



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 November 2014  
EMA/HMPC/573239/2014  
Committee on Herbal Medicinal Products (HMPC)

## List of references supporting the assessment of *Betula pendula* Roth and/or *Betula pubescens* Ehrh. as well as hybrids of both species, folium

Final

**The European Medicines Agency acknowledges that copies of the underlying works used to produce this monograph were provided for research only with exclusion of any commercial purpose.**

Baranov VI, Malinovskaya GV, Pokhilo ND, Makhan'kov VV, Uvarova NI, Gorovoi PG. Chemotaxonomic study of *Betula* species in the Soviet Far East. *Rastit Resur* 1983, 19(2):159-166

Bertram B. Flavonoide - Eine Klasse von Pflanzeninhaltsstoffen mit vielfältigen biologischen Wirkungen, auch mit karzinogener Wirkung? *Dtsch Apoth Ztg* 1989, 129(47):2561-2571

Blaschek W, Ebel S, Hilgenfeldt U, Holzgrabe U, Reichling J, Ruth P, *et al.*, editors. HagerROM 2013: Hagers Handbuch der Drogen und Arzneistoffe. Springer-Verlag, Berlin Heidelberg 2013

Blumenthal M, Busse WR, Goldberg A, Gruenwald J, Hall T, Riggins CW, *et al.*, editors. The Complete German Commission E monographs. American Botanical Council, Austin Texas 1998

Borkowski B. Diuretische Wirkung einiger Flavondrogen. *Planta Med* 1960, 8(1):95-104

Bormann H, Melzig MF. Inhibition of metallopeptidases by flavonoids and related compounds. *Pharmazie* 2000, 55(2):129-132

Braun H. Die therapeutische Verwendung wichtiger Drogen der Volksmedizin in der täglichen Praxis. IV. *Betula alba* (Birke). *Fortschr Med* 1941, 59:114-116

Bunney S, editor. The illustrated encyclopedia of herbs. Chancellor Press, Prague 1993

Carnat A, Lacouture I, Fraisse D, Lamaison J-L. Standardisation de la feuille de bouleau. *Ann Pharm Fr* 1996, 5:231-235

Chevallier A. The encyclopedia of medicinal plants. Dorling Kindersley, London 1996

Culpeper N. Culpeper's complete herbal. Wordsworth Editions Ltd, Hertfordshire 1995



