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List of references supporting the assessment of *Serenoa repens* (W. Bartram) Small, fructus

Draft

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

Abe M, Ito Y, Oyunzul L, Oki-Fujino T, Yamada S. Pharmacologically relevant receptor binding characteristics and 5alpha-reductase inhibitory activity of free Fatty acids contained in saw palmetto extract. *Biol Pharm Bull.* 2009 Apr; 32(4):646-50.

American Urological Association. Guideline on the management of benign prostatic hyperplasia (BPH). Edited by the American Urological Association Education and Research 2010.

Avins AL, Bent S, Staccone S, Badua E, Padula A, Goldberg H, et al. A detailed safety assessment of saw palmetto extract. *Complementary Therapies in Medicine* 2008; 16: 147-154.

Avins AL, Lee JY, Meyers CM, Barry MJ; CAMUS Study Group. Safety and toxicity of saw palmetto in the CAMUS trial. *J Urol* 2013; 189: 1415-1420.

Barnes J, Anderson LA, Phillipson JD. *Herbal Medicines* 3rd Edition, Pharmaceutical Press, London 2007 pp. 521-529.

Baron A, Mancini M, Caldwell E, Cabrelle A, Bernardi P, Pagano F. *Serenoa repens* extract targets mitochondria and activates the intrinsic apoptotic pathway in human prostate cancer cells. *BJU Int* 2009; 103(9): 1275-1283.

Barry MJ, Meleth S, Lee JY, Kreder KJ, Avins AL, Nickel JC, et al. Effect of increasing doses of Saw palmetto extract on lower urinary tract symptoms. *JAMA* 2011; 306(12): 1344-51.

Bayne CW, Ross M, Donnelly F, Habib FK. The selectivity and specificity of the actions of the lipido-sterolic extract of *Serenoa repens* (permixon) on the prostate. *J Urol* 2000; 164(3 Pt1): 876-881.

Bent S, Kane C, Shinohara K, Nehaus J, Hudes ES, Goldberg H, Avins AL. *NEJM* 2006 ; 354(6) : 557-566 .



Boccafoschi C, Annoscia S. *Serenoa repens* extract and placebo in prostatic benign hyperplasia: clinical results [Confronto fra estratto di serenoa repens e placebo mediate prova clinica controllata in pazienti con adenomatosi prostatica]. *Urologia* 1983; **50**: 1257–68.

Boyle P, Robertson C, Lowe F, Roehrborn C. Updated meta-analysis of clinical trials of *Serenoa repens* extract in the treatment of symptomatic benign prostatic hyperplasia. *Br J Urol International* 2004; **93**: 751-756.

Braeckman J. The extract of *Serenoa repens* in the treatment of benign prostatic hyperplasia : a multicenter open study. *Curr Ther Res* 1994; **55**: 776-85.

Braeckman J, Denis L, de Leval J, Keuppens F, Cornet A, De Bruyne, et al. A double-blind, placebo-controlled study of the plant extract *Serenoa repens* in the treatment of benign hyperplasia of the prostate. *European Journal of Clinical Research* 1997a; **9**: 247–59.

Braeckman J, Bruhwylter J, Vandekerckhove K, Geczy J. Efficacy and safety of the extract of *Serenoa repens* in the treatment of benign prostatic hyperplasia: therapeutic equivalence between twice and once daily dosage forms. *Phytother Res* 1997b; **11**: 558-563.

Bressler R. Herb-drug interactions. Interactions between saw palmetto and prescription medications. *Geriatrics* 2006; **60**(11): 32-34.

Breu W, Hagenlocher M, Redi K, Tittel G, Stadler F, Wagner H. Anti-inflammatory activity of Sabal fruit extracts prepared with supercritical carbon dioxide. In vitro antagonists of cyclo-oxygenase and 5-lipoxygenase metabolism. *Arzneimittelforschung* 1992a; **42**: 547-551.

Breu W, Stadler F, Hagenlocher M, Wagner H. Der Sabalfrucht-Extrakt SG 291. *Z Phytotherapie* 1992; **13**: 107-115.

