

NATURAL HEALTH PRODUCT

WITCH HAZEL – *HAMAMELIS VIRGINIANA* Ophthalmic

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

February 18, 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 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 of administration

Ophthalmic

Dosage form(s)

The following dosage forms are acceptable when used according to the requirements indicated in this monograph: Liquid; Solution.



Use(s) or Purpose(s)

(Traditionally) used in Herbal Medicine for the temporary relief of eye discomfort due to dryness of the eye or to exposure to wind or sun (EMA 2008; Bradley 2006).

Note

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

Dose(s)

Subpopulation(s)

Adolescents 14-17 years and Adults 18 years and older (EMA 2008)

Quantity(ies)

Method of preparation: Distillation

10% of Hamamelis water¹ (EMA 2008)

¹Note:

- One part Hamamelis water diluted with 10 parts sterile water (EMA 2008).

Direction(s) for use

Put 2 drops of diluted Hamamelis water in each eye, 3-6 times per day (EMA 2008).

Duration(s) of use

Use for a maximum of 4 days (EMA 2008)

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.
- ▶ Stop use and consult a health care practitioner/health care provider/health care professional/doctor/physician if you experience eye pain, changes in vision, continued redness, or irritation of the eye (EMA 2008).

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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