

## 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 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

June 3, 2019

#### 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)	Preparation(s)
<i>Hydrastis canadensis</i>	<ul style="list-style-type: none"> <li>▶ Goldenseal</li> <li>▶ Orangeroot</li> <li>▶ Yellow-puccoon</li> <li>▶ Yellow root</li> </ul>	<i>Hydrastis canadensis</i>	Root and rhizome	Dried

References: Proper name: USDA 2019; Common names: McGuffin et al. 2000, Wiersema and León 1999; Source material: Blumenthal 2003, Hoffmann 2003, Bradley 1992.

#### 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 for the age category listed in this monograph 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)**

Traditionally used in Herbal Medicine to help relieve mucous membrane inflammations of the mouth (Bradley 1992; Ellingwood 1983; Grieve 1971).

### **Note**

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

### **Dose(s)**

#### **Subpopulation(s)**

Adults 18 years and older

#### **Quantity(ies)**

Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

0.6 - 3 grams of dried root and rhizome, per day (Bradley 1992).

#### **Direction(s) for use**

- ▶ Rinse as needed.
- ▶ Do not exceed maximum daily dose.

### **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.



- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you have a kidney disorder or blood pressure problems (Brinker 2018; Hoffmann 2003; Brinker 2001).
- ▶ Avoid taking with alcohol, other medications and/or natural health products with sedative properties (Boon and Smith 2004; Brinker 2001).

### **Contraindication(s)**

Do not use this product if you are pregnant or breastfeeding (Barnes and al. 2007; Mills and Bone 2005; Boon and Smith 2004; Hoffmann 2003; Brinker 2001; 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**

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 manufacturer must have proof of sale or a permit of the cultivated *Hydrastis canadensis* (Goldenseal) because the wild population is threatened:
  - *Hydrastis canadensis* is listed in Schedule 1 of the *Species at Risk Act* (SARA) as a “threatened” species and is afforded protection under this Act. Under section 32(2) of SARA, no person shall possess, collect, buy, sell or trade an individual of a wildlife species that is listed as an extirpated species, an endangered species or a threatened species, or any part or derivative of such an individual (JC 2003). Proof of purchase of cultivated *Hydrastis canadensis* is require
  - The Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) sets controls on the movement of animal and plant species that are, or may be, “threatened” due to excessive commercial exploitation. To import *Hydrastis canadensis* (including the whole, part of, or the powdered root and/or rhizome) into Canada requires an accompanying CITES export permit from exporting countries. For permit information

see <https://www.canada.ca/en/environment-climate-change/services/convention-international-trade-endangered-species/permits.html>.

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