Bruminhent J, Carrera P, Li Z, Amankona R, Roberts I. Acute pancreatitis with saw palmetto use: a case report. *J Medical Case Reports* 2011; **5**: 414-419.

Canadian Prostate Health Council and CUA Guidelines Committee. Update: Guidelines for the management of benign prostatic hyperplasia 2009.

Carraro JC, Raynaud JP, Koch G, Chisholm GD, Di Silverio F, Teillac P, et al. Comparison of phytotherapy (Permixon®) with finasteride in the treatment of benign prostate hyperplasia: a randomized international study of 1,098 patients. *The Prostate* 1996; **29**: 231-240.

Carilla E, Briley M, Fauran F, Sultan CH, Duvilliers C. Binding of Permixon®, a new treatment for prostatic benign hyperplasia, to the cytosolic androgen receptor in the rat prostate. *J Steroid Biochem* 1984; **20**: 521-523.

Casarosa C, Cosci o di Coscio M, Fratta M. Lack of effects of a liposterolic extract of *Serenoa repens* on plasma levels of testosterone, follicle-stimulating hormone and luteinizing hormone. *Clin Ther* 1988; **10**: 585-588.

Champault G, Patel JC, Bonnard AM. A double-blind trial of an extract of the plant *Serenoa repens* in benign prostatic hyperplasia. *British Journal of Clinical Pharmacology* 1984; **18**: 461–2.

Che Y, Hou S, Kang Z, Lin Q. *Serenoa repens* induces growth arrest and apoptosis of human multiple myeloma cells via inactivation of STAT 3 signaling. *Oncol Rep* 2009; **22**(2): 377-383.

Cheema P, El-Mefty O, Jazieh AR. Intraoperative haemorrhage associated with the use of extract of Saw Palmetto herb: a case report and review of literature. *J Int Medicine* 2001; **250**: 167-169.

Chevalier G, Benard P, Cousse H, Bengone T. Distribution study of radioactivity in rats after oral administration of the lipido/sterolic extract of *Serenoa repens* (Permixon®) supplemented with [1-¹⁴C]-

lauric acid, [1-¹⁴C]-oleic acid or [4-¹⁴C]-beta-sitosterol. *Eur J Drug Metab Pharmacokinetics* 1997; 22: 73-83.

Cockett AT, Aso Y, Denis L, Khoury S, Barry M, Carlton CE, Coffey D, Fitzpatrick J, Griffiths K, Hald T. World Health Organisation Consensus Committee recommendations concerning diagnosis of BPH. *Prog Urol* 1991; Dec 1 (6): 957-972.

Cukier J, Ducassou J, Le Guillou M, Leriche A, Lobel B, Toubol J. [Permixon® versus placebo; resultats d'une étude multicentrique]. *Comptes Rendus de Therapeutique et de Pharmacologie Clinique* 1985; 4:15–21.

Dathe G, Schmid H, Phytotherapie der benignen Prostatahyperplasie (BPH) mit Extractum *Serenoa repens* (Permixon®). *Urologie* 1991 ; 31 : 220-3.

De la Taille A. Therapeutic approach. The Importance of controlling prostatic inflammation. *Uropean Urology Supplements* 2013; 12: 116-122.

de la Rosette J, Alivizatos G, Madersbacher S, Rioja Sanz C, Nordling J, Emberton M, et al. Guidelines on benign prostatic hyperplasia. Edited by the European Association of Urology 2009.

Descotes JL, Rambeaud JJ, Deschaseaux P, Faure G. Placebo-controlled evaluation of the efficacy and tolerability of Permixon® in benign prostatic hyperplasia after the exclusion of placebo responders. *Clinical Drug Investigation* 1995;5:291–7.

De Bernardi di Valserra M, Tripodi AS, Contos S, Germogli R. *Serenoa repens* capsules: a bioequivalence study. *Acta Toxicol Ther* 1994; 15: 21-39.

Debruyne F, Koch G, Boyle P, Calais Da Silva F, Gillenwater JG, Hamdy FC, et al. Comparison of a phytotherapeutic agent (Permixon®) with an alpha-blocker (Tamsulosin) in the treatment of benign prostatic hyperplasia: a 1-year randomized international study. *European Urology* 2002; 41: 497-507.

