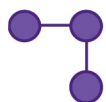


Saw Palmetto



ADVANCED BIOIDENTICAL
HORMONE THERAPY

Clinical Applications

- Supports Healthy Lower Urinary Tract (LUT) Function in Men*
- Supports Normal Urinary Flow and Nocturnal Frequency*
- Supports Healthy Prostate-Related Hormone Metabolism*
- Supports Prostate Health*

Saw Palmetto supports normal male lower urinary tract function and prostate health. Clinically meaningful levels of key ingredients target urinary flow and frequency as well as prostate-related hormone metabolism. This formula features FLOWENS®—a full-spectrum cranberry powder optimized for men's health—combined with beta-sitosterol, pyridoxal 5'-phosphate, Albion® TRAACS® zinc bisglycinate chelate, and highly concentrated, standardized extracts of saw palmetto and pygeum.*

All Advanced Bioidentical Hormone Therapy Formulas Meet or Exceed cGMP Quality Standards

Discussion

As men age, the need for maintaining or supporting normal prostate and lower urinary tract (LUT) health and function increases. Saw Palmetto represents the latest in specialized formulations for men.

FLOWENS®

Cranberry fruit has a history of use among Native Americans for kidney and urinary health.^[1] Modern research supports this traditional use.^[1-4] Cranberry fruit is recognized as a rich source of oligosaccharides and phytochemicals, including proanthocyanidins, flavonols, and triterpenoids. FLOWENS is a 100% all-natural, full-spectrum cranberry powder designed and optimized for men's health. In a clinical study, FLOWENS was shown to improve quality of life and support urinary tract function with improvements noted within the first month of supplementation. In a six-month double-blind, randomized, placebo-controlled study, supplementation with 250 or 500 mg/d of FLOWENS resulted in clinically-relevant, dose-dependent improvements in primary (a clinically validated questionnaire) and secondary (e.g., uroflowmetry scores, urine storage) outcome measures related to prostate function in men older than 45 years. No side effects were reported. The researchers suggested that the observed effects may have resulted from activities on detrusor contraction and relaxation, modulation of the micturition reflex, or a reduction in certain cytokines.*^[1]

Saw Palmetto (*Serenoa repens*)

Saw palmetto extracts have been widely used in Europe and more recently in the United States as a natural way to help maintain normal prostate health and LUT function. A systematic review^[5] of 18 randomized controlled trials involving 2,939 men and another analysis of 21 clinical trials involving 3,000 men and reviewed by Cochrane^[6] support the safety and efficacy of saw palmetto extract preparations, and animal and human clinical trials continue to support a role for saw palmetto in prostate health.^[7-10] Mechanisms of action have not been fully elucidated, but there is evidence that saw palmetto inhibits 5-alpha reductase (5AR)—the enzyme that reduces testosterone to the more potent androgen dihydrotestosterone (DHT).^{*(11,12)} Other effects have been proposed, including that saw palmetto prevents DHT from binding to androgen receptors, has antiestrogenic and antiproliferative effects, inhibits growth factors, affects alpha-1 adrenoceptors and 1,4-dihydropyridine receptors, and helps maintain healthy fluid balance in prostate tissues.^[7,12-15] Saw Palmetto features a high-quality, standardized (85% free fatty acids) extract to assure the opportunity for the best clinical outcomes.*

Pygeum Africanum (*Pygeum africanum*)

The use of pygeum dates back approximately 300 years, and extracts are a well-known and often-used alternative for supporting prostate health in many European countries.^[16] Numerous open and placebo-controlled studies in large populations have demonstrated its efficacy and acceptability for supporting healthy urine flow and volume, reducing nocturnal voiding, and improving quality of life.^[17-21] Multiple mechanisms of action have been proposed for the genitourinary effects of pygeum, which contains numerous beneficial constituents, such as beta-sitosterol. Mechanisms are thought to include 5AR inhibition; estrogenic, antiandrogenic, and antiproliferative effects; and modulation of cell signaling molecules, including cytokines.*^[18,20]

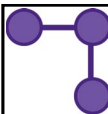
Beta-Sitosterol

Beta-sitosterol is a plant phytosterol commonly used to promote LUT function in men. In a randomized, double-blind, placebo-controlled, multicenter study, 200 patients were supplemented with 20 mg of beta-sitosterol three times per day or placebo. Significant improvements in urinary flow parameters were observed in the beta-sitosterol group only.^[22] In a follow-up study, the beneficial effects of beta-sitosterol treatment were maintained for 18 months.^[23] In a six-month randomized, double-blind, placebo-controlled clinical trial (n = 177), 130 mg/d of beta-sitosterol resulted in significant improvements in patients' quality of life, urinary flow rate, and residual volume compared to placebo.^[24] A systematic review of clinical trials also supported the benefits of beta-sitosterol to LUT function in men.*^[25]

