Deglycyrrhizinated licorice - Buccal

DEGLYCYRRHIZINATED LICORICE Buccal 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 - 77 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 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 Table 2 Footnotes Table 2 Footnote 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. Return to Table 2 footnote 1 referrer Table 2 Footnote 2 Adult doses are supported by Pizzorno and Murray 2006 and Das et al. 1989. Return to Table 2 footnote 2 referrer 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). References Cited Blumenthal M, Goldberg A, Brinkmann J, editors. 2000. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications. Bove M. 1996. An Encyclopedia of Natural Healing for Children and Infants. New Canaan (CT): Keats Publishing Incorporated. BP 2008: British Pharmacopoeia Commission. 2007. British Pharmacopoeia 2008, Volume 2. London (GB): The Stationary Office. Bruneton J. 1999.

Pharmacognosy, Phytochemistry, Medicinal Plants, 2 nd edition. Paris (FR) Lavoisier Publishing, Das SK, Das V, Gulati AK, Singh VP. 1989. Deglycyrrhizinated liquorice in aphthous ulcers. Journal of Association of Physicians of India 37(10):647. EMEA/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 2018 June 1]. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003782.pdf
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. JC 2018: Justice Canada. Food and Drug Regulations . (C.01.021). Ottawa (ON): Justice Canada; 2018. [Accessed 2018 August 13] Available from: http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-95.html#docCont McIntyre A. 2005. Herbal Treatment of Children - Western and Ayurvedic Perspectives. Toronto (ON): Elsevier Limited. Ph. Eur. 2008: European Pharmacopoeia Commission. 2008. European Pharmacopoeia, 6 th edition, Volume 2. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM). Pizzorno Jr JEP, Murray MT. 2006. Textbook of Natural Medicine, 3 rd edition, Volume 1. StLouis (MI): Churchill Livingstone Elsevier. PPRC 2005: Pharmacopoeia of the People's Republic of China, Volume 1, English edition 2005. Beijing (CN): The State Pharmacopoeia Commission of the People's Republic of China. Schilcher H. 1997. Phytotherapy in Paediatrics: Handbook for Physicians and Pharmacists. Stuttgart (DE): Medpharm Scientific Publishers. USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2018 August 13]. Available at: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl USP 32 2009: United States Pharmacopeial Convention. 2009. United States Pharmacopeia and the National Formulary (USP 32 - NF 27). Rockville (MD): The United States Pharmacopeial Convention. References Reviewed Agarwal A, Gupta D, Yadav G, Goyal P, Singh PK, Singh U. 2009. An evaluation of the efficacy of licorice gargle for attenuating postoperative sore throat: a prospective, randomized, singleblind study. Ambulatory Anesthesiology 109(1):77-81. Anonymous. 1971. Treatment of duodenal ulcer with glycyrrhizinic-acid-reduced liquorice. British Medical Journal 3:501-503. Bardhan KD, Cumberland DC, Dixon RA, Holdsworth CD. 1978. Clinical trial of deglycyrrhizinised liquorice in gastric ulcer. Gut 19:779-782. Blumenthal M. 2003. The ABC Clinical Guide to Herbs. New York (NY): Thieme. Brinker F. 2010. Online Updates and Additions to Herb Contraindications and Drug Interactions, 3 rd edition. Sandy (OR): Eclectic Medical Publications; 2007. [Accessed 2010 April 10]. Available from: http://www.eclecticherb.com/emp/updatesHCDI.html Brinker F. 2001. Herb Contraindications and Drug Interactions, 3 rd edition. Sandy (OR): Eclectic Medical Publications. Brogden RN, Speight TM, Avery GS. 1974. Deglycyrrhizinised liquorice: a report of its pharmacological properties and therapeutic efficacy in peptic ulcer. Drugs 8(5):330-339. D'Imperio N, Piccari GG, Sarti F, Soffritti M, Spongano P, Benvenuti C, Dal Monte PR. 1978. Double-blind trial in duodenal and gastric ulcers: Cimetidine and deglycyrrhizinized liquorice. Acta Gastro-Enterologica Belgica 41:427-434. Doll R, Langman MJS, Shawdon HH. 1968. Treatment of gastric ulcer with carbenoxolone: antagonistic effect of spironolactone. Gut 1969(9):42-45. Engqvist A, von Feilitzen F, Pyk E, Reichard H. 1973. Double-blind trial of deglycyrrhizinated liquorice in gastric ulcer. Gut 14(9):711-715. Feldman H, Gilat T. 1971. A trial of deglycyrrhizinated liquorice in the treatment of duodenal ulcer. Gut 12(6):449-451. Goldman L, Ausiello D, editors. 2004. CECIL Textbook of Medicine, 22 nd edition, Volume 1. Philadelphia (PA), Elsevier Inc. Kassir ZA. 1985. Endoscopic controlled trial of four drug regimens in the treatment of chronic duodenal ulceration. Irish Medical Journal 78:153-156. Larkworthy W, Holgate PF. 1975. Deglycyrrhizinized liquorice in the treatment of chronic duodenal ulcer. A retrospective endoscopic survey of 32 patients. Practitioner 215(1290):787792. Martin MD, Sherman J, van der Ven P, Burgess J. 2008. A controlled trial of a dissolving oral patch concerning glycyrrhiza (licorice) herbal extract for the treatment of aphthous ulcers. General Denistry 56(2):206-210: quiz 211-2, 224. Mills S, Bone K. 2005. The Essential Guide to Herbal Safety. St. Louis (MO): Churchill Livingstone. Morgan AG, Pacsoo C, McAdam WAF. 1985. Maintenance therapy: a two year comparison between Caved-S and cimetidine treatment in the prevention of symptomatic gastric ulcer recurrence. Gut 26:599-602. Natural Standard 2009. Licorice (Glycyrrhiza glabra L.) and DGL (deglycyrrhizinated licorice). [Accessed 2009 August 2]. Available from: http://www.nlm.nih.gov/medlineplus/print/druginfo/natural/patient-licorice.html PasseportSanté.net. 2006. Réglisse. [Online]. [Accessed 2009 November 24]. Available at: http://www.passeportsante.net/fr/Solutions/PlantesSupplements/Fiche.aspx?doc=reglisse Räikkönen K, Pesonen A-K, Heinonen K, Lahti J, Komsi N, Eriksson JG, Seckl JR, Järvenpää A-L, Strandberg TE. 2009. Maternal licorice consumption and detrimental cognitive and psychiatric outcomes in children. American Journal of Epidemiology 170(9):1137-1146. Strandberg TE, Andersson S, Järvenpää AL, McKeigue PM. 2002. Preterm birth and licorice consumption during pregnancy. American Journal of Epidemiology 156(9):803-805. Sweetman S, editor. 2009. Martindale: The Complete Drug Reference. London (GB): Pharmaceutical Press.