Debruyne F, Koch G, Boyle P, Calais Da Silva F, Gillenwater JG, Hamdy FC, et al. Comparaison d'un produit de phytothérapie (Permixon®) et d'un alpha-bloquant (tamsulosine) dans le traitement de l'hypertrophie bénigne de la prostate : étude internationale randomisée d'une durée de 12 mois. *Progrès en Urologie* 2002 ; 12 : 384-394.

Debruyne F, Boyle P, Calais Da Silva F, et al. Evaluation of the clinical benefit of Permixon® and tamsulosin in severe BPH patients – PERMAL study subset analysis. *Eur Urol* 2004; 45: 773-780.

Delfosse M. Drogues végétales et plantes médicinales. APB Brussels, 1998 pp. 356-357.

Descotes JL, Rambeaud JJ, Deschaseaux P, Faure G. Placebo-controlled evaluation of the efficacy and tolerability of Permixon® in benign prostatic hyperplasia after exclusion of placebo responders. *Clin Drug Invest* 1995; 9: 291-297.

Di Silverio F, D'Eramo G, Lubrano C, Flammia GP, Sciarra A, Palma E, et al. Evidence that *Serenoa repens* extract displays an antiestrogenic activity in prostatic tissue of benign prostatic hypertrophy patients. *Eur. Urol* 1992; 21: 309-314.

- Di Silverio F, Monti S, Sciarra A, Varasano PA, Martini C, Lanzara S et al. Effects of long-term treatment with *Serenoa repens* (Permixon®) on the concentrations and regional distribution of androgens and epidermal growth factor in benign prostatic hyperplasia. *Prostate* 1998; 37: 77-83.
- Elghamry MI, Hänsel R. Activity and isolated phytoestrogen of shrub palmetto fruits (*Serenoa repens* Small), a new estrogen plant. *Experientia* 1969; 25: 828-829.
- el-Sheikh MM, Dakkak MR, Saddique A. The effect of Permixon on androgen receptors. *Acta Obstet Gynecol Scand* 1988; 67: 397-399.
- Emberton M. Definition of at-risk patients : dynamic variables. *Br J Urol International* 2006; 97 Suppl 2: 12-15.
- Emili E, Lo Cigno M, Petrone U. [Risultati clinici su un nuovo farmaco nella terapia dell'ipertrofia della prostata (Permixon®)]. *Urologia* 1983; 50:1042-8.
- ESCOPE Monographs. *Serenoae repentis fructus* (*Sabal fructus*), 2nd Edition, Thieme Verlag, Stuttgart 2003: pp. 477-486.
- European Medicines Agency. Guideline on the clinical investigation of medicinal products for the treatment of urinary incontinence: 27 June 2013.
- European Pharmacopoeia. Saw palmetto fruit. *Sabalıs serrulata fructus*. Edition 07/2012: 1848
- Fabricius PG, Vahlensieck W. Therapie der benignen Prostatahyperplasie. Sabalfrucht-Extract: Einmalgabe reicht. *Therapiewoche* 1993; 43: 1616-20.
- Gerber GS, Kuznetsov D, Johnson B, Burstein JD. Randomized, double-blind, placebo-controlled trial of saw palmetto in men with lower urinary tract symptoms. *Urology* 2001; 58: 960-965.
- Giannakopoulos X, Baltogiannis D, Giannakis D, et al. The lipidosterolic extract of *Serenoa repens* in the treatment of benign prostatic hyperplasia: a comparison of two dosage regimens. *Advances in Therapy* 2002; 19: 285-296.
- Glémain P, Coulange C, Billebaud T, Gattengno B, Muszynski R, Loeb G. Tamsulosine avec ou sans *Serenoa repens* dans l'hypertrophie bénigne de la prostate : l'essai OCOS. *Progrès en Urologie* 2002; 12: 395-403.
- Giulianelli R, Pecoraro S, Sepe G, Leonardi R, Gentile BC, Albanesi L, et al. Multicentre study on the efficacy and tolerability of an extract of *Serenoa repens* in patients with chronic benign prostate conditions associated with inflammation. *Archivio Italiano di Urologica e Andrologia* 2012; 84: 94-98.
- Goepel M, Hecker U, Krege S, Rübber H, Michel MC. Saw palmetto extracts potently and noncompetitively inhibit human alpha1-adrenoceptors in vitro. *The prostate* 1999; 38: 208-215.
- Grasso M, Montesano A, Buonaguidi A, et al. Comparative effects of alfuzosin versus *Serenoa repens* in the treatment of symptomatic benign prostatic hyperplasia. *Arch Exp de Urol* 1995; 48: 97-103.

