

NATURAL HEALTH PRODUCT

WITCH HAZEL – HAMAMELIS VIRGINIANA Oral

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

Proper name(s)	Common name(s)	Source information		
		Source material(s)	Part(s)	Preparation(s)
Hamamelis	 Hamamelis 	Hamamelis	Bark	Dry
virginiana	 Spotted alder 	virginiana	Leaf	
	 Winter bloom 			
	 Witchazel 			
	 Witch-hazel 			

Table 1. Proper name(s), Common name(s), Source information

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

Route of administration

Oral

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 oral use are indicated in the dosage form drop-down list of the webbased Product Licence Application form for Compendial applications.



Use(s) or Purpose(s)

Bark or Leaf

(Traditionally) used in Herbal Medicine (as an astringent) to help relieve diarrhoea (Bradley 2006; Blumenthal et al. 2000; Ellingwood 1983; Grieve 1971).

Leaf only

(Traditionally) used in Herbal Medicine (as an astringent) to help relieve symptoms associated with varicose veins (such as painful and heavy legs) (ESCOP 2003; Hoffmann 2003; Felter 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)

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

Bark

0.6 – 9 grams of dried bark, per day (Bradley 2006; ESCOP 2003; Blumenthal et al. 2000; Mills and Bone 2000)

Leaf

1.2 – 12 grams of dried leaf, per day (Bradley 2006; ESCOP 2003; Blumenthal et al. 2000; Mills and Bone 2000)

Direction(s) for use

Take a few hours before or after taking minerals and/or B-vitamin supplements (Brinker 2008; Mills and Bone 2000).



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 are pregnant or breastfeeding (Barnes et al. 2007; ESCOP 2003).

Contraindication(s)

No statement required.

Known adverse reaction(s)

Some people may experience gastric irritation (ESCOP 2003; Berardi et al. 2002; Mills and Bone 2000; McGuffin et al. 1997).

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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