

Gentian

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Gentiane - Gentiana Lutea (PDF Version - 49 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. Date January 10, 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) Preparation(s) Gentiana lutea Bitterwort Gentian Gentian-root Yellow gentian Gentiana lutea Root Dry References: Proper name: USDA 2024; Common names: Gardner and McGuffin 2013, Wiersema and León 1999; Source information: Blumenthal et al. 2000. 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compndial applications. Use(s) or Purpose(s) (Traditionally) used in Herbal Medicine to help relieve digestive disturbances (such as dyspepsia) (Mills and Bone 2005; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992; Williamson et al. 1988; Felter and Lloyd 1983; Grieve 1971). (Traditionally) used in Herbal Medicine (as a digestive tonic and bitter) to help stimulate appetite and (as a stomachic) to aid digestion (Mills and Bone 2005; Wichtl 2004; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992; Williamson et al. 1988; Felter and Lloyd 1983; Grieve 1971). (Traditionally) used in Herbal Medicine (as an anti-emetic) to help prevent nausea (Bradley 1992; Williamson et al. 1988). Used in Herbal Medicine (as a cholagogue) to help increase bile flow (Wichtl 2004; Hoffmann 2003; Blumenthal et al. 2000). Notes The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g., Traditionally used in Herbal Medicine to help prevent nausea and to help relieve digestive disturbances). 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., Gentian is traditionally used in Herbal Medicine to help prevent nausea). 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) Adults 18 years and older Quantity(ies) Methods of preparation: Dry, Powdered, Non-Standardized Extracts (Dry extract*, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) 0.1 - 6 grams of dried root, per day (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. Direction(s) for use (optional) Take 15 - 60 minutes before meals (ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000; Bradley 1992). 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. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding. Contraindication(s) Do not use if you are pregnant (Hoffmann 2003; Morimoto et al. 1983). Do not use if you have stomach or duodenal acute inflammation or ulcer (Brinker 2010; ESCOP 2003; Bradley 1992). Known adverse reaction(s) When using this product you may experience headaches (ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000). 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 Blumenthal M, Goldberg A, Brinkmann J, editors. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications; 2000. 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; 2001. 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. American Herbal Products Association's Botanical Safety Handbook. Second Edition. Boca Ration (FL): Taylor and Francis Group; 2013. Grieve M. A Modern Herbal, Volume 1. New York (NY): Dover Publications; 1971 [Reprint of 1931 Harcourt, Brace & Company publication]. Hoffmann D. Medical Herbalism. Rochester (VT): Healing Arts Press; 2003. Mills S, Bone K. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone; 2005. Morimoto I, Nozaka T, Watanabe F, Ishino M, Hirose Y, Okitsu T. Mutagenic activities of gentisin and isogentisin from Gentianae radix (Gentianaceae). Mutation Research 1983;116(2):103-117. USDA 2024: United States Department of Agriculture, Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2024 November 14]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> Wichtl M, editor. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, 3 rd edition. Stuttgart (D): Medpharm GmbH Scientific Publishers; 2004. Wiersema J, León B. World Economic Plants: A Standard Reference. Boca Raton (FL): CRC Press LLC; 1999. Williamson EM, Evans FJ, Wren RC. Potter's New Cyclopaedia of Botanical Drugs and Preparations. Saffron Walden (UK): C.W. Daniel Company Limited; 1988. References Reviewed Barnes J, Anderson LA, Philipson JD. Herbal Medicines, 3 rd edition. London (UK): The Pharmaceutical Press; 2007. BHP 1983: British Herbal Pharmacopoeia. Cowling (UK): British Herbal Medical Association; 1983. Report a problem on this page Date modified: 2019-03-01

DOSAGE FORM(S)

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) Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are breastfeeding. Contraindication(s) Do not use if you are pregnant (Hoffmann 2003; Morimoto et al. 1983). Do not use if you have stomach or duodenal acute inflammation or ulcer (Brinker 2010; ESCOP 2003; Bradley 1992). Known adverse reaction(s) When using this product you may experience headaches (ESCOP 2003; Hoffmann 2003; Blumenthal et al. 2000).

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 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.

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Gentiana lutea	BitterwortGentianGentian-rootYellow gentian	Gentiana lutea	Root	Dry