Gurley BJ, Gardner SF, Hubbard MA, Williams KW, Gentry WB, Carrier J, Khan IA, Edwards DJ, Shah A. In vivo assessment of botanical supplementation of human cytochrome P450 phenotypes: *Citrus aurantium*, *Echinacea purpurea*, milk thistle and saw palmetto. *Clin Pharmacol Ther* 2004; 76: 428-440.

Gutiérrez M, Hidalgo A, Cantabrana B. Spasmolytic activity of a lipidic extract from *Sabal serrulata* fruits: further study of the mechanisms underlying this activity. *Planta Med* 1996a; 62: 507-511.

Gutiérrez M, Garcia de Boto MJ, Cantabrana B, Hidalgo A. Mechanism involved in the spasmolytic effect of extracts from *Sabal serrulata* fruit on smooth muscle. *Gen Pharmac* 1996b; 27: 171-176.

Hänsel R, Keller K, Rimpler H, Schneider G. Hagers Handbuch der Pharmazeutischen Praxis, Drogen P-Z, Springer-Verlag, Berlin 1994 pp. 680-687.

Helfand BT, Lee JY, Sharp V, et al. Associations between improvements in lower urinary tract symptoms and sleep disturbances over time in the CAMUS trial. *J Urol* 2012; 188: 2288-2293.

Helpap B, Oehler U, Weisser H, Bach D, Ebeling L. Morphology of benign prostatic hyperplasia after treatment with Sabal extract IDS 89 or placebo. Results of a prospective, randomized, double-blind trial. *J Urologic Pathol* 1995; 3: 175-182.

Hiermann A. The contents of sabal fruits and testing of their anti-inflammatory effect. *Arch Pharm (Weinheim)* 1989; 322: 111-114.

Hizli F, Uygur MC. A prospective study of the efficacy of *Serenoa repens*, tamsulosin, and *Serenoa repens* plus tamsulosin treatment for patients with benign prostate hyperplasia. *Int Urol Nephrol* 2007; 39: 879-886.

Hostanska K, Suter A, Melzer J, Saller R. Evaluation of cell death caused by a ethanolic extract of *Serenoa repens* fructus (Prostasan) on human carcinoma cell lines. *Anticancer Res* 2007; 27(2): 873-881.

Iehlé C, Délos S, Guiro O, Tate R, Raynaud JP, Martin PM. Human prostatic steroid 5-alpha-reductase isoforms – a comparative study of selective inhibitors. *J Steroid Biochem Molec Biol* 1995; 54: 273-279.

Iglesias-Gato D, Carsten T, Vesterlund M, Pousette A, Schoop R, Norstedt G. Androgen-independent effects of *Serenoa repens* extract (Prostasan®) on prostatic epithelial cell proliferation and inflammation. *Phytother Res.* 2012 Feb; 26(2):259-64. doi: 10.1002/ptr.3537. Epub 2011 Jun 8.

Jibrin I, Erinle A, Saidi A, Aliyu Z. Saw palmetto-induced pancreatitis. *Southern Med J* 2006; 99: 611-612.

Kaplan SA, Volpe MA, Te AE. A prospective 1-year trial using saw palmetto versus finasteride in the treatment of category III prostatitis / chronic pelvic pain syndrome. *J Urol* 2004; 171: 284-288.