- Dallenbach-Tölke K, Nyiredy S, Gross GA, Sticher O. Flavonoid glycosides from *Betula pubescens* and *Betula pendula*. *J Nat Prod* 1986, 49(6):1155-1156
- Dallenbach-Tölke K, Nyiredy S, Meier B, Sticher O. HPLC-Analyse der Flavonoidglykoside aus *Betulae folium*. *Planta Med* 1987a, 53(2):189-192
- Dallenbach-Tölke K, Nyiredy S, Sticher O. Birkenblätter-Qualität. Vergleich der Einzel- und Gesamtbestimmungsmethoden der Flavonoidglykoside von *Betulae folium*. *Dtsch Apoth Ztg* 1987b, 127:1167-1171
- Demina LN, Parshikova VN, Stepen RA. Composition, properties, and biocidal activity of a carbon dioxide extract of *Betula pendula* Roth leaves. *Khim i Khim Tekhnol* 2006, 49(1):75-78
- Dr. Willmar Schwabe Arzneimittel. Periodischer Sicherheitsbericht zur Verträglichkeit von Urorenal. Februar 1998, Date of Report 2 August 1999
- Duric K, Kovac-Besovic E, Mulabegovic N. Investigation of reaction of irritation and sensitization on experimental animals caused by triterpene substances from birch, *Betula pendula* Roth. *HealthMED* 2008, 2(3):138-145
- Elbanowska A, Kaczmarek F. Investigations of the flavonoid compounds content and the diuretic activity of *Betula verrucosa* Ehrh. leaves at different phases of growth. *Herba Pol* 1966, 11:47-56
- Engesser A, Bersch U, Berchtold J, Göcking K, Schaffner W. Birkenblätterttee (*Betulae folium*) gegen Infekte der unteren Harnwege – eine Pilotstudie. *Arch Pharm Pharm Med Chem* 1998, 331 (Suppl 1):V33
- ESCOP monographs 2<sup>nd</sup> ed.. *Betulae folium* – Birsch leaf. European Scientific Cooperative on Phytotherapy, editor. Thieme, Stuttgart 2003
- European Pharmacopoeia. 8<sup>th</sup> ed. Birch leaf – *Betulae folium*. Council of Europe. 04/2013:1174
- Evans WC. Trease and Evans pharmacognosy. 15<sup>th</sup> ed. Saunders, Edinburgh 2000
- Fischer FG, Seiler N. Die Triterpenalkohole der Birkenblätter II. *Justus Liebigs Ann Chem* 1961, 644(1):146-162
- Fischer FG, Seiler N. Die Triterpenalkohole der Birkenblätter. *Justus Liebigs Ann Chem* 1959, 626(1):185-205
- Gehrmann B, Koch W-G, Tschirch C, Brinkmann H. Medicinal herbs: A compendium. The Haworth Herbal Press, New York, London, Oxford 2005
- Göggelmann W, Schimmer O. Mutagenic activity of phytotherapeutical drugs. In: Knudsen I, editor. Genetic Toxicology of the Diet. Alan R. Liss, New York 1986, 63-72
- Grieve M. A modern herbal: The medicinal, culinary, cosmetic and economic properties, cultivation and folklore of herbs, grasses, fungi, shrubs and trees with all their modern scientific uses. Tiger Books International, London 1998
- Gruenwald J, Brendler T, Jaenicke C, editors. PDR for herbal medicines. 3<sup>rd</sup> ed. Thomson PDR, Montvale 2004
- Hänsel R, Sticher O. Pharmakognosie – Phytopharmazie. 9<sup>th</sup> ed. Springer, Heidelberg 2010
- Herb CD4: Herbal Remedies. CD-Rom. Medpharm Scientific Publishers, Stuttgart 2001

