NATURAL HEALTH PRODUCT

LICORICE – GLYCYRRHIZA GLABRA

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 18, 2017

Proper name(s):

_Glycyrrhiza glabra_ L. (Fabaceae) (USDA 2007)

Common name(s):

Licorice (McGuffin et al. 2000)

Source material(s):

Root and stolon (Mills and Bone 2005; ESCOP 2003; Blumenthal et al. 2000; Bradley 1992)

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 4-5 years**: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giacorea 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 an expectorant to help relieve chest complaints, such as catarrhs, coughs and bronchitis (Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992; Felter and Lloyd 1893 [1898], Grieve 1971 [1931]).
- Used in Herbal Medicine to help relieve inflammatory conditions of the gastrointestinal tract, such as gastritis in adults (ESCOP 2003; Hoffmann 2003; Bradley 1992).

**Dose(s):**

Table 1: Dose information for dried licorice root and stolon presented as dose per day

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Dried licorice root and stolon (g/day)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td></td>
<td>0.1</td>
<td>2.5</td>
</tr>
<tr>
<td>Children and adolescents</td>
<td></td>
<td>0.15</td>
<td>3.75</td>
</tr>
<tr>
<td>Adolescents</td>
<td></td>
<td>0.3</td>
<td>7.5</td>
</tr>
<tr>
<td>Adolescents and adults</td>
<td></td>
<td>0.6</td>
<td>15</td>
</tr>
</tbody>
</table>

1 Children and adolescent doses were calculated as a fraction of the adult dose (JC 2008). The use of licorice in children and adolescents is supported by the following references: McIntyre 2005; Schilcher 1997; Bove 1996.
2 Adult dose supported by the following references: Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992.
3 Includes breastfeeding women

Table 2: Dose information for glycyrrhizic acid presented as dose per day

<table>
<thead>
<tr>
<th>Subpopulation</th>
<th>Glycyrrhizic acid (mg/day)</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Children</td>
<td></td>
<td>10</td>
<td>100</td>
</tr>
<tr>
<td>Children and adolescents</td>
<td></td>
<td>15</td>
<td>150</td>
</tr>
<tr>
<td>Adolescents</td>
<td></td>
<td>30</td>
<td>300</td>
</tr>
<tr>
<td>Adolescents and adults</td>
<td></td>
<td>60</td>
<td>600</td>
</tr>
</tbody>
</table>

1 Children and adolescent doses were calculated as a fraction of the adult dose (JC 2008). The use of licorice in children and adolescents is supported by the following references: McIntyre 2005; Schilcher 1997; Bove 1996.
2 Adult dose supported by the following references: ESCOP 2003.
3 Includes breastfeeding women
See Appendix 1 for examples of appropriate dosage preparations, frequencies of use and directions for use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

**Duration of use:**

Consult a health care practitioner for use beyond 4-6 weeks (ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992).

**Risk information:**

**Caution(s) and warning(s):**

- Consult a health care practitioner if symptoms persist or worsen.
- Consult a health care practitioner prior to use if you are pregnant (ESCOP 2003; Hoffmann 2003; Bradley 1992).
- Consult a health care practitioner prior to use if you have a liver disorder (Brinker 2007; ESCOP 2003; Bradley 1992; McGuffin et al. 1997).

**Contraindication(s):**

- Do not use if you have hypokalemia, high blood pressure, or a kidney or cardiovascular disorder (Brinker 2007; ESCOP 2003; Bradley 1992).
- Do not use if you are taking thiazide diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance (Brinker 2007; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; McGuffin et al. 1997).

**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.

**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 3 below.

Table 3: Licorice monographs published in British, European and US Pharmacopoeias

<table>
<thead>
<tr>
<th>Pharmacopoeia</th>
<th>Monograph</th>
</tr>
</thead>
<tbody>
<tr>
<td>British Pharmacopoeia</td>
<td>Liquorice, Liquorice Root for use in THM,</td>
</tr>
<tr>
<td></td>
<td>Liquorice Root for use in THMP</td>
</tr>
<tr>
<td>European Pharmacopoeia</td>
<td>Liquorice Root, Liquorice Ethanolic Liquid</td>
</tr>
<tr>
<td></td>
<td>Extract</td>
</tr>
<tr>
<td>US Pharmacopoeia</td>
<td>Licorice, Powdered Licorice, Powdered Licorice</td>
</tr>
<tr>
<td></td>
<td>Extract</td>
</tr>
</tbody>
</table>

References cited:


Felter HW, Lloyd JU. King’s American Dispensatory, Volume 2, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original].

References reviewed:


Appendix 1: Examples of appropriate dosage preparations, frequencies of use and directions for use

Dried root and stolon:
- 3-12 g, per day (Mills and Bone 2005)
- 1.5-15 g, per day (ESCOP 2003)
- 5-15 g, per day (Blumenthal et al. 2000)
- 1-5 g, 3 times per day (Bradley 1992)

Decoction:
3-12 g dried root and stolon, per day (Mills and Bone 2005)
1.5-15 g dried root and stolon, per day (ESCOP 2003)
2-4 g dried root and stolon, 3 times per day (Blumenthal et al. 2000)
1-5 g dried root and stolon, 3 times per day (Bradley 1992)

**Directions for use:**
Place ½ - 1 tsp of dried root and stolon in 250 ml (1 cup) of cold water, bring to a boil and simmer for 10-15 minutes (Hoffmann 2003).
Take after meals (Blumenthal et al. 2000).
3 g = 1 tsp. (Hoffmann 2003)

**Fluidextract:**
2-6 g dried equivalent, per day
(1:1, 2-6 ml) (Mills and Bone 2005)
2-4 g dried equivalent, 3 times per day
(1:1, 2-4 ml) (Blumenthal et al. 2000)

**Directions for use:** Take after meals (Blumenthal et al. 2000).

**Tincture:**
0.2-0.6 g dried equivalent, 3 times per day
(1:5, 40% alcohol, 1-3 ml) (Hoffmann 2003)

**Preparations providing the following quantity of glycyrrhizic acid:**
60-600 mg, per day (ESCOP 2003)