

NATURAL HEALTH PRODUCT

WITCH HAZEL – *HAMAMELIS VIRGINIANA* Buccal and Oromucosal

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 January 28, 2022

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)
<i>Hamamelis virginiana</i>	<ul style="list-style-type: none"> ▶ Hamamelis ▶ Spotted alder ▶ Winter bloom ▶ Witchazel ▶ Witch-hazel 	<i>Hamamelis virginiana</i>	<ul style="list-style-type: none"> ▶ Bark ▶ Leaf 	Dry
<i>Hamamelis virginiana</i>	<ul style="list-style-type: none"> ▶ Hamamelis water¹ ▶ Witch hazel water¹ 	<i>Hamamelis virginiana</i>	Twig dormant	Dry ²

References: Proper name: USDA 2019; Common names: Bradley 2006, ESCOP 2003, McGuffin et al. 2000; Source information: Bradley 2006, ESCOP 2003.

¹Hamamelis/Witch hazel water: macerate in water recently cut and partially dried dormant twigs of *Hamamelis virginiana* in a ratio of 1:2 w/w (twigs:water) for 24 hours, distill twigs to a ratio of 1:0.80-0.85 w/v (twigs:distillate). To the distillate, add 14-15% of ethanol (% of volume of distillate) (USP 32).

²Dry = partially dried as per the USP preparation.

Route(s) of administration

- ▶ Buccal
- ▶ Oromucosal



Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

The following dosage forms are acceptable when used according to the requirements indicated in this monograph (allow for direct contact between the affected tissue and the medicinal ingredient): Gargle; Liquid; Mouthwash; Solution.

Use(s) or Purpose(s)

(Traditionally) used in Herbal Medicine (as an astringent) to help relieve mild inflammations of the mucous membranes of the mouth (Bradley 2006; ESCOP 2003; Felter 1983; Ellingwood 1983).

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)

Hamamelis; Bark and/or Leaf

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

2 – 10 grams of dried bark and/or leaf (Bradley 2006; ESCOP 2003; Blumenthal et al. 2000).

Hamamelis Water

Method of preparation: Distillation

100% of Hamamelis water (Bradley 2006).



Direction(s) for use

All products

Rinse and/or gargle as needed (Bradley 2006).

Tinctures

Dilute with water (Bradley 2006).

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.

Contraindication(s)

No statement required.

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* (NHPR).



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.

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