Koch E. *Pharmakologie und Wirkungsmechanismen von Extrakten aus Sabalfrüchten (Sabal fructus), Brennesselwurzeln (Urtica radix) und Kürbissamen (Cucurbita peponis semen) bei der Behandlung der benignen Prostatahyperplasie*; in *Phytopharmaka VII*, Shulz V, Rietbrock N, Roots I, Loew D (Hrsg.): Steinkopff, Darmstadt 1995, pp. 57-79.

Lapi F et al. Acute liver damage due to *Serenoa repens*: a case report. *Br J Clin Pharmacol* 2010; 69: 558-560.

Latil A, Libon C, Templier M, Junquero D, Lantoine-Adam F, Nguyen T. Hexanic lipidosterolic extract of *Serenoa repens* inhibits the expression of two key inflammatory mediators, MCP-1/CCL2 and VCAM-1, *in vitro*. *BJU Int.* 2012 Sep; 110(6 Pt B):E301-7. doi: 10.1111/j.1464-410X.2012.11144.x. Epub 2012 Apr 23.

Loew D, Habs M, Klimm H-D, Trunzler G. *Phytopharmaka Report*, 2^{te} Auflage, Steinkopff Darmstadt 1999, pp. 174-190.

Löbelenz J. Extractum Sabal fructus bei benignen Prostatahyperplasie (BPH). *Therapeutikon* 1992; 6(1-2): 34-37.

Markowitz JS, Donovan JL, DeVane CL, Taylor RM, Ruan Y, Wang JS, Chavin KD. Multiple doses of saw palmetto did not alter cytochrome P450 2D6 and 3A4 activity in normal volunteers. *Clin Pharmacol Ther* 2003; 74: 536-542.

Mattei FM, Capone M, Acconcia A. [Medikamentöse therapie der benignen prostatahyperplasie mit einem extrakt der sagepalme]. *TW Urologie Nephrologie* 1990; 2: 346-50.

Miroddi M, Carni A, Mannucci C, Moleti M, Navarra M, Calapai G. Hot flashes in a young girl: a wake-up call concerning *Serenoa repens* use in children. *Pediatrics* 2012 ; 130: 1373-1376.

Mooiman KD, Maas-Bakker RF, Hendriks JJ, Bank PC, Rosing H, Beijnen JH, Schellens JH, Meijerman I. The effect of complementary and alternative medicines on CYP3A4-mediated metabolism of three different substrates: 7-benzyloxy-4-trifluoromethyl-coumarin, midazolam and docetaxel. *J Pharm Pharmacol.* 2014; 66: 865-74.

Niederprüm HJ, Schweikert HU, Zänker KS. Testosterone 5-alpha-reductase inhibition by free fatty acids from Sabal serrulata fruits. *Phytomedicine* 1994; 1: 127-133.

Palin MF, Faguy M, LeHoux JG, Pelletier G. inhibitory effect of *Serenoa repens* on the kinetic of pig prostatic microsomal 5-alpha-reductase activity. *Endocrine* 1998; 9: 65-69.

Paubert-Braquet P, Richardson FO, Servent-Saez N, Gordon WC, Monge MC, Bazan NG, Authie D, Braquet P. Effect of *Serenoa repens* extract (Permixon®) on estradiol/testosterone-induced experimental prostate enlargement in the rat. *Pharmacological Research* 1996; 34 (3/4): 171-179.

Paubert-Braquet M, Mencia Huerta JM, Cousse H, Braquet P. Effect of the lipidic lipidosterolic extract of *Serenoa repens* (Permixon®) on the ionophore A23187-stimulated production of leukotriene B4 (LTB4) from human polymorphonuclear neutrophils. *Prostaglandins, Leukotrienes and Essential Fatty Acids* 1997; 57(3): 299-304.

Petrangeli E, Lenti L, Buchetti B, Chinzari P, Sale P, Salvatori L, et al. Lipido-sterolic extract of *Serenoa repens* (LSESr, Permixon) treatment affects human prostate cancer cell membrane organisation. *J Cell Physiol* 2009; 219(1): 69-76.

Popa G. *Phytotherapie der Prostata – die Rolle des praktisch tätigen Urologen*; in: *Phytopharmaka in Forschung und klinischer Anwendung*, Loew D, Rietbrock N (Hrsg): Steinkopff, Darmstadt 1999, pp. 157-177.

