

Goldenseal - Oral

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GOLDENSEAL - HYDRASTIS CANADENSIS - Oral 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 - 79 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 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) Hydrastis canadensis Goldenseal Orangeroot Yellow-puccoon Yellow root Hydrastis canadensis Root and rhizome Dry References: Proper name: USDA 2024; Common names: Gardner and McGuffin 2013, Wiersema and León 1999; Source information: Blumenthal 2003, Hoffmann 2003, 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 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) (Traditionally) used in Herbal Medicine to help relieve infectious and inflammatory conditions of the digestive tract such as gastritis (Mills and Bone 2005; Boon and Smith 2004; Bradley 1992; Wren 1907). (Traditionally) used in Herbal Medicine as a bitter (and stomachic) to aid digestion (and to increase appetite) (Mills and Bone 2005; Boon and Smith 2004; Hoffmann 2003; Moerman 1998; Ellingwood 1983; Wren 1907). (Traditionally) used in Herbal Medicine to help treat/relieve digestive troubles/(such as) upset stomach/indigestion/dyspepsia (Mills and Bone 2005; Boon and Smith 2004; Moerman 1998; Bradley 1992; Ellingwood 1983; Grieve 1971). (Traditionally) used in Herbal Medicine as a mild laxative (Hoffmann 2003; Grieve 1971; Wren 1907). 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 relieve infectious and inflammatory conditions of the digestive tract such as gastritis and relieve digestive troubles). 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., Goldenseal is traditionally used in Herbal Medicine as a bitter to aid digestion). 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) 0.6 - 3 grams of dried root and rhizome, per day (Mills and Bone 2005; Boon and Smith 2004; Hoffmann 2003; 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 Take a few hours before or after taking other medications or health products (Gardner and McGuffin 2013). 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 before use if you have a kidney or blood pressure disorder (Brinker 2010; Hoffmann 2003). Contraindication(s) Do not use if you are pregnant or breastfeeding (Gardner and McGuffin 2013; Brinker 2010; Barnes and al. 2007; Mills and Bone 2005; Boon and Smith 2004; Hoffmann 2003; Bradley 1992). 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. *Hydrastis canadensis* is listed in Schedule 1 of the Species at Risk Act (SARA) as a “special concern” species and is afforded protection under this Act. The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) regulates international trade in underground parts (that is, roots, rhizomes) as well as whole plants. CITES export permits are required for whole plants as well as underground parts in whole, parts, or powdered. Finished products are not regulated (for example, extracts or capsules). Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Barnes J, Anderson LA, Philipson JD. 2007. Herbal Medicines, 3rd edition. London (GB): The Pharmaceutical Press. Blumenthal M. 2003. ABC Clinical Guide to Herbs. New York (NY): Theime. Boon H, Smith MJ. 2004. The Complete Natural Medicine Guide to the 50 Most Common Medicinal Herbs, 2nd edition. Toronto (ON): Robert Rose Inc. Bradley PR, editor. 1992. British Herbal Compendium, Volume 1. Bournemouth (GB): British Herbal Medicine Association. Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010. Ellingwood F. 1983. American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications [Reprint of 1919 original]. Gardner Z, McGuffin M, editors. American Herbal Products Association's Botanical Safety Handbook. Second Edition. Boca Raton (FL): Taylor and Francis Group; 2013. Grieve M. 1971. A Modern Herbal, Volume 1. New York (NY): Dover Publications [Reprint of 1931 Harcourt, Brace & Company publication]. Hoffmann D. 2003. Medical Herbalism. Rochester (VT): Healing Arts Press. Mills S, Bone K. 2005. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone. Moerman DE. 1998. Native American Ethnobotany. Portland (OR): Timber Press. 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 March 9]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> Wiersema J, León B. 1999. World Economic Plants: A Standard Reference. Boca Raton (FL): CRC Press LLC. Wren RC. 1907. Potter's Cyclopedia of Botanical Drugs and Preparations. London (GB): Potter and Clark. References Reviewed Barnes J, Anderson LA, Philipson JD. 2002. Herbal Medicines: A Guide for Healthcare Professionals, 2nd edition. London (GB): The Pharmaceutical Press. Bown D. 1995. The Herb Society of North America Encyclopedia of Modern Herbs & Their Uses. New York (NY): Dorling Kindersley Publishing Incorporated. Chevallier A. 1996. The Encyclopaedia of Medicinal Plants. New York (NY): Dorling Kindersley. Duke JA, Bogenschutz-Godwin MJ, DuCellier J, Duke PK. 2002. Handbook of Medicinal Herbs, 2nd edition. Boca Raton (FL): CRC Press. Felter HW, Lloyd JU. 1983. King's American Dispensatory, Volume 2, 18th edition. Sandy (OR): Eclectic Medical Publications [Reprint of 1898 original]. Mills S, Bone K. 2000. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone; 2000. 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 before use if you have a kidney or blood pressure disorder (Brinker 2010; Hoffmann 2003). Contraindication(s) Do not use if you are pregnant or breastfeeding (Gardner and McGuffin 2013; Brinker 2010; Barnes and al. 2007; Mills and Bone 2005; Boon and Smith 2004; Hoffmann 2003; Bradley 1992). 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.

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. *Hydrastis canadensis* listed in Schedule 1 of the Species at Risk Act (SARA) as a “special concern” species and is afforded protection under this Act. The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) regulates international trade in underground parts (that is, roots, rhizomes) as well as whole plants. CITES export permits are required for whole plants as well as underground parts in whole, parts, or powdered. Finished products are not regulated (for example, extracts or capsules). Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details.

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
<i>Hydrastis canadensis</i>	Goldenseal Orangeroot Yellow-puccoon Yellow-root	<i>Hydrastis canadensis</i>	Root and rhizome	Dry