Zinc and Vitamin B6

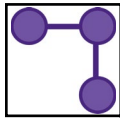
Zinc is highly concentrated in the prostate gland, and a lack of zinc may be associated with a reduced DNA damage and repair response in prostate tissue.^[26] Therefore, zinc adequacy is vital for optimal prostate health, especially with advancing age.^[27] In this formula, zinc is provided as the highly absorbable Albion® TRAACS® zinc bisglycinate chelate. Pyridoxal 5'-phosphate (P5P) is the active form of vitamin B6. In a population-based prospective study of 525 men, Kasperzyk et al found that high vitamin B6 intake had an inverse association with prostate-related mortality.*^[28]

***These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**



Advanced Bioidentical Hormone Therapy
1808 Barak Lane, Suite 100
Bryan, TX 77802
(979) 485-9926

Saw Palmetto



Supplement Facts

Serving Size: 2 Softgels
Servings Per Container: 30

	Amount Per Serving	%Daily Value
Vitamin B6 (as pyridoxal 5'- phosphate)	10 mg	500%
Zinc (as TRAACS® zinc bisglycinate chelate)	30 mg	200%
FLOWENS® Cranberry Fruit Solids (<i>Vaccinium macrocarpon</i>)(fruits)	500 mg	**
Saw Palmetto Extract (<i>Serenoa repens</i>)(dried fruits) (85% free fatty acids)	320 mg	**
Beta-Sitosterol	180 mg	**
Pygeum Extract (<i>Prunus africana</i>)(bark)(2.5% beta-sitosterol)	100 mg	**

** Daily Value not established.

Other Ingredients: Organic flaxseed oil, softgel (bovine gelatin, vegetable glycerin, purified water, and natural caramel color), sunflower lecithin, tricalcium phosphate, maltodextrin, citric acid, and silica.

Albion and TRAACS are registered trademarks of Albion Laboratories, Inc.

FLOWENS® is a trademark of Naturex.

