Goldenseal - Buccal

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GOLDENSEAL - HYDRASTIS CANADENSIS - 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 - 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 March 28, 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) 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 Le■n 1999; Source information: Blumenthal 2003; Hoffmann 2003; Bradley 1992. Route of Administration Buccal Dosage Form(s) Acceptable dosage forms when used according to the requirements indicated in this monograph: Gargle; Loose; Mouthwash; Powder (Bradley 1992; Ellingwood 1983). Use(s) or Purpose(s) (Traditionally) used in Herbal Medicine to help relieve minor mucous membrane inflammations of the mouth and throat (Mills and Bone 2000; Bradley 1992; Ellingwood 1983; Grieve 1971). 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., Goldenseal is traditionally used in Herbal Medicine to help relieve minor mucous membrane inflammations of the mouth and throat). 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) Note: On the PLA form, quantities can be expressed as percentage weight by weight (% w/w), percentage weight by volume (% w/v) or percentage volume by volume (% v/v), depending on the product formulation. On the product label, quantities can also be expressed in other equivalent concentration units (e.g., mg/mL). Loose/Powder dosage forms Methods of preparation: Dry, Powdered 100% dried root and rhizome (Mills and Bone 2005; Boon and Smith 2004; Bradley 1992). Note: Powdered and dried root and rhizome must be prepared as an infusion by the consumer prior to use (see direction for use) and must provide an equivalent of 20 to 70 milligrams dried root and rhizome per 1 milliliter of finished product. Gargle/Mouthwash dosage forms Methods of preparation: Non-Standardized Aqueous Liquid Extracts (Decoction, Decoction concentrate, Infusion, Infusion concentrate) 4 - 100% dried root and rhizome extract preparation in the finished product (Mills and Bone 2005; Boon and Smith 2004; Hoffmann 2003; Bradley 1992). Note: The extract ratio must be between 1:2 to 1:50. The formulation must be prepared in a way which is equivalent to a quantity of 20 to 70 milligrams crude dried root and rhizome per 1 milliliter of finished product. For example, for an infusion prepared with a 1:10 w/v ratio, the concentration of infusion in the finished product must be 20 to 70% (20 - 70 mg crude dried root and rhizome * 10 w/v (dilution) = 0.2 - 0.7 mL liquid extract in 1 mL finished product = 20 - 70% v/v extract preparation in the finished product). Methods of preparation: Non-Standardized Ethanolic Liquid Extracts (Fluid extract, Tincture) 2 - 100% dried root and rhizome extract preparation in the finished product (Mills and Bone 2005; Boon and Smith 2004; Bradley 1992). Note: The extract ratio must be between 1:1 (fluid extract) to 1:15. The formulation must be prepared in a way which is equivalent to a quantity of 20 to 70 milligrams crude dried root and rhizome per 1 milliliter of finished product. For example, for a tincture prepared with a 1:5 w/w ratio, the concentration of tincture in the finished product must be 10 to 35% (20 - 70 mg crude dried root and rhizome * 5 w/w (dilution) = 100 - 350 mg liquid extract in 1 mL finished product = 10 - 35% w/v extract preparation in the finished product). Methods of preparation: Non-Standardized Dry Extracts (Extract dry) 0.5 - 7% dried root and rhizome extract preparation in the finished product (Mills and Bone 2005; Boon and Smith 2004; Bradley 1992). Notes: The extract ratio must be between 2:1 to 14:1. The formulation must be prepared in a way which is equivalent to a

quantity of 20 to 70 milligrams crude dried root and rhizome per 1 milliliter of finished product. For example, for a dry extract prepared with a 2:1 w/w ratio, the concentration of dry extract in the finished product must be 1 to 3.5% (20 - 70 mg crude dried root and rhizome / 2 w/w (concentration) = 10 - 35 mg dry extract in 1 mL finished product = 1 - 3.5% w/v extract preparation in the finished product). The minimum quantity of 0.5% still applies for more concentrated extracts (e.g., a product containing 0.5% of a dry extract contains 5 mg dry extract in 1 gram finished product; 5 mg of a 10:1 w/w dry extract is equivalent to 50 mg crude dried root and rhizome). Solvents allowed for this method of preparation are ethanol and/or water. Direction(s) for use Loose/Powder dosage forms Place [insert volume to be measured by consumer in order to obtain 2.5 to 8.5 grams dried root and rhizome, e.g., 1 teaspoon] of product in ½ cup (125 mL) of boiling water, infuse for 10 minutes and strain. Let cool. Use 1 tablespoon (15 mL) as a mouthwash/gargle, 3 times per day (Keukenmeester et al. 2012; Boon and Smith 2004; Hoffman 2003; Bradley 1992). Do not swallow (Berardi et al. 2002). Gargle/Mouthwash dosage forms Use 1 tablespoon (15 mL) as a mouthwash/gargle, 3 times per day (Keukenmeester et al. 2012; Boon and Smith 2004; Hoffman 2003; Bradley 1992). Do not swallow (Berardi et al. 2002). Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or last (for) more than 7 days. Ask a health care practitioner/health care provider/health care professional/ doctor/physician 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. Herbal Medicines, 3 rd edition. London (GB): The Pharmaceutical Press; 2007. Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self- Care, 13th edition. Washington (DC): American Pharmaceutical Association; 2002. Blumenthal M. ABC Clinical Guide to Herbs. New York (NY): Theime; 2003. Boon H, Smith MJ. The Complete Natural Medicine Guide to the 50 Most Common Medicinal Herbs, 2 nd edition. Toronto (ON): Robert Rose Inc; 2004. Bradley PR, editor. British Herbal Compendium, Volume 1. Bournemouth (GB): British Herbal Medicine Association; 1992. Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010. Ellingwood F. American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1919 original]. Gardner Z, McGuffin M, editors. American Herbal Products Association's Botanical Safety Handbook. 2nd edition. Boca Raton (FL): Taylor and Francis Group; 2013. Grieve M. A Modern Herbal, Volume 1. 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Boco Raton (FL): CRC Press LLC; 1999. Wren RC. Potter's Cyclopedia of Botanical Drugs and Preparations. London (GB): Potter and Clark; 1907. References Reviewed Barnes J, Anderson LA, Philipson JD. Herbal Medicines: A Guide for Healthcare Professionals, 2 nd edition. London (GB): The Pharmaceutical Press; 2002. Bown D. The Herb Society of North America Encyclopedia of Modern Herbs & Their Uses. New York (NY): Dorling Kindersley Publishing Incorporated; 1995. Chevallier A. The Encyclopaedia of Medicinal Plants. New York (NY): Dorling Kindersley; 1996. Duke JA, Bogenschutz-Godwin MJ, DuCellier J, Duke PK. Handbook of Medicinal Herbs, 2 nd edition. Boca Raton (FL): CRC Press; 2002. Felter HW, Lloyd JU.

King's American Dispensatory, Volume 2, 18 th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original]. Small E, Catling PM. Canadian Medicinal Crops. Ottawa (ON): National Research Council of Canada Monograph Publishing Program, NRC Research Press; 1999. Report a problem on this page Date modified: 2019-03-01

RISK INFORMATION

Caution(s) and warning(s) Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or last (for) more than 7 days.Ask a health care practitioner/health care provider/health care professional/ doctor/physician 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 theNatural Health Products Regulations.

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.Hydrastis canadensisis listed in Schedule 1 of theSpecies 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 Productsfor more details.

REFERENCES

Route of Administration Buccal

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Hydrastis canadensis	GoldensealOrangerootYellow-puccoonYellowroot	Hydrastis canadensis	Root and rhizome	Dry