- Herb CD5: Herbal Remedies. CD-Rom. Medpharm Scientific Publishers, Stuttgart 2003
- Hilpisch U, Hartmann R, Glombitza KW. New dammaranes, esterified with malonic acid, from leaves of *Betula pendula*. *Planta Med* 1997, 63(4):347-351
- Janicki S, Fiebieg A. Farmacja stosowana. PZWL, Warsaw 1996
- Karonen M, Ossipov V, Sinkkonen J, Loponen J, Haukioja E, Pihlaja K. Quantitative analysis of polymeric proanthocyanidins in birch leaves with normal-phase HPLC. *Phytochem Anal* 2006, 17(3):149-156
- Kavelenova LM, Lishchinskaya SN, Karandaeva LN. Characteristics of water-soluble phenols seasonal dynamics in *Betula pendula* Roth. leaves in forest-steppe urban environment (case study of Samara). *Khimiya Rastitel'nogo Syr'ya* 2001, (3):91-96
- Keinänen M, Julkunen-Tiitto R. Effect of sample preparation method on birch (*Betula pendula* Roth) leaf phenolics. *J Agric Food Chem* 1996, 44(9):2724-2727
- Klinger W, Hirschelmann R, Süß J. Birch sap and birch leaves extract: screening for antimicrobial, phagocytosis-influencing, antiphlogistic and antipyretic activity. *Pharmazie* 1989, 44(8):558-560
- Ladynina EA, Morozova RS. Fitoterapija. [Phytotherapy.] Meditsina, Leningrad 1987
- Lahti A, Hannuksela M. Immediate contact allergy to birch leaves and sap. *Contact Dermatitis* 1980, 6(7):464-465
- Lahtinen M, Lempa K, Salminen J-P, Pihlaja K. HPLC analysis of leaf surface flavonoids for the preliminary classification of birch species. *Phytochem Anal* 2006, 17(3):197-203
- Lavrjonov VK, Lavrjonova GV. 500 vazneishih lekarstvenn, h pastenii (500 important herbs). Stalker, Donetsk 2003
- Lavrjonov VK, Lavrjonova GV. Polnaya entsiklopediya lekarstvennoh rasteni A-L. [Complete encyclopedia of herbs A-L.] Vol. 1. Olma-Press, Saint-Petersburg, Neva, Moscow 1999
- Lutomski J, Małek B. Technologia leku roślinnego. PZWL, Warsaw 1973
- Marx H, Büchmann R. Über harntreibende Heilpflanzen. *Dtsch Med Wochenschr* 1937, 63(10):384-386
- Muravjova DA. Farmakognozija. [Pharmacognosy.] Meditsina, Moscow 1991
- Muravjova DA, Sam'lina IA, Yakovlev GP. Farmakognozija. [Pharmacognosy.] Meditsina, Moscow 2002
- Müller B, Schneider B. Anwendungsbereiche eines Trockenextrakts aus Birkenblättern bei Harnwegserkrankungen: Ergebnisse einer Anwendungsbeobachtung. In: Abstracts of Phytotherapie an der Schwelle zum neuen Jahrtausend, 10. Jahrestagung der Gesellschaft für Phytotherapie. Münster, 11-13 November 1999, 106-108 (Abstract P16)
- Ossipov V, Nurmi K, Loponen J, Haukioja E, Pihlaja K. High-performance liquid chromatographic separation and identification of phenolic compounds from leaves of *Betula pubescens* and *Betula pendula*. *J Chromatogr A* 1996, 721(1):59-68
- Petkov V, editor. Sovremennaja fitoterapija. [A modern phytotherapy.] Meditsina i fizkultura, Sofia 1988
- Pokhilo ND, Denisenko VA, Makhan'kov VV, Uvarova NI. Terpenoids and flavonoids from the leaves of Siberian species of the genus *Betula*. *Chem Nat Compd* 1983, 19(3):374-375

- Pokhilo ND, Denisenko VA, Makhan'kov VV, Uvarova NI. Triterpenoids of the leaves of *Betula pendula* from different growth sites. *Chem Nat Compd* 1986, 22(2):166-171
- Rafsanjany N, Lechtenberg M, Petereit F, Hensel A. Traditionell angewandte Drogen bei unkomplizierten Entzündungen der ableitenden Harnwege verursacht durch uropathogene *E. coli*. [Traditional herbal drugs against uncomplicated urinary tract infections. *In vitro* investigations of their anti-adhesive effects against uropathogenic *Escherichia coli*.] *Z Phytother* 2013, 34(5):214-220
- Rauha JP, Remes S, Heinonen M, Hopia A, Kähkönen M, Kujala T, *et al.* Antimicrobial effects of Finnish plant extracts containing flavonoids and other phenolic compounds. *Int J Food Microbiol*, 2000, 56(1):3-12
- Remington JP, Wood HC, *et al.*, editors. The Dispensatory of the United States of America. 20<sup>th</sup> ed. Lippincott, Philadelphia 1918
- Rickling B. Identifizierung hämolytisch aktiver Triterpenester aus *Betula pendula*. PhD Thesis, Rheinischen Friedrich-Wilhelms-Universität, Bonn 1992
- Rickling B, Glombitza KW. Saponins in the leaves of birch? Hemolytic dammarane triterpenoid esters of *Betula pendula*. *Planta Med* 1993, 59(1):76-79
- Schilcher H. Pflanzliche Urologika. *Deutsch Apoth Ztg* 1984, 124(47):2429-2436
- Schilcher H. Pflanzliche Diuretika. *Urologe B* 1987, 27:215-222
- Schilcher H, Boesel R, Effenberger S, Segebrecht S. Neuere Untersuchungsergebnisse mit aquaretisch, antibakteriell und prostatotrop wirksamen Arzneipflanzen. Pharmakologische und phytochemische Untersuchungen von Goldrutenkraut, Birkenblättern, Wacholderbeeren, Gewürzsumachwurzelrinde, Liebstöckelwurzel, Queckenwurzel und Medizinalkürbissamen. *Urologe B* 1989a, 29:267-271
- Schilcher H, Boesel R, Effenberger S, Segebrecht S. Neuere Untersuchungsergebnisse mit aquaretisch, antibakteriell und prostatotrop wirksamen Arzneipflanzen. *Z Phytother* 1989b, 10:77-82
- Schilcher H, Emmrich D. Pflanzliche Urologika zur Durchspülungstherapie. *Dtsch Apoth Ztg* 1992, 132(47):2549-2555
- Schilcher H, Rau H. Nachweis der aquaretischen Wirkung von Birkenblätter - und Goldrutenkrautauszügen im Tierversuch. *Urologe B* 1988, 28:274-280
- Schilcher H, Wülkner A. Allgemeine Einführung und Übersicht. In: Schilcher H. Phytotherapie in der Urologie. Hippocrates Verlag GmbH, Stuttgart 1992, 11-19
- Shulyakovskaya TA, Vetchinnikova LV, Kanyuchkova GK, Il'inova MK. Content of lipids and fatty acid composition of their fractions during different phases of bud and leaf development in *Betula pendula* Roth and *Betula pubescens* Ehrh. *Rastitel'nye Resursy* 2004, 40(1):69-76
- Sokolov SJ, Zamotaev IP. Spravochnik po lekarstvennim rastenijam. Meditsina, Moscow 1988
- Szentmihályi K, Kéry Á, Then M, Lakatos B, Sándor Z, Vinkler P. Potassium-sodium ratio for the characterization of medicinal plant extracts with diuretic activity. *Phytotherapy Res* 1998, 12(3):163-166
- Tammeorg J, Kook O, Vilbaste G. Eesti NSV ravimtaimed. [The herbs of Soviet Estonia.]. 5<sup>th</sup> ed. Valgus, Tallinn 1984