Pytel YA, Vinarov A, Lopatkin N, Sivkov A, Gorilovsky L, Raynaud JP. Long-term clinical and biological effects of the lipidosterolic extract of *Serenoa repens* in patients with symptomatic benign hyperplasia. *Adv Ther* 2002; 19: 297-306.

Pytel' IuA, Lopatkin NA, Gorilovskii LM, Vinarov AZ, Sivkov AV, Medvedev AA. The results of long-term treatment in patients with symptoms of lower urinary tract dysfunction due to benign prostatic hyperplasia. *Urologia* 2004; Mar-Apr (2): 3-7.

Ravenna L, Di Silverio F, Russo MA, Salvatori L, Morgante E, Morrone S, et al. Effects of the lipidosterolic extract of *Serenoa repens* (permixon) on human prostatic cell lines. *Prostate* 1996; 29(4): 219-230.

Reece-Smith H, Memon A, Smart CJ, Dewbury K. The value of Permixon® in benign prostatic hypertrophy. *British J Urology* 1986; 58: 36-40.

Rhodes L, Primka RL, Berman C, Vergult G, Gabriel M, Pierre-Malice M, Gibelin B. Comparison of finasteride (Proscar), a 5-alpha reductase inhibitor, and various commercial plant extracts in vitro and in vivo 5-alpha-reductase inhibition. *Prostate* 1993; 22: 43-51.

Roehrborn CG. Definitions of at-risk patients; baseline variables. *Br J Urol International* 2006; 97 Suppl 2: 7-11.

Royal United Hospital Bath NHS: International Prostate Symptom Score (access 1 November 2013).

Sachs B. Stellungnahme zum nationale periodisch Bericht; Project-Nr.: PSUR-0764128-004.

Scaglione F, Lucini V, Pannacci M, Caronno A, Leone C. Comparison of the potency of different brands of *Serenoa repens* extract on 5alpha-reductase types I and II in prostatic co-cultured epithelial and fibroblast cells. *Pharmacology*. 2008;82(4):270-5.

Scaglione F, Lucini V, Pannacci M, Dugnani S, Leone C. Comparison of the potency of 10 different brands of *Serenoa repens* extracts. *Rev Med Pharmacol Sci*. 2012 May; 16(5):569-74.

Schneider HJ, Uysal A. Internationaler Prostata Symptomenscore (IPPS) im klinischen Alltag. *Urologie (B)* 1994 ; 34 : 443-447.

Sirab N, Robert G, Fasolo V, Descazeaud A, Vacherot F, Taille Ade L, Terry S. Lipidosterolic extract of *serenoa repens* modulates the expression of inflammation related-genes in benign prostatic hyperplasia epithelial and stromal cells. *Int J Mol Sci*. 2013;14(7):14301-20.

Shi R, Xie Q, Gang X, Lun J, Cheng L, Pantuck A, Rao J. Effect of saw palmetto soft gel capsule on lower urinary tract symptoms associated with benign prostatic hyperplasia: a randomized trial in Shanghai, China. *J Urology* 2008; 179: 610-615.

Stepanov VN, Siniakova LA, Sarrazin B, Raynaud JP. Efficacy and tolerability of the lipidosterolic extract of *Serenoa repens* (permixon) in benign prostatic hyperplasia: a double-blind comparison of two dosage regimens. *Adv Ther* 1999; 16(5): 231-241.

Strauch G, Perles P, Vergult G, Gabriel M, Gibelin B, Cummings S et al. Comparison of finasteride (Proscar®) in the inhibition of 5-alpha reductase in healthy male volunteers. *Eur. Urol*. 1994; 26: 247-252.

Sultan C, Terraza A, Devillier C, Carilla E. Inhibition of androgen metabolism and binding by a liposterolic extract of 'Serenoa repens B' in human foreskin fibroblasts. *J. steroid Biochem* 1984; 20: 515-519.

Sweetman SC. *Martindale: the Complete Drug Reference* 36th Edition, London 2009 pp. 2192-2193.

