NATURAL HEALTH PRODUCT

DEGLYCYRRHIZINATED LICORICE (DGL) – ORAL

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.

Note:

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

Date: July 18, 2017

Proper name(s):

- *Glycyrrhiza glabra* L. (Fabaceae) (BP 2008; USDA 2007)
- *Glycyrrhiza inflata* Bat. (Fabaceae) (BP 2008; USDA 2002)
- *Glycyrrhiza uralensis* Fisch. Ex DC. (Fabaceae) (BP 2008; USDA 2001)

Common name(s):

- Deglycyrrhizinated licorice (Pizzorno and Murray 2006; Blumenthal et al. 2000)
- DGL (Pizzorno and Murray 2006; Blumenthal et al. 2000)

Source material(s):

- Root (BP 2008; Ph. Eur. 2008)
- Root and stolon (BP 2008; Ph. Eur. 2008)
- Root and rhizome (BP 2008; PPRC 2005)
- Root, rhizome and stolon (USP 32)

Route(s) of administration:

Oral

Dosage form(s):

The acceptable pharmaceutical dosage form for oral administration is limited to chewables (e.g. gummies, tablets).

Use(s) or Purpose(s):

- (Used in Herbal Medicine to) help(s) relieve inflammatory conditions of the gastrointestinal tract (demulcent) (Pizzorno and Murray 2006; Blumenthal et al. 2000; Bradley 1992).
- (Used in Herbal Medicine to) help(s) relieve abdominal pain and burning sensation in the stomach (demulcent) (Pizzorno and Murray 2006; Blumenthal et al. 2000; Bradley 1992).

Dose(s):

Table 1: Dose information for oral Deglycyrrhizinated licorice (chewable dosage forms only)

Subpopulation		Deglycyrrhizinated licorice (mg/day)	
		Minimum	Maximum
Children[1]	3-4 y	190	760
Children[1]	5-9 y	285	1 140
Children and Adolescents[1]	10-14 y	570	2 280
Adolescents and adults[1,2]	≥ 15 y	1 140	4 560

[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 doses are supported by Pizzorno and Murray 2006

Direction(s) for use:

- Chew between meals or 20 minutes before meals (Pizzorno and Murray 2006).
- Take in 3 divided doses (Pizzorno and Murray 2006).

See Appendix 1 for examples of 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(s) of use:

No statement required.

Risk information:

Caution(s) and warning(s):

Consult a health care practitioner if symptoms persist or worsen.

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.

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 finished product must not contain more than 3% of the original quantity of glycyrrhizic acid found in the source material (Bradley 1992).
- The medicinal ingredient may comply with the specifications outlined in the Deglycyrrhizinised Liquorice Extract of the British Pharmacopoeia (BP 1988).

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

- 380 mg DGL chewable tablets (1-4) between meals or 20 minutes before meals, 3 times per day (Murray and Pizzorno 2006).