

NATURAL HEALTH PRODUCT

BIRCH – *BETULA PENDULA*

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 August 28, 2018

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 pendula</i>	<ul style="list-style-type: none"> ▶ Birch ▶ Chui zhi hua ▶ European white birch ▶ Silver birch ▶ Weeping birch 	<i>Betula pendula</i>	Leaf	Dried

References: Proper name: USDA 2018; Common names: USDA 2018, 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-Standardised 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).

Duration(s) of use

For occasional use only (Berardi et al. 2002; CPhA 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 or breastfeeding, or have swelling due to a kidney or cardiovascular disorder (Brinker 2010; Bradley 2006; ESCOP 2003; Blumenthal et al. 1998).

Contraindication(s)

No statement required.

Known adverse reaction(s)

Stop use if hypersensitivity/allergy occurs (Brinker 2010).



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

Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 13th edition. Washington (DC): American Pharmaceutical Association; 2002.

Blumenthal M, Busse W, Goldberg A, Gruenwald J, Hall T, Riggins C, Rister R, editors. The Complete German Commission E Monographs: Therapeutic Guide to Herbal Medicines. Austin (TX): American Botanical Council; 1998.

Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 2. Bournemouth (UK): British Herbal Medicine Association; 2006.

Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010.

CPhA 2002: Canadian Pharmacists Association. Patient Self-Care. Helping Patients Make Therapeutic Choices. Ottawa (ON): Canadian Pharmacists Association; 2002.

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

Hoffmann D. Medical Herbalism. Rochester (VT): Healing Arts Press; 2003.

McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. Herbs of Commerce, 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000.



USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). *Betula pendula* Roth., *Betula alba* L./*Betula pubescens* Ehrh. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2018 June 15]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx>

References reviewed

Brinker F. Online Updates and Additions to Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications; 2008. [Accessed 2008 April 24]. Available from: <http://www.eclecticherb.com/emp/updatesHCIDI.html>

Grieve M. A Modern Herbal, Volume 1. New York (NY): Dover Publications; 1971 [Reprint of 1931 Harcourt, Brace & Company publication].

McGuffin M, Hobbs C, Upton R, Goldberg A, editors. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press; 1997.