Health Canada Santé Canada

NATURAL HEALTH PRODUCT

GOLDENSEAL - *HYDRASTIS CANADENSIS*
Buccal

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 León 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.

Product Facts
Medicinal ingredient (v/v) *Hydrastis canadensis* (Goldenseal) 1:X extract XX% Equivalent to YY mg dried root and rhizome in 1 mL of product
Uses Traditionally used in Herbal Medicine to help relieve minor mucous membrane inflammations of the mouth and throat.
Warnings
If applicable[1]: **Allergens: food allergen, gluten (gluten source), sulphites** **Contains aspartame**
Do not use if you are pregnant or breastfeeding.
Ask a health care practitioner before use if you have a kidney or blood pressure disorder.
Stop use and ask a health care practitioner if symptoms worsen or last more than 7 days.
Directions Adults 18 years and older: • Use 1 tablespoon (15 mL) as a gargle, 3 times per day • Do not swallow.
Other information (Add storage information)
Non-medicinal ingredients List all NMIs
Questions? (Call) 1-XXX-XXX-XXXX

[1]This section can be removed from the table if the product contains no allergen or aspartame.

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