

#### NATURAL HEALTH PRODUCT

# DEGLYCYRRHIZINATED LICORICE Oral

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	<ul><li>Deglycyrrhizinated</li></ul>	► Glycyrrhiza glabra	▶ Root	
licorice	licorice	► Glycyrrhiza inflata	Root and stolon	
	▶ DGL	▶ Glycyrrhiza uralensis	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

Oral

## **Dosage form(s)**

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

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are limited to chewables.



### Use(s) or Purpose(s)

- ▶ (Used in Herbal Medicine to) help(s) relieve minor inflammations 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).

The following combined use(s) or purpose(s) is/are also acceptable:

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

### Dose(s)

## **Subpopulation(s)**

As listed below.

# **Quantity(ies)**

Method of preparation: Dry extract

Table 2. Dose information for Deglycyrrhizinated licorice extract (chewable dosage forms only)

Subpopulation(s)		Deglycyrrhizinated licorice extract (milligram)				
		Minimum/single dose Maximum/single dose	Frequency			
			dose	Minimum	Maximum	
Children <sup>1</sup>	3-4 years	63 mg	253 mg	3	3	
	5-9 years	95 mg	380 mg	3	3	
	10-11 years	190 mg	760 mg	3	3	
Adolescents <sup>1</sup>	12-14 years	190 mg	760 mg	3	3	
	15-17 years	380 mg	1520 mg	3	3	
Adults <sup>2</sup>	18 years and older	380 mg	1520 mg	3	3	

<sup>&</sup>lt;sup>1</sup> 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.

### Direction(s) for use

Chew between meals or 20 minutes before meals, 3 times a day (Pizzorno and Murray 2006).



<sup>&</sup>lt;sup>2</sup> Adult doses are supported by Pizzorno and Murray 2006



### **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).

### References cited

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