

# Birch

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Birch (PDF Version - 62 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 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 on the label. Date August 28, 2024 Proper name(s), Common name(s), Source material(s) Table 1. Proper name(s), Common name(s), Source information(s) Proper name(s) Common name(s) Source information(s) Source material(s) Part(s) Preparation(s) *Betula pendula* Birch Chui zhi hua European white birch Silver birch Weeping birch *Betula pendula* Leaf Dry *Betula pubescens* Birch Downy birch White birch *Betula pubescens* Leaf Dry References: Proper names: USDA 2023; Common names: USDA 2023, Gardner and McGuffin 2013; 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 web-based Product Licence Application form for Compendial applications. 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, Powdered, Non-Standardized Extracts (Dry extract\*, Tincture, Fluid extract, Decoction, Decoction concentrate, Infusion, Infusion concentrate) 0.6 -9 grams of dried leaf, per day (Bradley 2006, ESCOP 2003, Hoffmann 2003, Blumenthal et al. 1998). \*Note: Solvents allowed for the method of preparation "Non-standardized extracts (Dry extract)" as part of this monograph are ethanol and/or water only. Direction(s) for use No statement required. Combination rule The medicinal ingredients included in this monograph may be combined together as long as the combined dose is within the dose limits indicated above. Duration(s) of Use Diuretic For occasional use only (Berardi et al. 2002; CPhA 2002) Risk Information Caution(s) and warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have kidney or cardiovascular disorders (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 Must be established in accordance with the requirements described in the Natural Health Products Regulations . 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. Example of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. 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, 13 th 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, 4 th 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, 2 nd edition. Exeter (UK): European Scientific Cooperative on Phytotherapy and Thieme; 2003. Gardner Z. and McGuffin M. editors. American Herbal Products Association's Botanical Safety Handbook, 2nd edition. CRC Press. Boca Raton (FL): American Herbal Products Association;

2013. Hoffmann D. Medical Herbalism. Rochester (VT): Healing Arts Press; 2003. USDA 2023: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). - Global. U.S. National Plant Germplasm System. [Accessed 2023 December 27]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> References Reviewed 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. Report a problem on this page Date modified: 2019-03-01

## DOSAGE FORM(S)

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

## RISK INFORMATION

Caution(s) and warning(s) Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have kidney or cardiovascular disorders (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 CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations.

## 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(s)		
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Source material(s)	Part(s)	Preparation(s)		
Betula pendula	BirchChui zhi huaEuropean white birchSilver BirchWeeping birch	Betula pendula	Leaf	Dry
Betula pubescens	BirchDowny birchWhite birch	Betula pubescens	Leaf	Dry