<tr>
<td>BP</td>
<td>Marshmallow Root</td>
</tr>
<tr>
<td>Ph.Eur.</td>
<td></td>
</tr>
</tbody>
</table>

References cited:


References reviewed:


Brinker 2010: Brinker F. Final updates and additions for Herb Contraindications and Drug Interactions, 3rd edition, including extensive Appendices addressing common problematic conditions, medications and nutritional supplements, and influences on Phase I, II & III metabolism with new appendix on botanicals as complementary adjuncts with drugs. [Internet]. Sandy (OR): Eclectic Medical Publications. [Updated July 13, 2010; Accessed 2012 April 18]. Available from: http://www.eclecticherb.com/emp/updatesHCDI.html


Felter HW, Lloyd JU. King’s American Dispensatory. Volume 1, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original].

Felter HW. The Eclectic Materia Medica, Pharmacology and Therapeutics. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1922 original].


Wren RC, Evans FJ. Potter’s New Encyclopedia of Botanical Drugs and Preparations. Essex (GB); Potter’s (Herbal Supplies) Limited; 1985 (Reprint of 1907).