

#### 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 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 on the label.

Date

January 31, 2025

# Proper name(s), Common name(s), Source information

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

Proper name(s)	Common name(s)	Source information		
		Source material(s)	Part(s)	
Deglycyrrhizinated licorice	licorice	<ul><li>Glycyrrhiza glabra</li><li>Glycyrrhiza inflata</li><li>Glycyrrhiza uralensis</li></ul>	<ul> <li>Root</li> <li>Root and stolon</li> <li>Root and rhizome</li> <li>Root, rhizome and stolon</li> </ul>	

References: Proper name: NHPID 2025; Common names: Pizzorno and Murray 2006; Blumenthal et al. 2000; Source information: USDA 2024; USP-NF 2024; PPRC 2020; 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.

In order to ensure efficacy, DGL must be mixed with saliva. Thus, the acceptable dosage forms are: Bar, chewable; Chewable gel<sup>1</sup>; Granule<sup>2</sup>; Tablet, chewable.

<sup>1</sup>Gummy

<sup>&</sup>lt;sup>2</sup>To be chewed



# Use(s) or Purpose(s)

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

**Note:** The above uses can be combined on the product label (e.g., Used in Herbal Medicine to help relieve minor inflammations of the gastrointestinal tract and abdominal pain and burning sensation in the stomach).

## Dose(s)

## Subpopulation(s)

As listed below.

# Quantity(ies)

**Method of preparation:** Prepared and dry

Table 2. Dose information (milligrams) and frequencies for Deglycyrrhizinated licorice extract

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

<sup>&</sup>lt;sup>1</sup>Children and adolescent doses were calculated as a fraction of the adult dose (JC 2023). The use of licorice in children and adolescents is supported by the following references: McIntyre 2005; Schilcher 1997; Bove 1996. <sup>2</sup>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).





## **Duration(s)** of use

No statement required.

#### **Risk information**

## Caution(s) and warning(s)

Ask 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**

Must be established in accordance with the requirements described in the *Natural Health Products Regulations*.

# **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).





#### **EXAMPLE OF PRODUCT FACTS:**

Consult the Guidance Document, <u>Labelling of Natural Health Products</u> for more details.

## **Product Facts**

Medicinal ingredient in each chewable tablet

Deglycyrrhizinated licorice (*Glycyrrhiza glabra* – root)

XX mg

#### Uses

- Used in Herbal Medicine to help relieve minor inflammations of the gastrointestinal tract.
- Used in Herbal Medicine to help relieve abdominal pain and burning sensation in the stomach.

## Warnings

# If applicable<sup>1</sup>:

Allergens: food allergen, gluten (gluten source), sulphites

**Contains aspartame** 

Ask a health care practitioner if symptoms persist or worsen.

#### Directions

Children 3 to 11 years: • Take X chewable tablet(s), 3 times per day • Chew between meals or 20 minutes before meals.

Adults, adolescents 12 years and older: • Take Y chewable tablet(s), 3 times per day • Chew between meals or 20 minutes before meals.

#### Other information

(Add storage information).

## Non-medicinal ingredients

List all NMIs.

# Questions? (Call) 1-XXX-XXX-XXXX

#### References cited

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<sup>&</sup>lt;sup>1</sup>This section can be removed from the table if the product contains no allergen or aspartame.



[Accessed 2024 February 21] Available from: http://laws.justice.gc.ca/eng/regulations/c.r.c.,\_c.\_870/page-95.html#h-156

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