Licorice

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LICORICE Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 373 KB) 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. Restrictions when this monograph is combined with other monographs (Class II and III applications): Licorice and stimulant laxatives: As licorice may potentiate potassium depletion of laxatives, the combination of licorice with stimulant laxatives is only permitted if: licorice is deglycyrrhizinated (consult the Deglycyrrhizinated licorice monograph), or; for non deglycyrrhizinated preparations, if licorice is present in sufficiently small amount to provide no more than 16 mg glycyrrhizin/glycyrrhizic acid per day. In this case, this monograph may be used for safety only as the effective dose as per Tables 2 and 3 below may not be met. (Gardner and McGuffin 2013; Brinker 2010; Isbrucker and Burdock 2006; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Van Gelderen et al. 2000). Licorice and diuretics: Not more than 1 ingredient with diuretic properties may be combined with the medicinal ingredient licorice due to potential of electrolyte imbalance at Class II. Combinations with more diuretics may be submitted as a Class III application. Date November 29, 2024 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) Preparation(s) Glycyrrhiza glabra Guang guo gan cao Licorice Liquorice Glycyrrhiza glabra Root Root and rhizome Root and stolon Root and rhizome and stolon Dry Glycyrrhiza inflata Chinese licorice Zhang guo gan cao Glycyrrhiza inflata Root Root and rhizome Dry Glycyrrhiza uralensis Chinese licorice Gan cao Glycyrrhiza uralensis Root Root and rhizome Dry References: Proper names: USDA 2024; Common names: Gardner and McGuffin 2013; Bensky et al. 2004; Source information: Mills and Bone 2005, Bensky et al. 2004; 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 (Giacoia et al. 2008; EMA/CHMP 2006). Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older: The acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. Use(s) or Purpose(s) All subpopulations (Traditionally) used in Herbal Medicine as an expectorant to help relieve (mucous buildup (catarrhs) and) cough associated with upper respiratory tract infections/cold (EMA 2012; Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992; Felter and Lloyd 1983, Grieve 1971). Adults only Used in Herbal Medicine to help relieve inflammatory conditions of the gastrointestinal tract, such as gastritis in adults (ESCOP 2003; Hoffmann 2003; Bradley 1992). Notes For multi-ingredient products: To prevent the product from being represented as a "traditional medicine", any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Licorice is used in Herbal Medicine as an expectorant to help relieve cough associated with upper respiratory tract infections). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required. Dose(s) Subpopulation(s) As specified below. Quantity(ies) Methods of preparation: Dry, Powdered, Non-Standardized Extracts (Dry extract*, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) Table 2. Dose information for licorice dried root/root and rhizome/root and stolon/root and rhizome and stolon per day Subpopulations Dried root/rhizome/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 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. *Note: Solvents allowed for the method of preparation “Non-standardized extracts (Dry extract)” as part of this monograph are ethanol and/or water only. Methods of preparation: Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) Table 3. Dose information for glycyrrhizin per day Subpopulations 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 18 years and older 60 600 1 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. 2 Adult dose supported by the following references: ESCOP 2003. Direction(s) for use No statement required. Duration(s) of Use Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 4 weeks (EMA 2012). Risk Information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding (Gardner and McGuffin 2013). Cough relief Ask a health care practitioner/health care provider/health care professional/doctor/physician if cough worsens or persists (for) more than 1 week (EMA 2012). Gastritis relief Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) All products Do not use if you are pregnant (EMA 2012). Do not use if you have hypokalemia, high blood pressure, or a kidney, liver or cardiovascular disorder (EMA 2012; Brinker 2010; ESCOP 2003; Bradley 1992). Do not use if you are taking heart medications, corticosteroids, stimulant laxatives, or other health products that may contribute electrolyte imbalance (Brinker 2010; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000). 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. Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Bensky D, Clavey, Stöger E, Gamble A. Chinese Herbal Medicine: Materia Medica. 3rd edition. Seattle (WA): Eastland Press, Incorporated; 2004. 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, 4 th edition. Sandy (OR): Eclectic Medical Publications; 2010. EMA 2012. European Medicines Agency. Community Herbal Monograph on Glycyrrhiza glabra L. and/or Glycyrrhiza inflata Bat. and/or Glycyrrhiza uralensis Fisch., radix. London (UK): EMA Committee on Herbal Medicinal Products (HMPC), 22 May 2012. [Accessed 2024 January 6]. Available from: https://www.ema.europa.eu/en/documents/herbal-monograph/final-community-herbal-monograph-glycyrrhiza-glabra-l-andor-glycyrrhiza-inflata-bat-andor-glycyrrhiza-uralensis-fisch-radix-first-version_en.pdf 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. [Accessed on 2024 January 6]. Available from: https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-formulations-choice-paediatric-population_en.pdf ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2 nd edition. Exeter (UK): European Scientific Cooperative on Phytotherapy and Thieme; 2003. Felter HW, Lloyd JU. King's American Dispensatory, Volume 2, 18 th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original]. Gardner Z, McGuffin M. editors. 2013. American Herbal Products Association's Botanical Safety Handbook, 2nd edition. Boca Raton (FL): CRC Press. 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. Isbrucker RA, Burdock GA. Risk and safety assessment on the consumption of Licorice root (Glycyrrhiza sp.), its extract and powder as a food ingredient, with emphasis on the pharmacology and toxicology of glycyrrhizin. Regulatory Toxicology and Pharmacology 2006;46(3):167-192. JC 2023: Justice Canada. Food and Drug Regulations . (C.01.021). Ottawa (ON): Justice Canada. [Accessed 2024 January 6] Available from https://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html 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 2024: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2024 January 6]. Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch Van Gelderen CE, Bijlsma JA, Van Dokkum W, Savelkoul. Glycyrrhizic acid: the assessment of a no effect level. Human & Experimental Toxicology 2000; 19(8):434-439. Report a problem on this page Date modified: 2019-03-01