[Accessed 2009 August 6]. Available from: http://www.medicinescomplete.com/mc/martindale/current/2021-1.htm Tewari SN, Trembalowicz FC. 1968. Some experience with deglycyrrhizinated liquorice in the treatment of gastric and duodenal ulcers with special reference to its spasmolytic effect. Gut 9:48-51. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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.

DOSAGE FORM(S)

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.

DOSE(S)

Return to Table 2 footnote1referrer

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.

STORAGE CONDITION(S)

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

Route of Administration Buccal

me(s)	Common name(s)	Source material(s)	
e(s)	Part(s)		
zinated licorice	Deglycyrrhizinated licoriceDGL	Glycyrrhiza glabraGlycyrrhiza inflataGlycyrrhiza uralensis	Root and stolonRoot and

Subpopulation(s)	Deglycyrrhizinated licorice extract (milligram)			
Minimum/single dose	Maximum/single dose	Frequency		
Minimum	Maximum			
Children1	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
Adolescents1	12-14 years	100 mg	570 mg	4 4
15-17 years	200 mg	1140 mg	4	4
Adults2	18 years and older	200 mg	1140 mg	4 4
Table 2 FootnotesTable 2 Footnote 1Children and adolescent doses were calculated as a fraction of the adult dose (JC 2018). The use o				