- Turova AD, Sapozhnikova JH, Li VD. Lekarstvennye rastenija SSSR i Vetnama. [Herbs in USSR and Vietnam.] Meditsina, Moscow 1987
- Turova AD. Lekarstvennye rastenija SSSR i ikh primenenie. [Herbs in USSR and their use.] Meditsina, Moscow 1974
- Vollmer H, Hübner K. Untersuchungen über die diuretische Wirkung der *Fructus juniperi*, *Radix levistici*, *Radix ononidis*, *Folia betulae*, *Radix liquiritiae* und *Herba equiseti* an Ratten. *Naunyn Schmiedebergs Arch Pharmacol Exp Pathol* 1937, 186(2-5):592-605
- Vollmer H. Untersuchungen über die diuretische Wirkung der *Folia betulae* an Kaninchen und Mäusen. Vergleich mit anderen Drogen. *Naunyn Schmiedebergs Arch Pharmacol Exp Pathol* 1937, 186(2-5):584-591
- Wang S, Pei Y. Review on chemical constituents of *Betula* L. *Shenyang Yao Ke Da Xue Xue Bao* 2000, 17(5):378-382
- Wichtl M, editor. Teedrogen und Phytopharmaka. 5<sup>th</sup> ed. Wissenschaftliche Verlagsgesellschaft mbH, Stuttgart 2009
- Wojnicz D, Kucharska AZ, Sokół-Łętowska A, Kicia M, Tichaczek-Goska D. Medicinal plants extracts affect virulence factors expression and biofilm formation by the uropathogenic *Escherichia coli*. *Urol Res* 2012, 40(6):683-697
- Yakovlev GP, Blinova KF. Entsiklopeditsheski slovar lekarstvenn'ih rasteni i productov zhivogo proiishozhdeniya. [Encyclopedical dictionary of medicinal plants and products of animal origin.] Spetsialnaya Literatura, Saint-Petersburg 1999
- Yakovlev GP, Blinova KF. Rastenija dlja nas. [Herbs for us.] Utchebnaja kniga, Saint-Petersburg 1996