Health Canada Santé Canada

NATURAL HEALTH PRODUCT

DEGLYCYRRHIZINATED LICORICE
Buccal

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 October 30, 2018

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)	
		Proper name(s)	Part(s)
Deglycyrrhizinated licorice	▶ Deglycyrrhizinated licorice ▶ DGL	▶ *Glycyrrhiza glabra* ▶ *Glycyrrhiza inflata* ▶ *Glycyrrhiza uralensis*	▶ Root ▶ Root and stolon ▶ Root and rhizome ▶ Root, rhizome and stolon

References: Proper name: NHPID 2018; Common names: Pizzorno and Murray 2006, Blumenthal et al. 2000; Source materials: USDA 2018, USP 32 2009, BP 2008, Ph. Eur. 2008.

Route of administration

Buccal

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms by age group:

Children 2 years: The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations (Giacoia et al. 2008; EMEA/CHMP 2006).
Children 3-5 years: The acceptable dosage forms are limited to emulsion/suspension, powders and solution/liquid preparations (Giacoia et al. 2008; EMEA/CHMP 2006).
Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older: The acceptable dosage forms for this age category and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Note
Dosage forms must be suited for buccal administration which allow for direct contact between the affected tissue and the medicinal ingredient (i.e. liquid preparations, gargles, and mouthwashes.

Use(s) or Purpose(s)

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

Dose(s)

Subpopulation(s)

As specified below.

Quantity(ies)

Method of preparation: Dry extract

Table 2. Dose information for Deglycyrrhizinated licorice extract.

Subpopulation(s)		Deglycyrrhizinated licorice extract (milligram)			
		Minimum/single dose	Maximum/single dose	Frequency	
				Minimum	Maximum
Children[1]	2-4 years	33 mg	190 mg	4	4
	5-9 years	50 mg	285 mg	4	4
	10-11 years	100 mg	570 mg	4	4
Adolescents[1]	12-14 years	100 mg	570 mg	4	4
	15-17 years	200 mg	1140 mg	4	4
Adults[2]	18 years and older	200 mg	1140 mg	4	4

[1] Children and adolescent doses were calculated as a fraction of the adult dose (JC 2018). 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

- For each milligram (1 mg) of DGL extract, mix with 1 milliliter of warm water (Das et al. 1989).
- Rinse and/or gargle, 4 times per day (Das et al. 1989).

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

Consult a health care practitioner/health care provider/health care professional/doctor/physician 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.

Storage conditions

No statement required.

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).

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