



NATURAL HEALTH PRODUCT

DEGLYCYRRHIZINATED LICORICE (DGL) – BUCCAL

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.

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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:

Buccal

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 2 years:** The acceptable dosage forms are limited to emulsion/suspension and solution/drops (Giacoaia et al. 2008; EMEA/CHMP 2006) and allow for direct contact between the affected tissue and the medicinal ingredient.
- **Children 3-5 years:** The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/drops (Giacoaia et al. 2008; EMEA/CHMP 2006) and allow for direct contact between the affected tissue and the medicinal ingredient.
- **Children 6-12 years, Adolescents 13-17 years, and Adults ≥ 18 years:** Those dosage forms suited for buccal administration which allow for direct contact between the affected tissue and the medicinal ingredient, such as gargles, rinses, and mouthwashes.

Use(s) or Purpose(s):

(Used in Herbal Medicine to) help(s) relieve minor inflammations of mucous membranes of the mouth (aphthous stomatitis/canker sore) (demulcent) (Pizzorno and Murray 2006; Bruneton 1999; Das et al. 1989).

Dose(s):

Table 1: Dose information for buccal Deglycyrrhizinated licorice

Subpopulation		Deglycyrrhizinated licorice (mg/day)	
		Minimum	Maximum
Children ¹	2-4 y	132	760
Children ¹	5-9 y	200	1 140
Children and Adolescents ¹	10-14 y	400	2 280
Adolescents and adults ^{1,2}	≥ 15 y	800	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 and Das et al. 1989.

Direction(s) for use:

Rinse mouth 4 times per day (Das et al. 1989).

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

- ▶ Gargle with 200 mg DGL powder dissolved in 200 ml of warm water, 4 times per day (Das et al. 1989).