

# Witch Hazel - Hamamelis Virginiana Buccal and Oromucosal

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WITCH HAZEL - HAMAMELIS VIRGINIANA Buccal and Oromucosal 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 - 51.3 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 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) Hamamelis virginiana Hamamelis Spotted alder Winter bloom Witchazel Witch-hazel Hamamelis virginiana Bark Leaf Dry Hamamelis virginiana Hamamelis water 1 Witch hazel water 1 Hamamelis virginiana 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. 1 Hamamelis/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). 2 Dry = 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. References Cited Blumenthal M, Goldberg A, Brinkmann J, editors. 2000. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications. Bradley PR, editor. 2006. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (GB): British Herbal Medicine Association. Ellingwood F. 1983. American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications [Reprint of 1919 original]. 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## MEDICINAL INGREDIENT(S)

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).

## DOSAGE FORM(S)

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.

## 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).

## STORAGE CONDITION(S)

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.

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Hamamelis virginiana	Hamamelis Spotted alder Winter bloom Witch hazel Hamamelis virginiana	Hamamelis virginiana	Bark Leaf	Dry
Hamamelis virginiana	Hamamelis water 1 Witch hazel water 1	Hamamelis virginiana	Twig dormant	Dry 2