References

- Vidlar A, Student V Jr, Vostalova J, et al. Cranberry fruit powder (Flowens™) improves lower urinary tract symptoms in men: a double-blind, randomized, placebo-controlled study. *World J Urol.* 2016 Mar;34(3):419-24. [PMID: 26049866]
- Vasileiou I, Katsargyris A, Theocharis S, et al. Current clinical status on the preventive effects of cranberry consumption against urinary tract infections. *Nutr Res.* 2013 Aug;33(8):595-607. [PMID: 23890348]
- Sun J, Marais JP, Khoo C, et al. Cranberry (*Vaccinium macrocarpon*) oligosaccharides decrease biofilm formation by uropathogenic *Escherichia coli*. *J Funct Foods.* 2015 Aug;17:235-42. [PMID: 26613004]
- Blumberg JB, Camesano TA, Cassidy A, et al. Cranberries and their bioactive constituents in human health. *Adv Nutr.* 2013 Nov 6;4(6):618-32. [PMID: 24228191]
- Wilt TJ, Ishani A, Stark G, et al. Saw palmetto extracts for treatment of benign prostatic hyperplasia: a systematic review. *JAMA.* 1998 Nov 11;280(18):1604-09. Erratum in: *JAMA* 1999 Feb 10;281(6):515. [PMID: 9820264]
- Wilt T, Ishani A, MacDonald R. *Serenoa repens* for benign prostatic hyperplasia. *Cochrane Database Syst Rev.* 2002;(3):CD001423. Review. Update in: *Cochrane Database Syst Rev.* 2009;(2):CD001423. [PMID: 12137626]
- Saw palmetto: clinical overview. In: Blumenthal M, Goldberg A, Kunz T, Dinda K, eds. *The ABC Clinical Guide to Herbs.* Austin, TX: American Botanical Council; 2003:309-319. http://abc.herbalgram.org/site/DocServer/Saw_Palmetto.pdf?docID=167. Accessed May 24, 2016.
- Mantovani F. *Serenoa repens* in benign prostatic hypertrophy: analysis of 2 Italian studies. *Minerva Urol Nefrol.* 2010 Dec;62(4):335-40. [PMID: 20944533]
- Iii Colado-Velázquez J, Mailloux-Salinas P, Medina-Contreras J, et al. Effect of *Serenoa repens* on oxidative stress, inflammatory and growth factors in obese wistar rats with benign prostatic hyperplasia. *Phytother Res.* 2015 Oct;29(10):1525-31. [PMID: 26104840]
- Tacklind J, MacDonald R, Rutks I, et al. *Serenoa repens* for benign prostatic hyperplasia. *Cochrane Database Syst Rev.* 2012 Dec 12;12:CD001423. [PMID: 23235581]
- Marks LS, Hess, DL, Dorey FJ, et al. Tissue effects of saw palmetto and finasteride: use of biopsy cores for in situ quantification of prostatic androgens. *Urology.* 2001 May;57(5):999-1005. [PMID: 11337315]
- Suzuki M, Ito Y, Fujino T, et al. Pharmacological effects of saw palmetto extract in the lower urinary tract. *Acta Pharmacol Sin.* 2009 Mar;30(3):227-81. [PMID: 19262550]
- Saw Palmetto. Somerville, MA: Natural Medicines; 2016. <https://naturalmedicines.therapeuticresearch.com/databases/food,-herbs-supplements/professional.aspx?productid=971>. Accessed May 24, 2016.
- Di Silverio F, D'Armeo G, Lubrano C, et al. Evidence that *Serenoa repens* extract displays an antiestrogenic activity in prostatic tissue of benign prostatic hypertrophy patients. *Eur Urol.* 1992;21(4):309-14. [PMID: 1281103]
- Wadsworth TL, Carroll JM, Mallinson RA, et al. 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 Jul;145(7):3205-14. [PMID: 15033918]
- Levin RM, Das AK. A scientific basis for the therapeutic effects of Pygeum africanum and *Serenoa repens*. *Urol Res.* 2000 Jun;28(3):201-09. [PMID: 10929430]
- Breza J, Dzurny O, Borowka A, et al. Efficacy and acceptability of tadenan (Pygeum africanum extract) in the treatment of benign prostatic hyperplasia (BPH): a multicentre trial in central Europe. *Curr Med Res Opin.* 1998;14(3):127-39. [PMID: 9787978]
- Pygeum Africanum. Somerville, MA: Natural Medicines; 2016. <https://naturalmedicines.therapeuticresearch.com/databases/food,-herbs-supplements/professional.aspx?productid=388>. Accessed May 24, 2016.
- Ishani A, MacDonald R, Nelson D, et al. Pygeum africanum for the treatment of patients with benign prostatic hyperplasia: a systematic review and quantitative meta-analysis. *Am J Med.* 2000 Dec 1;109(8):654-64. [PMID: 11099686]
- Quiles MT, Arbós MA, Fraga A, et al. Antiproliferative and apoptotic effects of the herbal agent Pygeum africanum on cultured prostate stromal cells from patients with benign prostatic hyperplasia (BPH). *Prostate.* 2010 Jul 1;70(10):1044-53. [PMID: 20503393]
- Wilt T, Ishani A, MacDonald R, et al. Pygeum africanum for benign prostatic hyperplasia. *Cochrane Database Syst Rev.* 2002;(1):CD001044. [PMID: 11869585]
- Berges RR, Windeler J, Trampisch HJ, et al. Randomised, placebo-controlled, double-blind clinical trial of beta-sitosterol in patients with benign prostatic hyperplasia. Beta-sitosterol study group. *Lancet.* 1995 Jun 17;345(8964):1529-32. [PMID: 7540705]
- Berges RR, Kassen A, Senge T. Treatment of symptomatic benign prostatic hyperplasia with beta-sitosterol: an 18-month follow-up. *BJU Int.* 2000 May;85(7):842-46. [PMID: 10792163]
- Klippel KF, Hiltl DM, Schipp B. A multicentric, placebo-controlled, double-blind clinical trial of beta-sitosterol (phytosterol) for the treatment of benign prostatic hyperplasia. German BPH-Phyto Study group. *Br J Urol.* 1997 Sep;80(3):427-32. [PMID: 9313662]
- Wilt TJ, MacDonald R, Ishani A. Beta-sitosterol for the treatment of benign prostatic hyperplasia: a systematic review. *BJU Int.* 1999 Jun;83(9):976-83. [PMID: 10368239]
- Yan M, Song Y, Wong CP, et al. Zinc deficiency alters DNA damage response genes in normal human prostate epithelial cells. *J Nutr.* 2008 Apr;138(4):667-73. [PMID: 18356318]
- Costello LC, Franklin RB, Tan MT. A critical assessment of epidemiology studies regarding dietary/supplemental zinc and prostate cancer risk. *Open Urol Nephrol J.* 2008;1. [PMID: 24204440]
- Kasperzyk JL, Fall K, Mucci LA, et al. One-carbon metabolism-related nutrients and prostate cancer survival. *Am J Clin Nutr.* 2009 Sep;90(3):561-69. [PMID: 19571228]

***These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

Advanced Bioidentical Hormone Therapy
1808 Barak Lane, Suite 100
Bryan, TX 77802
(979) 485-9926

DRS-311
REV. 06/17/16

Directions

Take one to two softgels daily, or use as directed by your healthcare practitioner.

Consult your healthcare practitioner prior to use. Individuals taking medication should discuss potential interactions with their healthcare practitioner. Do not use if tamper seal is damaged.

Does Not Contain

Wheat, gluten, yeast, soy protein, dairy products, fish, shellfish, peanuts, tree nuts, egg, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, or artificial preservatives.