

NATURAL HEALTH PRODUCT

LICORICE – *GLYCYRRHIZA GLABRA*

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

December 18, 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)	Preparation(s)
<i>Glycyrrhiza glabra</i>	<ul style="list-style-type: none"> ▶ Guang guo gan cao ▶ Licorice ▶ Liquorice 	<i>Glycyrrhiza glabra</i>	<ul style="list-style-type: none"> ▶ Root ▶ Root and stolon 	Dried

References: Proper name: USDA 2018; Common names: McGuffin et al. 2000; Source materials: Mills and Bone 2005, ESCOP 2003, Blumenthal et al. 2000, Bradley 1992.

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 by age group:

Children 4-5 years: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/liquid preparations (Giaccoia 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.

Use(s) or Purpose(s)

- ▶ Traditionally used in Herbal Medicine as an expectorant to help relieve chest complaints, such as mucous buildup (catarrhs), coughs and bronchitis (Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992; Felter and Lloyd 1983, Grieve 1971).
- ▶ Used in Herbal Medicine to help relieve inflammatory conditions of the gastrointestinal tract, such as gastritis in adults (ESCOP 2003; Hoffmann 2003; Bradley 1992).

Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

Dose(s)

Subpopulation(s)

As specified below.

Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Table 2. Dose information for licorice root/root and stolon per day

Subpopulation(s)		Dried root/root and stolon (gram/day)	
		Minimum	Maximum
Children ¹	4 years	0.1	2.5
	5-9 years	0.15	3.75
	10-11 years	0.3	7.5
Adolescents ¹	12-14 years	0.3	7.5
	15-17 years	0.6	15
Adults ^{1,2,3}	18 years and older	0.6	15

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 dose supported by the following references: Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992.

³ Includes breastfeeding women.

Methods of preparation: Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Table 3. Dose information for glycyrrhizin per day

Subpopulation(s)		Glycyrrhizin (milligram/day)	
		Minimum	Maximum
Children ¹	4 years	10	100
	5-9 years	15	150
	10-11 years	30	300
Adolescents ¹	12-14 years	30	300
	15-17 years	60	600
Adults ^{1,2,3}	18 years and older	60	600

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 dose supported by the following references: ESCOP 2003.

³ Includes breastfeeding women.

Direction(s) for use

No statement required.

Duration(s) of use

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 4-6 weeks (ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992).

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.
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant or have a liver disorder (Brinker 2010; ESCOP 2003; Hoffmann 2003; McGuffin et al. 1997; Bradley 1992).

Contraindication(s)

- ▶ Do not use this product if you have hypokalemia, high blood pressure, or a kidney or cardiovascular disorder (Brinker 2010; ESCOP 2003; Bradley 1992).



- ▶ Do not use this product if you are taking thiazide diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance (Brinker 2010; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; McGuffin et al. 1997).

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.

References cited

Blumenthal M, Goldberg A, Brinkmann J, editors. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications; 2000.

Bove M. An Encyclopedia of Natural Healing for Children and Infants. New Canaan (CT): Keats Publishing, Incorporated; 1996.

Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 1. Bournemouth (UK): British Herbal Medicine Association; 1992.

Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010.

EMA/CHMP 2006: European Medicines Agency: Pre-authorization Evaluation of Medicines for Human Use. Committee for Medicinal Products for Human Use. Reflection Paper: Formulations of choice for the paediatric population. Adopted September 2006.

EMA/CHMP/PEG/194810/2005. [Accessed on 2018 September 28]. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003782.pdf

ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. Exeter (UK): European Scientific Cooperative on Phytotherapy and Thieme; 2003.

Felter HW, Lloyd JU. King's American Dispensatory, Volume 2, 18th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original].

Giacoia GP, Taylor-Zapata P, Mattison D. Eunice Kennedy Shriver National Institute of Child Health and Human Development Pediatric Formulation Initiative: selected reports from working groups. *Clinical Therapeutics* 2008; 30(11):2097-2101.

Grieve M. A Modern Herbal, Volume 2. New York (NY): Dover Publications; 1971 [Reprint of 1931 Harcourt, Brace & Company publication].

Hoffmann D. Medical Herbalism. Rochester (VT): Healing Arts Press; 2003.

JC 2018: Justice Canada. 2018. *Food and Drug Regulations*. (C.01.021) [online]. Ottawa (ON): Justice Canada. [Accessed 2018 September 28] Available from: http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-95.html#docCont

McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. *Herbs of Commerce*, 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000.

McGuffin M, Hobbs C, Upton R, Goldberg A, editors. *American Herbal Products Association's Botanical Safety Handbook*. Boca Raton (FL): CRC Press; 1997.

McIntyre A. *Herbal Treatment of Children - Western and Ayurvedic Perspectives*. Toronto (ON): Elsevier Limited; 2005.

Mills S, Bone K. *The Essential Guide to Herbal Safety*. St. Louis (MO): Elsevier Churchill Livingstone; 2005.

Schilcher H. *Phytotherapy in Paediatrics: Handbook for Physicians and Pharmacists*. Stuttgart (D): Medpharm Scientific Publishers; 1997.

USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). *Glycyrrhiza glabra* L. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2018 September 28]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxonomydetail.aspx?id=17820>



References reviewed

Brinker F. Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications; 2001.