

NATURAL HEALTH PRODUCT

WHITE BIRCH – *BETULA PUBESCENS*

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

July 1, 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>Betula pubescens</i> | <ul style="list-style-type: none"> ▶ Birch ▶ Downy birch ▶ White birch | <i>Betula pubescens</i> | Leaf | Dried |

References: Proper name: USDA 2019; Common names: McGuffin et al. 2000; Source material: 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 the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.



Use(s) or Purpose(s)

Used in Herbal Medicine as a diuretic (Bradley 2006; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 1998).

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 - 9 grams of dried leaf, per day (Bradley 2006; ESCOP 2003; Hoffmann 2003; Blumenthal et al. 1998).

Direction(s) for use

No statement required.

Duration(s) of use

For occasional use only (Berardi et al. 2002; CPA 2002).

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, breastfeeding or if you have swelling due to a kidney or cardiovascular disorder (Bradley 2006; ESCOP 2003; Brinker 2001; Blumenthal et al. 1998).

Contraindication(s)

No statement required.



Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs (Brinker 2001).

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.

References cited

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ESCOP 2003: ESCOP Monographs: The Scientific Foundation for Herbal Medicinal Products, 2nd edition. Exeter (UK): European Scientific Cooperative on Phytotherapy and Thieme; 2003.



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