Tacklind J, MacDonald R, Rutks I, Stanke JU, Wilt TJ. *Serenoa repens* for benign prostatic hyperplasia. *The Cochrane Library* 2012, Issue 12.

Tarayre JP, Delhon A, Laressergues H, Stenger A., Barbara M, Bru M, Villanova G, Caillol V, Allaga M. Anti-edematous action of a hexane extract of the stone fruit of *Serenoa repens* Bartr *Ann Pharm Fr* 1983; 41: 559-570.

Tasca A, Barulli M, Cavazzana A, Zattoni F, Artibani W, Pagano F. Treatment of obstructive symptomatology caused by prostatic adenoma with an extract of *Serenoa repens*. Double-blind clinical study vs placebo [Trattamento della sintomatologia ostruttiva da adenoma prostatico conestratto di *Serenoa repens*. Studio clinico in doppio cieco vs. placebo]. *Minerva Urologica e Nefrologica* 1985; 37:87-91.

Vahlensieck W, Volp A, Lubos W, Kuntze M. Benigne Prostathyperplasie – Behandlung mit Sabalfrucht Extract. Eerine Anwendungsbeobachtung an 1334 Patienten. *Fortschr Med* 1993a; 111: 323-6.

Vahlensieck W, Volp A, Kuntze M, Lubos W. Änderung der Miktion bei Patienten mit benigner Prostatahyperplasie unter Sabalfruchtbehandlung. *Urologie (B)* 1993; 33: 380-3.

Van Hellemont J. *Fytotherapeutisch Compendium*, APB Brussels, 1985 pp. 534-535.

Vela Navarrete V, Garcia Cardoso JV, Barat A, Manzarbeitia F, López Farré A. BPH and inflammation: pharmacological effects of Permixon on histological and molecular inflammation markers. Markers of o a double blind pilot clinical assay. *European Urology* 2003; 44: 549-555.

Verhelst G. *Groot handbook geneeskrachtige planten*, 4^{de} druk, BVBA Mannavita 2010, Wevelgem pp.

Wadsworth TL, Carrol JM, Mallinson RA, Roberts CT Jr, Roselli CE. Saw palmetto extract suppresses insulin-like growth factor-I signaling and induces stress-activated protein kinase/c-Jun N-terminal kinase phosphorylation in human prostate epithelial cells. *Endocrinology* 2004; 145(7): 3205-3214.

Wagner H, Flachsbarth H. A new antiflogistic principle from *Sabal serrulata* I. *Planta Med* 1981; 41: 244-251.

Wagner H, Flachsbarth H, Vogel G. A new antiflogistic principle from *Sabal serrulata* II. *Planta Med* 1981; 41: 252-258.

Wargo KA, Allman EI, Ibrahim F. A possible case of saw palmetto induced pancreatitis. *Souther Med J* 2010; 103: 683-685.

Weisser H, Tunn S, Behnke B, Krieg M. Effects of the *Sabal serrulata* extract IDS 89 and its subfractions on 5-alpha-reductase activity in human benign prostatic hyperplasia. *The Prostate* 1996; 28: 300-306.

Weisser H, Behnke B, Helpap B, Bach D, Krieg M. Enzyme activities in tissue of human benign prostatic hyperplasia after three months' treatment with the *Sabal serrulata* extract IDS 89 (Strogen[®]) or placebo. *Eur. Urol.* 1997; 31: 97-101.

Willets KE, Clements MS, Champoin S, Ehsman S, Eden JA. *Serenoa repens* extract for benign prostatic hyperplasia: a randomized controlled trial. *British Journal of Urology International* 2003; 92: 267-270.

Williamson E, Driver S, Baxter K. editors: *Stockley's Herbal Medicines Interactions. A guide to the interactions of herbal medicines.* 2nd Ed. The Pharmaceutical Press, 2013 London pp. 415-417.

Yue Q-Y, Jansson K. Letter to the Editor: Herbal drug curbicin and anticoagulant effect with and without warfarin: possibly related to the vitamin E component. *J Am Geriatr Soc* 2001; 49: 838.