DOSAGE FORM(S)

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 (Giacoia et al. 2008; EMA/CHMP 2006). Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older:The acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

RISK INFORMATION

Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding (Gardner and McGuffin 2013). Cough relief Ask a health care practitioner/health care provider/health care professional/doctor/physician if cough worsens or persists (for) more than 1 week (EMA 2012). Gastritis relief Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Contraindication(s) All products Do not use if you are pregnant (EMA 2012).Do not use if you have hypokalemia, high blood pressure, or a kidney, liver or cardiovascular disorder (EMA 2012; Brinker 2010; ESCOP 2003; Bradley 1992).Do not use if you are taking heart medications, corticosteroids, stimulant laxatives, or other health products that may contribute electrolyte imbalance (Brinker 2010; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000). 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 CONDITION(S)

Must be established in accordance with the requirements described in theNatural 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.

r name(s)	Common name(s)	Source information	
material(s)	Part(s)	Preparation(s)	
hiza glabra	Guang guo gan caoLicoriceLiquorice	Glycyrrhiza glabra	RootRoot and rhizomeRoot and stolonR
hiza inflata	Chinese licoriceZhang guo gan cao	Glycyrrhiza inflata	RootRoot and rhizome
hiza uralensis	Chinese licoriceGan cao	Glycyrrhiza uralensis	RootRoot and rhizome

Subpopulations	Dried root/rhizome/stolon (gram/day)		
Minimum	Maximum		
Children1	4 years	0.1	2.5
5-9 years	0.15	3.75	
10-11 years	0.3	7.5	
Adolescents1	12-14 years	0.3	7.5
15-17 years	0.6	15	
Adults1,2	18 years and older	0.6	15

Subpopulations	Glycyrrhizin (milligram/day)		
Minimum	Maximum		
Children1	4 years	10	100
5-9 years	15	150	
10-11 years	30	300	
Adolescents1	12-14 years	30	300
15-17 years	60	600	
Adults1,2	18 years and older	60	600